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## Telemedicine: Rx for the Future of Health Care

Susan E. Volkert

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# TELEMEDICINE: RX FOR THE FUTURE OF HEALTH CARE

Susan E. Volkert\*

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INTRODUCTION .....	148
I. DEFINING TELEMEDICINE.....	151
II. CURRENT LAWS, POLICIES, AND POSITIONS RELATING TO THE PRACTICE OF TELEMEDICINE .....	160
A. <i>Current Federal Law and Applications</i> .....	161
B. <i>State Telemedicine Laws</i> .....	165
III. REGULATING THE QUALITY OF CARE: LICENSURE, MEDICAL MALPRACTICE AND THE DOCTRINE OF INFORMED CONSENT .....	165
A. <i>Regulation by Licensure</i> .....	165
1. Current Licensure Laws .....	166
2. National Initiatives: Professional Organizations, Institutions, and Commissions .....	173
3. Current Legislative Activity .....	174
B. <i>Regulating Quality: Serving the Best Interests of           the Patient</i> .....	180
C. <i>Informed Consent</i> .....	188
IV. REGULATING ACCESS AND STANDARDS .....	191
A. <i>Regulating Access: The FCC and “Universal” Access</i> .....	192
B. <i>Regulating “Teledevices”</i> .....	204
C. <i>Regulating Access Excess: Protecting The Patient’s           Privacy, Confidentiality and Security Interests</i> .....	214
1. Privacy, Confidentiality and Telemedicine.....	214
2. Federal Protections.....	217
3. State laws .....	223
4. Professional Codes of Ethics and Private Positions.....	224
5. Proposals .....	225
V. REGULATING COSTS: WHAT SERVICE AT WHAT PRICE?.....	228

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A. <i>Federal Funding</i> .....	228
B. <i>State Approaches To Reimbursement</i> .....	233
C. <i>Private Funding of Telemedicine</i> .....	234
VI. TELEMEDICAL POLITICAL PROPOSALS .....	239
VII. A CALL TO ACTION .....	242
CONCLUSION .....	245

## INTRODUCTION

In 1996, eleven people died while trying to climb Mount Everest.<sup>1</sup> Shortly thereafter, physicians worldwide began turning to technology to provide remote medical treatment. In May 1998, physicians, scientists and technologists determined it was time to safeguard the health of another team attempting to scale the world's highest mountain.<sup>2</sup> They turned to telemedicine, equipping the climbers with "Bio-Packs" that measured the climbers' surface and core temperatures, pulse rates and oxygen saturation levels,<sup>3</sup> "Geo-Packs" that constantly updated the climbers' location using a geonavigation system, and EKG and EEG telemetry devices.<sup>4</sup> Just one week before the Mount Everest expedition, a physician in New Jersey practiced a far simpler and more modest form of telemedicine: he answered medical queries using his web site. Three months later, physicians at the University of Colorado Health Science Center developed and implemented plans to make "house calls" to the three Texas RE/MAX pilots during their attempt to fly around the world in a balloon.<sup>5</sup>

Telemedicine is not just for those seeking lofty goals or technologically adept physicians. A mobile telemedicine platform was employed by the U.S. military in Bosnia. Because there were radiologists, orthopedists and other specialists in the United States to immediately address

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1. See Claudia Glenn Dowling, *Death on the Mountain*, LIFE, Aug., 1996 at 32.

2. See *Bio-Logic Systems' Traveler Product Chosen as Neurological Testing Device for Telemedicine Study on Mount Everest; Product Proves Effective and Reliable in Remote, Extreme Environments*, Sept. 1, 1998, available in Lexis Nexis Financial News. See also Tim Friend, *NASA's Discoveries Have Earthbound Applications From Cooling Suits to X-rays*, USA TODAY, Oct. 27, 1998, at 2.

3. The monitoring devices used to record the vital signs during the experiment at 18,000 feet provided multi-channel recordings of EEG, ECG, EOG, airflow, respiratory effort, body position, pulse rate and other physiological functions.

4. See Ruth SoRelle, *Vision for the Future; Telemedicine May Be Just What Doc Ordered in Space*, THE HOUSTON CHRONICLE, July 6, 1998 at A1.

5. See Ann Schrader, *Balloon 'House Calls' Set Med Center to Keep Tabs on Adventurers*. DENV. POST, Sept. 18, 1988, at B-02.

soldiers' illnesses or injuries, soldiers did not need to evacuate to Germany.<sup>6</sup> Patients can effectively now 'dial a treatment'. Telemedicine promises to save lives, improve the quality of medical services, increase access to treatment and even control the skyrocketing costs of health care delivery. In fact, telemedicine is a mechanism to address health care delivery issues that plague the United States. If the goals are quality, access and curtailing costs, telemedicine is one part of a complex answer. And yet, with health care costs escalating, society struggles to realize telemedicine's promise.

Quite simply, telemedicine symbolizes and catalyzes the clash between the reality of our legal and political approach to health care and the American dream of bringing health care to all patients. Telemedicine, like our health care delivery systems, is regulated by many layers of government. Unlike other issues, telemedicine cuts through and challenges the traditional controls of access and cost. As such, telemedicine is a microcosm of our health care delivery system and a lens through which one may analyze the obstacles to access in the current system. This article examines these issues, proposes that telemedicine's goal should be to improve quality, access, and, costs for the American patient, and offers suggestions for obtaining these goals.

In the past five years, professional, governmental, and private organizations' interest in telemedicine has grown exponentially. Although telemedicine is still in its infancy, the technology driving telemedicine continues to advance more rapidly than the laws that apply to its use. Three main issues remain unresolved: (1) who controls quality; (2) how patients gain access; and, (3) who pays for that access? The combination of innovative application of technology and the regulated world of medicine, governed by our unique political landscape, compels us to examine and resolve issues relating to quality, access and costs.

Over the next five years, we are poised to spend over \$100 billion on telemedicine and other emerging information technologies.<sup>7</sup> For this investment to pay off, the current framework for regulating telemedicine must be replaced with one that facilitates the delivery of these services.<sup>8</sup>

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6. See Israel Kloss, *Telemedicine Brings D.C. Specialists to World*, WASH. TIMES, NOV. 17, 1996, at D8.

7. See *A White House Challenge to Telemedicine*, FORBES, Aug. 14, 1996, at 37.

8. Telemedicine and telehealth are used by many interchangeably. For the purposes of this paper "telehealth" is given a broader application than "telemedicine." Telehealth will include the use of electronic communication networks for the transmission of information and data that focus on health promotion, disease prevention, and the public's overall health. It encompasses "patient/community education and information, population-based data collection and management, and linkages for health care resources and referrals." See TELEHEALTH & TELEMEDICINE TAKING DISTANCE OUT OF CARING, CALIFORNIA TELEHEALTH/TELEMEDICINE

Those seeking to deliver telemedicine must contemplate cost, access and quality, and must pay particular attention to the best interests of the patient.<sup>9</sup>

Although telemedicine has been heralded, it has also been criticized,<sup>10</sup> both for advancing too quickly and for moving too slowly<sup>11</sup>, for taking on too much, for not taking on enough and for adding costs to health care. The telemedicine subject has raised a plethora of questions. This article will examine those questions in the context of our legal, regulatory and political/ethical framework. Part I defines "telemedicine" and "telehealth," and explores current and future applications. Part II addresses regulation of quality and focuses on licensure, credentialing, and malpractice actions. Part III considers access and the regulatory monitors of telemedicine: the Federal Communications Commission ("FCC"), the Food Drug and Cosmetic Administration ("FD&CA") and Health Care Financing Administration ("HCFA"). Part IV focuses on the cost of telemedicine, including funding and payment systems for telemedicine delivery services, and suggests guidelines that should provide fiscal support for telemedicine projects. Part V discusses current federal, state and private telemedicine proposals and suggests model approaches for achieving access, quality and cost objectives. Part VI suggests that telemedicine is a means to improving medical treatment. To that end, this article proposes solutions that will drive telemedicine toward improved quality and access for our entire health care delivery system.

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COORDINATION PROJECT (Jan. 1997) at 27. [hereinafter TELEHEALTH & TELEMEDICINE]. "Telemedicine" will apply to "the use of electronic communication networks for the transmission of information and data related to the diagnosis and treatment of medical conditions." *Id.* at 9.

9. On Jan. 27, 1998, President Clinton called on Congress to pass a "Consumer Bill of Rights" with federally enforceable consumer-health protections. It states that "every American deserves quality care" and urges "the Congress to write into law a Consumer Bill of Rights that says this: You have the right to know all your medical options, not just the cheapest. You have the right to choose the doctor you want for the care you need. You have the right to emergency room care, wherever and whenever you need it. You have the right to keep your medical records confidential." STATE OF THE UNION ADDRESS, Jan. 27, 1998.

10. *Telemedicine Programs Spreading Like Wildfire: But Is It Premature to Embrace the New Technology?* THE BACK LETTER, VOL. 11: NO. 5, May, 1996 at 54; W. Gray et al., *Benefits and Pitfalls of Telemedicine in Neurosurgery*, J. TELEMED. TELE CARE, 3 SUPPLE. 1: 7-9 (1997).

11. One advocate summing up her frustration told BNA "people are dying." *Telemedicine: Views on Impact of Telecom Law Differ in Telemedicine Community*, 4 HCPR 49 (May 20, 1994). See also Douglas A. Peredina, M.D., *Payment For Telemedicine Services: It May Be Time to Take a Step-by-Step Approach*, TELEMEDICINE TODAY, Special Issue 1997, 69.

## I. DEFINING TELEMEDICINE

Telemedicine can be described as the use of electronic communication and information technologies to provide or support clinical care at a distance.<sup>12</sup> This simple definition is used throughout this paper. Today in the United States, telemedicine is being used in academic medical centers,<sup>13</sup> community hospitals, managed-care companies, and in rural hospitals.<sup>14</sup> Telemedicine is also being used internationally to link providers in developing countries to hospitals in the United States and Europe.<sup>15</sup> Advances in digital communication, telecommunication, and the Internet<sup>16</sup> introduce an unprecedented opportunity to remote access to medical care.

Telemedicine is currently employed in patient care, professional and patient education, research and public-health applications.<sup>17</sup> It has been applied and studied in rural and city environments, by the public and private sector. It is being used in space,<sup>18</sup> on the prairies, on

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12. JOINT WORKING GROUP ON TELEMEDICINE, [hereinafter "JWGT"] is charged with coordinating federal telemedicine programs. Pursuant to the Telecommunications Act of 1996, the Secretary of Commerce and the Secretary of Health and Human Services, must report to Congress regarding the JWGT's activities. These activities are to address patient safety, the quality of services provided and legal, medical and economic issues. See 47 U.S.C. 151; See also INSTITUTE OF MEDICINE, *TELEMEDICINE, A GUIDE TO ASSESSING TELECOMMUNICATIONS IN HEALTH CARE* (1996) at 9. Telemedicine is "the use of electronic information and communications technologies to provide and support health care when distance separates the participants." *Id.* at 28.

13. In fact, the Mount Everest endeavor involved a collaborative effort of the best and the brightest, including NASA, Yale University School of Medicine, MIT Media Lab, Boston Museum of Science, the U.S. Army, Defense Advanced Research Projects Agency and AT&T. See PR NEWSWIRE, (September 1, 1998).

14. See Cepelwicz, 15 No. 2 MED. MALPRACTICE L. & STRATEGY. See also, BARRY B. CEPELEWICZ, *Malpractice Over the Phone? Telemedicine Provides Benefits for the Patient, But it May Mean Greater Liability for the Provider*, THE CONN. LAW TRIBUNE (September 15, 1997) at 8.

15. The international use of telemedicine is expanding exponentially. Unlike the many telemedicine barriers in the United States, most industrialized countries are not hindered by threats of malpractice actions. The scope of international telemedical practice is beyond this article. Telemedicine is used from Australia to Malaysia, and many telemedical centers outside of U.S. borders would like to avail of the expertise of U.S. physicians. See generally A.C. Dumay, *MEDICINE IN VIRTUAL ENVIRONMENTS*, 3 (Oct. 1995) at 75-89.

16. M. Ohki describes a prototype image conference system for radiology on the World Wide Web. The users could upload radiology images and pose questions for experts. The system itself has a drawback, "poor image resolution," but the authors state they have been consulted for 147 cases and that the system has "been deemed helpful in providing additional input for patient care." M. Ohki, M. Tsuru, T. Yamada, et al. *Computers in Radiology. A Remote Conference System For Image Diagnosis on the World-Wide Web*. AM. J. RADIO 1997 September 169(3): 627-9 cited in WL Database HDA.

17. Institute of Medicine, *Telemedicine* (1996) at 40-54.

18. See KRUG *Telemedicine System to Fly Abroad Space Shuttle Endeavour*, Jan. 30, 1998, available in Lexis Nexis Financial News.

mountaintops<sup>19</sup> and under the sea, domestically and internationally,<sup>20</sup> on the battlefield<sup>21</sup> and in peacetime.<sup>22</sup> It is used in triage<sup>23</sup> and post-surgically,<sup>24</sup> by generalist and specialist alike, for home and clinical care. Telemedicine providers are expanding and cover the entire spectrum of health care practices, from cardiology to trauma medicine, from dentistry to toxicology, and from gynecology to ophthalmology.<sup>25</sup> Telemedicine now and in the future will include the full panoply of health related fields, from administrative services to utilization review,<sup>26</sup>

19. See Ed Susman, *Everest Climbers to Get Space Age Gadgets*, UPI SCIENCE NEWS, Jan. 29, 1998. With the application of telemedicine, hopefully the deaths of mountain climbers, which Jon Krausher described in the book *IN THIN AIR*, will be avoided. Space-age telemedicine technology was "strapped" onto American climbers last May with the hope of preventing a disaster similar to the 1996 climb which took 11 lives on the world's tallest mountain. The climbers wore four pounds of "sensor-laden straps and suspenders which will transmit to a base-camp information on their vital signs." Dr. Richard Satava, director of the Center for Medical Informatics and Technology at Yale School of Medicine, hopes to avoid plights by monitoring the climbers. Telemedicine is moving into every conceivable arena imaginable, especially where it may be the only available means of delivering health care.

20. This article will focus on the domestic, e.g. within U.S. borders, uses of telemedicine but draw some comparisons with the international use of telemedicine. See *Telemedicine Today* for up-to-date surveys of ongoing telemedicine programs and projects. International telemedicine is big business. See John George, *Foreign Patients Focus of Hospitals*, PHILADELPHIA BUSINESS JOURNAL (Nov. 14, 1997) Vol. 16, No. 40, p. 2 ("[I]n addition to attracting international patients to Philadelphia, the hospitals also want to help healthcare providers in selected countries improve the delivery of medical services through education and physician exchange programs and telemedicine efforts"); David J. Killman, David Fordslurd, *An International Collaboratory Based on Virtual Patient Records*, COMMUNICATIONS OF THE ACM, No. 8, Vol. 40, p. 110 (Aug. 1997) (discussing development of Telemed, a virtual patient record. Telemed uses a "media-rich graphical patient record to allow multiple physicians, possibly located remotely across a wide-area network, to consult on a patient record." *Id.*

21. Researchers report they can create a "smart shirt" with a life-saving potential for wounded soldiers on the battlefield. A fiber-optic cable is woven into the fabric of a soldier's shirt, allowing him to be tracked from a base camp. If a wound is sustained, the shirt will pinpoint its location, detect organ and blood vessel damage and report the soldier's vital signs so that by the time a medic arrives, the medical state will be known. Ed Susan, UPI SCIENCE NEWS, Jan. 30, 1998 (Lexis Nexis).

22. See Marilyn J. Field, Editor, *TELEMEDICINE, A GUIDE TO ASSESSING TELECOMMUNICATIONS IN HEALTH CARE*, INSTITUTE OF MEDICINE, 1996 (discussing telemedicine in Somalia).

23. See Terese Hudson, *When Every Second Counts*, HOSP. & HEALTH NETWORKS, Sept. 5, 1996 at 61.

24. See *AT&T Donates Telesurgery Link Between Endourology World Congress and Johns Hopkins*, PR NEWSWIRE, September 4, 1998.

25. Medical specialties currently employing telemedicine include: cardiology, dentistry, dermatology, gynecology, neurology, neurosurgery, teleradiology, telepathology, telephysician, telepharmacology, teledermatology, telecardiology, telepresence, telepsychiatry. See Dorothy Fishman, *Telemedicine: Bringing the specialist to the patient*, NURSING MANAGEMENT, Vol. 28, No. 7 (July) at 30-32.

26. Often the terms telemedicine and telehealth are used interchangeably. In this article, telemedicine includes administrative services and utilization review if those services use elec-

from child-abuse assessment to home health care.<sup>27</sup> Other applications include back-up coverage for physicians, continuing medical education, disability evaluations, home health care, nursing care,<sup>28</sup> pre-operative meetings with patients, quality assurance, remote proctoring, utilization review and consumer education.<sup>29</sup> Care through telemedicine is being provided at home,<sup>30</sup> in prisons,<sup>31</sup> at VA hospitals, in urban settings and in rural areas, in acute and long-term facilities, and by medical specialties and nurses.<sup>32</sup> As technology revolutionizes the communications industry, clinicians' lives will be transformed as well. Specific examples of current applications include: physicians who answer patients' questions through on-line information services; consultation via electronic mail between patients' primary care physicians and tertiary care specialists; linking data systems for evaluations of CT scans or radiology studies; and real-time examination, treatment and diagnosis through interactive television and emergency centers where physicians and/or nurses remotely evaluate patients' symptoms and recommend an appropriate course of action.<sup>33</sup>

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tronic communication networks for the transmission of information and data which relate to the diagnosis and treatment of medical conditions. See IOM, *TELEMEDICINE*, *supra*.

27. *Id.*

28. Telemedicine could be very effective in long-term care, especially considering the growing aged population. "Although demographic changes contribute to the growing need for long-term care, economic pressures have determined the shape of the system. The most critical policy and research issue is how we can provide adequate high-quality long-term care services in an equitable manner to a growing and diverse older population." Steven P. Wallace, Emily K. Abel, and Pamela Stefanowicz, *Long-Term Care and the Elderly in Changing the U.S. Health care System*, p. 194.

29. *TELEHEALTH & TELEMEDICINE*, *supra* note 28.

30. Health application of interactive televideo is in fact considered to be the fastest growing telehealth area. Now available are computerized telemonitoring devices that allow healthcare providers in a central office to monitor a patient's vital signs, listen to bowel sounds, test blood oxygen levels, and schedule and monitor medications and treatment without the patient ever leaving home. *Ensuring Access to Care in Rural Areas: the Role of Communication Technology*, *GENERATIONS*, No. 3, Vol. 21 (Sept. 22, 1997); See also Mike McCue, *Telemedicine: A Healthcare Issue Coming Into Focus*, *MANAGED HEALTHCARE*, Vol. 7, No. II (Nov. 1997) p. 50. (*But see* home tuberculosis tests: even with training parents should not be allowed to read their children's Mantoux tests at home. "However, [telemedicine's] technology . . ." shows great promise, given its wide acceptance by parents and its relatively low cost." Harvey Kayman, Susan M. Howard, Pediatrics Department, Kaiser Permanente, *Health Partners Through Telephone Technology: Home Reading of Tuberculosis Tests*, *PEDIATRICS* 1966, 100 (Supple), 444 (Sept. 1997)

31. See Robert Cunningham, *Telemedicine Races Against Time to Earn Its Keep*, *TELEMEDICINE SOURCEBOOK*, 77-77-78 (John P. Recihared et al. eds., 1996).

32. See Dorothy Fishman, *Telemedicine: Bringing the Specialist to the Patient*, *NURSING MANAGEMENT*, Vol. 28, No. 7 (July 1997), pp. 30-32. *NURSING MANAGEMENT* discusses two types of telenurses: the teletriage nurse and the home health nurse. *Id.*

33. See A. GOLDBERG AND J. GORDON, *TELEMEDICINE: EMERGING LEGAL ISSUES*, *AHLA* (1998). Telemedicine has great potential, but much of the existing telemedicine lit-



By far, the greatest financial supporter of telemedicine has been the government, either directly, or through financial support to hospitals or medical centers. At least thirteen federal agencies and many states provide funding, grants and reimbursements for telemedicine program development.<sup>34</sup> There are reportedly over 150 telemedicine projects being conducted in over four-fifths of our states, involving well over 5000 patients.<sup>35</sup> Telemedicine is widely used by the military—to improve quality and access, and to reduce costs. The Department of Defense has developed battlefield and peacetime telemedicine applications. One of the uses is a “reality helmet” that allows combat medics to communicate with physicians during the critical minutes after a soldier is wounded and before the soldier can be brought from the battlefield. A handheld device monitors the vital signs of the wounded.<sup>36</sup>

Recently, home telemedicine has been growing. A company in the midwest is using telemedicine to provide home health care. A two-way video interaction system, using the existing telephone system, is installed in the patient’s home and run through regular telephone lines. The patient and the health care provider can communicate, and the system provides blood pressure, pulse checks and like medical

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erature focuses on radiology, pathology and dermatology. Applications include medical specialties including cardiology, dentistry, dermatology, gynecology, neurology, neurosurgery, nephrology, obstetrics, oncology, orthopedics, ophthalmology, pediatrics, psychiatry and psychology, pathology, pharmacology, radiology, rheumatology, speech, surgery, toxicology and trauma medicine. Additionally, other services will include administrative duties, back-up coverage for physicians, child-abuse assessment, continuing medical education, disability evaluations, home health care, nursing care, pre-operative meetings with patients, quality assurance, remote proctoring, utilization review, consumer education and medical support services. See TELEHEALTH & TELEMEDICINE *supra* note 8, at 11.

34. The federal government has directed a wide variety of agencies and money at telemedicine. Just recently, the number of telemedicine-related statutes indicate the growth in this area, as well as the resources devoted to encourage more growth. For example, federal statutes that address telemedicine include: 7 U.S.C. § 950aaa (1997) (telemedicine and distance learning services in rural areas; appropriating 100,000,000 for each of the fiscal years 1996 through 2002); 42 U.S.C. § 254 (telemedicine rural health outreach, network development and telemedicine grant program; \$36,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 through 2001); 42 U.S.C. § 2487 (telemedicine and biomedical research in space, authorizing the establishment of emergency medical service telemedicine capability); 42 U.S.C. § 4206 (authorizing Medicare reimbursement for telehealth services); 17 C.F.R. § 1703 (encouraging through loan and grants telemedicine services and distance learning services in rural areas through telecommunications); Pub. L. 104-299, Sec. 3 Rural Health Outreach Telemedicine Grant Program.

35. See DEPARTMENT OF COMMERCE, TELEMEDICINE REPORT TO THE CONGRESS, p. 14 (Jan. 13, 1997).

36. See Karyn Snyder, *Telemedicine: The New Frontier*, Drug Topics, No. 15, Vol. 141 (1997). The Department of Defense (DOD) purports that telemedicine could help reduce battlefield morbidity and mortality by 30% to 50%. The Department of the Navy has also been working on systems which would allow a wounded sailor better access to medical care when miles from the ship. Peacetime medical communications link the networks to medical centers.

information.<sup>37</sup> Further, telecare often supports video telepharmacy. Pharmacists are able to dispense medication at physician's offices, rural clinics, nursing homes and assisted-living facilities "with just the touch of a button."<sup>38</sup> Telemedicine is a tool that provides enhanced care to rural patients—improving access and the quality of care.<sup>39</sup>

Telemedicine brings promises of reduced health care expenditures,<sup>40</sup> improved cost-monitoring, encouraging better record keeping, and augmented access to quality care.<sup>41</sup> It provides access to health care services by bringing care to the patients, increasing patient understanding of their own health issues, and permitting patients to examine their own health data. In addition, there are promised improvements to the health professional's role by increasing local medical self-reliance, diminishing the sense of professional isolation, expanding educational opportunities for health care providers and offering the potential to reduce malpractice insurance. There are benefits to the community in, for example, permitting nurses to provide greater assistance in the delivery of health care,

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37. The Personal Telemedicine Module (PTM) is another device that works in conjunction with a PC, accompanied by a 16-inch monitor for enhanced visualization of skin rashes and wounds. The system are priced between \$3900 and \$6700, but American TeleCare points out that the average annual bill for a nursing home is between \$30,000 and \$35,000. *Id.* Thus, devices may be capable of keeping patients at home, where they are more comfortable and out of costly nursing homes, without sacrificing the care of the patient, and simultaneously reducing costs.

38. See Snyder, *supra* note 37, at 62. Patient compliance with drug regimens promise to be improved.

39. By 1996, twenty-nine percent of rural hospitals were either using or planning to use telemedicine. See Mary Jane Gore, *Telediology Network Pioneers: Harris/UCLA and Teleguest*, TELEMEDICINE SOURCEBOOK 233; *Telemedicine Projects Begin to Multiply*, HEALTH DATA MANAGEMENT (March 19, 1996) at 1.

40. The issue of cost is no small matter. For quite some time the cost of health care in the U.S. [13.6 in 1992] is considerably more than in any other country including Canada, and the comparative spending is shocking. "U.S. growth exceeded that of all other countries, the 3.2 percent annual rate was almost three times that of the typical country. In 1992, the U.S. figure was about \$3,100, a full 50 percent higher than the next highest figure (for Switzerland)." Thomas H. Rice, *Measuring Health care Costs and Trends*, p. 78 in CHANGING THE U.S. HEALTH CARE SYSTEM.

41. One advantage of telemedicine is its ability to provide services where services simply could not otherwise be provided due to remote location, or due to a lack of specialists in a small town. To a patient in a rural area, telemedicine can literally be a lifesaver. So many excellent articles and studies have been written on this subject that this author will not focus on this particular issue. However, the absence of focus in no way conveys the critical importance that telemedicine brings to such patients. In fact, failure of the regulatory system to clear the barriers could, in essence, be actionable. With so many telemedical services being perfected, it should be up to the particular patient and doctor whether any risks outweigh the benefits of receiving such care and/or treatment from a faraway physician. *Hearing of the Health and Environment Subcommittee of the House Commerce Committee*, ELECTRONIC COMMERCE AND HEALTHCARE, Federal News Service, June 5, 1998.

reducing hospital stays, and in the potential for greatly improved epidemiological studies provided by telemedicine.

As the need for home health and long-term care grows, telemedicine will provide the opportunity to deliver care to those in need who otherwise might not receive care. For example, telemedicine is being used in correctional facilities, and its use shows great potential for further expansion. Other areas, such as hospices and schools, provide testing sites for telemedicine to bring care to patients, reducing the costs of travel without compromising the quality of care.<sup>42</sup> A hallmark of "distance medicine" is that it gives access to care for areas that are medically underserved, or for people that have been traditionally underserved. Medical hospitals such as Texas Tech and the Medical College of Georgia have employed telemedicine to link physicians with patients and other physicians located in remote areas.<sup>43</sup> In many states, physicians are evaluating state prisoners through the use of video-conferencing. In the prison context telemedicine has the additional benefits of reducing traveling time for physicians and minimizing security risks.

Regardless of telemedicine's potential, significant regulatory and policy barriers threaten to disrupt the development of distance medicine. These barriers include reimbursement limitations and uncertain funding, cumbersome credentialing requirements, legal liability uncertainties and malpractice exposure, unclear data on cost-effectiveness,<sup>44</sup> and a lack of uniform national practice standards and telemedicine standards. Additionally, telemedicine has neither practice guidelines nor measurement

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42. A good example is California, where telemedicine is still in its infancy. The improvements underway in communications technology and telemedicine equipment make it possible to provide telemedicine in such settings such as home health, long-term care and correctional facilities. "Telemedicine offers significant 'safety and security and cost advantages to correctional facilities' while being able to provide the services of specialists not readily available to incarcerated individuals." TELEHEALTH & TELEMEDICINE, *supra* note 8, at 13.

43. There is extensive documentation on the piloting efforts of university and teaching hospitals and institutions, which have, to date, employed telemedicine to link physicians with patients and other physicians located in remote areas. Most of the legal scholars commenting on telemedicine's positive worth focus on the ability of telemedicine to bring care to the under-served. See generally, Lynette A. Hersha, *Is There a Doctor in the House? Licensing and Malpractice Issues Involved in Telemedicine*, 2 B.U. J. SCI. & TECH. L., 8 (Apr. 8, 1996) at 10-11. Although I have no evidence to suggest that telemedicine will bring anything but improved access, there could be the real risk that telemedicine, instead of improving care to the prisoner, or the elderly or the inner-city populous, could be met with complaints about lack of access to physicians and nurses in the name of a system which states that care is "just a phone call away." *Id.*

44. In 1995, this was a key comment of Douglas A. Perednia & Ace Allen. Allen, a wealth of telemedicine knowledge, still agrees that more data on cost-effectiveness is needed and that this is an area that should be further researched (Telephone conversation between author and Dr. Allen on March 10, 1998).

criteria, and scant information exists regarding clinical efficacy. There is even debate in the medical community regarding telemedicine's direction and infrastructure.<sup>45</sup> As a result, telemedicine is being legislated, regulated, studied,<sup>46</sup> reported, journalized,<sup>47</sup> conferenced, advanced, propounded, debated, bibliographed,<sup>48</sup> and webbed.<sup>49</sup> Telemedicine is being researched and piloted, both on small scale and large commercial endeavors. Telemedicine is the subject of multi-government laws and laws in waiting. However great telemedicine's promise, its full potential to address issues of quality, access and costs are imperiled by the lack of a strategic plan.<sup>50</sup>

With all the promise that telemedicine brings to the treatment of the remote patient, or that the remote physician brings to the patient, telemedicine, is, in itself, an oxymoron. Potentially, it is one more tool in "distancing" the patient from the caretaker and a series of events culminating in taking the physician yet another "real" distance from his ward.

Not long ago, the patient's relationship with his doctor was not merely clinical, but personal as well. This relationship was built at the bedside, not on the "public" operating table. There weren't any intermediaries, or providers, or insurance forms. Since that time, health care has changed and many more parties are involved in the delivery of services: the federal and state governments, insurance companies, Medicare, Medicaid, managed care, and the litany of HMOs, IPOs, PPOs, MSOs—providers of care in every size, shape and form. The patient, once the sole focus of the doctors' attention, now must navigate a new regulatory course to obtain the very treatment sought. With the need to reduce health care costs, and improve access, the patient is, *de jure* and *de facto*, further distanced from the physician. In fact, many

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45. See *Even with Barriers, Telemedicine Still Potential Revenue Generation for Telco*, BROADBAND NETWORK NEWS, VOL. 6, No. 6, March 19, 1996.

46. Department of HHS was mandated to conduct demonstration project in rural underserved areas, P.L. 105; TELEMEDICINE REPORT TO THE CONGRESS, DEPARTMENT OF COMMERCE (January 13, 1997) (51).

47. TELEMEDICINE TODAY, published its first issue in the Fall of 1992 and is an up-to-date account of current research, events, projects and funding.

48. See TELEMEDICINE: PAST, PRESENT AND FUTURE, written in 1995, contains 1,634 citations to articles, books and dialogues relating to telemedicine. Today, a similar task would be daunting because of the exploding wealth of material. In the past few years web sites and numerous journals devoted to providing information on telemedicine have been created.

49. See FDA, Center For Devices and Radiological Health on the World Wide Web at <<http://www.FDA.gov/cdrh/telem.html>>.

50. The two physicians who many be considered the real "grandfathers" of telemedicine, Douglas A. Perednia and Ace Allen pointed out the incredible number of federal agencies and state agencies involved in both the funding; research and telemedicine demonstration programs. See Douglas A. Perednia and Ace Allen, *The Journal of the American Medical Association*, Feb. 8, 1995, WL Database AMA-JNLS.

physicians are torn between their regulators and the person they have sworn to treat. Telemedicine, used initially and primarily in rural areas, holds the promise of reuniting the doctor to the patient.<sup>51</sup> If indeed this is telemedicine's promise, the telemedical community should not lose sight of its axiomatic principle: to bring health care to the patient by bringing the physician to his patient.

The physician, however, is only "virtually" present with the patient. Telemedicine, for all of its potential glory, could, in its application, have a dark side. Although telemedicine is viewed as a panacea for the ills of the underserved, there is the potential that telemedicine will not be used to augment the quality of care to the underserved, but to provide a minimum care from a distance in lieu of care that should optimally be provided in person; e.g. that telemedicine could be employed as a cheaper method to provide the least-necessary care, and in the name of improved access, deny the quality of care to a population that both needs improved quality the most and would ordinarily not be able to get the best care by the best physicians. This underserved population, e.g. the homebound, the prisoner, the elderly, the inner-city populous, need to be protected from potential abuse in using telemedicine solely for the purpose of saving costs.

What, then, are the key legal, regulatory issues posed by the telemedical care? First, to address issues of quality, each state should allow its medical licensing authority to require that any physician practicing "distance" medicine on patients in the state obtain registration from their licensing board. The board should require distance providers to meet minimum practice standards.<sup>52</sup> Enforcement of this requirement would be a matter of comity among the states. For example, California deems it "unprofessional conduct" for a California physician to practice telemedicine into another state without satisfying legal requirements set forth for practice by that state.<sup>53</sup> The states should coordinate credentialing requirements with other states. In addition, each state

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51. See generally Daniel McCarthy, *The Virtual Health Economy: Telemedicine and the Supply of Primary Care Physicians in Rural America*, 21 AM. J.L. & MED. 11 (1995); Andrea Hassol, Gary Gaumer, et al., *Rural Applications of Telemedicine Final Report*, 73 N.D. L. REV. 145 (1997).

52. The standards would provide a screen to keep out applicants who do not meet the educational or training requirements and provide protection for the consumers. See TELEHEALTH & TELEMEDICINE, *supra* note 8, at 55.

53. It also would ensure that a physician who is registered to practice telemedicine in the state be licensed in and practice in a state with a similar prohibition in that state's law. By the states' addressing reciprocal enforcement, the best interests of the patients will be served. Cal. Bus. & Prof. Code. Sec. 2052.5.

should coordinate a plan with JCAHO<sup>54</sup> and NCQA<sup>55</sup> to set telemedical credentialing standards in an effort to reduce the burden of obtaining credentials in each location where a remote physician practices. Second, physicians should always obtain informed consent of the patient. With respect to the telemedical practice, this should include the benefits, the risks, and the option of not participating in the telemedical consultation.<sup>56</sup> Third, to protect the confidentiality and privacy of the patient's telemedical treatment, the federal government should set minimum standards requiring: (1) the telepractitioner to obtain the patient's consent before transmitting any information electronically; (2) regulatory protections to deter any violations of confidentiality or invasions of privacy; and, (3) patient access to his or her records—especially records of studies regarding treatment and the disclosure of the risks associated with particular telepractice. Guideposts for regulatory measurement should be thorough and should comprehensively protect the patient's rights. For the most part, current laws, although prolific in this area, do not address the panoply of issues facing the telemedicine practitioner and patient.

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54. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO provides accreditation programs for hospitals, nursing homes, and other health care facilities. NCQA accredits health maintenance organizations. JCAHO and NCQA, two of the leading not-for-profit organizations, offer private accreditation in a nongovernmental, voluntary manner. These organizations set standards and determine whether institutions have met with their "seal of approval." State laws, JCAHO and NCQA, among other bodies, have requirements or provisions for credentialing. Credentialing becomes important in many contexts because payers for health care services may allow payments to JCAHO-accredited institutions only. State and federal governments will rely upon JCAHO accreditation in both their hospital licensure and Medicare certification programs. For purposes of the Medicare state, JCAHO-accredited hospitals are "deemed" to have met the requirements for Medicare certification, 42 U.S.C. Secs. 1395x(e), 1395bb, and thus JCAHO accreditation carries a lot of weight. In the telemedical context, a question arises whether a consultant needs to be credentialed not only at his or her own institution, but also at the remote institution from which attending physicians request consultation. See TELEMEDICINE, A GUIDE TO ASSESSING TELECOMMUNICATIONS IN HEALTH CARE, INSTITUTE OF MEDICINE, 1996 at 93–94.

55. The National Committee for Quality Assurance (NCQA). As discussed above, NCQA, established by the Group Health Association of America accredits health maintenance organizations and managed-care organizations. See <<http://www.ncqa.org>>.

56. The quality aspect of telemedicine provides the opportunity to share best practice, and the opportunity to examine detailed questions such as: Does the telemedicine provider have expertise the patient could not otherwise get? Has the patient been adequately informed of the nature of care, the delivery system, and alternatives, if any, to the telecare? Has the patient been informed of the telepractitioner's experience in telemedicine? Has the patient been informed of the alternatives to tele-treatment, including his choice to no treatment at all?

## II. CURRENT LAWS, POLICIES, AND POSITIONS RELATING TO THE PRACTICE OF TELEMEDICINE

Telemedicine today is the confluence of a number of areas, with most of the laws, regulators and professionals sharing the principle that telemedicine's end should be to improve the public good. First, it is widely-held that universal health care is a worthwhile goal, and professionals in the health care field are striving to see that all citizens, regardless of their socioeconomic class, or geographic location, have access to quality health care. Second, federal and state governments are attempting, through a variety of laws, to promote more efficient health care and to remove unnecessary barriers to delivery of services. The Telecommunications Reform Act of 1996 reflects the government's aim to provide this access.<sup>57</sup> Many of these ends can be furthered by telemedicine, but telemedicine has barriers preventing universal acceptance.<sup>58</sup> Three regulatory questions dominate this area: (1) licensure, credentialing, and liability; (2) access concerns, including standards for use, confidentiality, privacy; and, (3) economic issues, reimbursement for services, funding and cost effectiveness. Although telemedicine is just one of many health care systems designed to improve access, it provides a model for examining the necessary means for universal access.<sup>59</sup> As is the case in any circumstance involving the use of innovative applications of technology in the regulated world of medicine, the advancement of telemedicine applications will require resolution of many issues, including resolution of many parochial barriers that have been raised.<sup>60</sup> These barriers are often raised to protect the entrenched medical professionals, and fail to put the best interest of the patient first.<sup>61</sup>

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57. The current law in telemedicine is scattered, constantly changing and, like an adolescent, gangly—its arms and legs are everywhere and oftentimes unaware of where they are going, let alone connected to a head that is driving it forward on some preconceived path.

58. There are a plethora of issues and problems relating to telemedicine: issues of physician licensing, privacy and confidentiality of patient records, reimbursement for physicians, and funding. A policy paper, released jointly by the United States House of Representatives Medical Technology Caucus and the National Information Infrastructure Testbed, stated its belief that if legal obstacles to telemedicine are not resolved, it will be difficult to implement telemedical delivery services. Margolis, at 15.

59. "Universal access" is a term used to describe having the availability of communication systems. This should be distinguished, and not confused, with the term "universal care."

60. TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, at 1.

61. By placing patients' needs first, data suggest, a great many issues raised to thwart telemedicine may not be the patients' concerns, but rather that of others—perhaps even physicians. Data suggest that most patients are satisfied with the telemedical services they receive, but until recently research has been scarce. In 1978 Bashshur examined community attitudes toward telemedicine and the effects of experience on telemedicine on those attitudes. Fol-

In order to understand what action plans may be most successful for the optimum regulation of telemedicine, it is important to track the current laws and plans. The federal government has contributed millions of dollars to telemedicine projects. In fact, many existing state projects depend on federal dollars. But the licensing of telemedicine is controlled at the state level. Although there are some federal laws that facilitate delivery of telemedicine, those laws primarily allocate and release funds to support telemedicine delivery systems and provide reimbursement for services. Each state has either created a telemedicine-friendly environment to facilitate the use of telemedicine or an environment that barricades telemedicine from its borders. After looking at the pieces that make this montage, it is easier to identify the real leverage points to ensure that the best interests of the patient are addressed by those who both have the authority and power to take action.<sup>62</sup> In this section, I will first examine the current applicable laws relating to telemedicine, both federal and state. Next, I will set forth the barriers and checkpoints for telemedical applications—licensure, credentialing laws, as well as the checks on quality delivery—and the potential liabilities.

#### A. Current Federal Law and Applications

Within the last two years, three major federal laws were enacted which directly influenced telemedicine.<sup>63</sup> The first, the Telecommunications Reform Act of 1996, requires the FCC to assure that health care providers in rural areas have access to telecommunications services at rates comparable to those found in urban areas.<sup>64</sup> The Telecommunications Reform Act speaks to the availability of communication services as

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lowing a telemedicine session, 67 percent thought their telemedicine experience was about the same as in-person care; only 17 percent thought it was less satisfactory and the remainder were unsure. Bashshur concluded that familiarity “did breed comfort.” R. Bashshur, *Public Acceptance of Telemedicine in a Rural Community*, Biosciences Communications, 4 (1978) 17, at 36. In a study done by Allen and Hayes in 1995, thirty-nine cancer patients were interviewed and all were generally satisfied with telemedicine, although they commented that it was more difficult to be candid over the video system. However, in other studies conducted patients reported that they were “very satisfied.” See discussion in *Telemedicine: Theory and Practice*, at 302–305 (Rashid L. Bashur et al. eds., 1997).

62. It is equally important to understand all of the proposals for telemedicine that have either been advanced or are in the process of being advanced – at the federal and state levels.

63. It should be noted that all three pieces of federal legislation had separate sponsors, separate tracks, separate agencies, with totally separate jurisdictional oversight, none of which is directly related to “providing” medical care itself. It should also be noted that the Acts appear to have no requirement for direct coordination of implementation. For instance, pursuant to the Telecommunications Reform Act of 1996, the FCC set up an Advisory Committee on Telecommunications and Health care. HCFA has its own Task Force and the FDA its own experts in telemedical devices.

64. 47 U.S.C. § 151 (1996).



a vehicle to provide health-delivery services impacting telemedical services.

In the Telecommunications Reform Act, Congress updated and clarified the notion of "universal service" first articulated in the Communications Act of 1934.<sup>65</sup> In enacting this legislation, Congress required the FCC to ensure that rural healthcare providers have access to telecommunications systems necessary to deliver services at rates comparable to those offered in urban areas.<sup>66</sup> Health care providers, schools and libraries are to have early access to the benefit of advanced telecommunications. As such, Congress gave special consideration to health care providers in rural areas, maintaining that rural health care providers were to receive subsidies to the extent their rural rates were higher than urban rates. The Act defined advanced telecommunications, mandated the FCC institute a Federal State Joint Board, and the FCC was charged to enhance access to "health care providers."<sup>67</sup> Under the law, states are authorized to develop their own definition of services which improve health care delivery. Moreover, states are to encourage the deployment on a reasonably and timely basis of advanced telecommunications capability to all Americans. What this means for telemedicine is yet to be

65. 47 U.S.C. § 151 (134). The Communications Act of 1934 states a goal "to make available, so far as possible, to all the people of the United States a rapid, efficient, nationwide . . . wire, and radio communication service with adequate facilities at reasonable charges." This goal has since become known as universal service.

66. 47 U.S.C. § 254 (1996).

67. Shortly thereafter, the FCC announced rules to implement the provisions. The FCC's Universal Service Rule and Order initiative was promulgated to address what the outgoing FCC Chairman Reed Hundt called "often prohibitively high costs of telecommunications services in rural areas and thereby act as a catalyst for the growth of telehealth." It was Hundt's wish that a United States telehealth technology could "establish a model for the rest of the world to get quality health care to people anywhere in the world . . . [t]he lack of interoperability of much telehealth equipment due to a lack of standards is a primary barrier." The rule promulgated by the FCC in May, 1997 to implement the law has been challenged. See *Telemedicine, Clinical, Technical Standards Called Inadequate to Advance Field*, BNA HEALTH CARE DAILY, July 1997 (quoting discussions at a July 17, 1997 Washington D.C. meeting to discuss standards development for telemedicine); *Telemedicine, Views on Impact of Telecom Law Differ in Telemedicine Community*, 4 HCPR 21 (May 20, 1996). Included in the Report and Order were rural health care providers such as educational institutions offering health care instruction, teaching hospitals and medical schools, community health centers or health centers providing health care to migrants, local health departments or agencies, community mental-health centers, not-for-profit hospitals, rural health clinics, and consortia of health care providers of any of the above. See also FCC Report and Order, CC DKT 96-45, In the Matter of Federal and State Board on Universal Service, May 7, 1997. Omitted from this list of entities are "correctional institutions, assisted living facilities, nursing homes, visiting nurse associations, nonprofit HMO's or any other health provider who cannot be brought within one of these enumerated categories." See Mary Gardiner Jones, *Telemedicine and the National Information Infrastructure: Are the Realities of Health care Being Ignored?* JOURNAL OF THE AMERICAN MEDICAL INFORMATICS ASSOCIATION, VOL. 4, NUMBER 6 (Nov/Dec. 1997), p. 399 at 405.

seen but the Telecommunications Reform Act certainly lined the potential wires with gold. The door is open for health care advocates to suggest, develop and deploy advanced telecommunications networks. Most importantly, the FCC authorized the use of up to \$400 million each year to help subsidize improvements to rural providers and telecommunications networks and charges for telecommunications services. These funds will provide toll-free access to the Internet, cover long-distance charges of rural healthcare providers using telemedicine applications, and subsidize other telemedicine projects.

The second major reform was the Balanced Budget Act of 1997.<sup>68</sup> On January 1, 1999, the Secretary of Health and Human Services began making Medicare Part B payments for certain telemedical consultations provided to Medicare beneficiaries residing in underserved rural areas. The Secretary is required to establish a methodology<sup>69</sup> for determining the amount to be paid for these kinds of consultations. The subsidy will be shared between the referring physician or practitioner and the consulting physician or practitioner.<sup>70</sup> The Secretary is to report to Congress with an analysis of the manner in which telemedicine and telehealth systems are expanding access to health care services, the clinical efficacy and cost-effectiveness of telemedicine and telehealth services, the quality of the services, and the reasonable costs of the charges relating to telecommunications in these specific rural, frontier and under-served areas. In addition, the Secretary is required to provide a report to Congress, discussing the possibility of expanding reimbursement to areas other than the rural and underserved. The Secretary is to look specifically at providing Part B Medicare coverage for telemedicine services for beneficiaries not located in the designated areas but who are nonetheless homebound and for whom transfer to a care facility would impose a hardship. The Secretary's report must include information regarding the potential costs and savings to Medicare.<sup>71</sup> The Secretary is

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68. 42 U.S.C. 4206 (1997).

69. *Id.* at 4206(b); *See generally*, *HHS Backs Telemedicine: IOM Sets the Standards, MEDICAL OUTCOMES AND GUIDELINES ALERT*, No. 20 Vol. 4 (Oct. 24, 1996) (Prior to the enactment of the law, were many discussions and suggestions addressing the funding and reimbursement for telemedical services. One of the suggestions by the IOM related directly to reimbursing physicians for telemedical services). As will be discussed, on Nov. 2, 1998, HCFA published final rules governing reimbursement under Medicare for teleconsultations in rural health professional shortage areas. 63 FR 588789-58886 (Nov. 2, 1998).

70. Estimates on the amount of reimbursements range from \$100 to \$200 million per year for telemedicine reimbursement starting Jan. 1, 1999. *See Congress Approves Telemedicine Reimbursement*, HEALTH CARE STRATEGIC MANAGEMENT, No. 9., Vol. 13, (Sept. 1, 1997).

71. The Department of HHS published its final rule on Medicare telemedicine reimbursement on Nov. 2, 1998. *See* 63 F.R. 58879-58886 (Nov. 2, 1998). The reimbursement

also to fund a single, four-year demonstration project to use “eligible” health care provider telemedicine networks to improve primary care, and to prevent health care complications to Medicare beneficiaries with Diabetes Mellitus who are residents of these medically under-served rural or inner-city areas.<sup>72</sup>

The third major reform occurred with the Food, Drug and Cosmetic Act. The FDA already regulates medical devices, but the FDA has provided notice that telemedical devices—both hardware and software—are under the jurisdictional arm and regulatory authority of the Food and Drug Administration.<sup>73</sup> FDA, although not regulating the delivery of health care services, regulates technologies associated with health care delivery. The provisions of the law that are most likely to impact telemedical delivery services are the risk-based regulation of medical devices and the standards for medical products, which include DRGs and related devices.<sup>74</sup>

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guidelines work out a fee schedule under which providers will be reimbursed for telemedicine consultations. Medicare beneficiaries residing in rural HPSAs are eligible for teleconsultation reimbursement.

72. The specific objectives of the projects include improving patient access to and compliance with the guidelines for individuals with Diabetes Mellitus by a direct telecommunications link for information networks to improve patient quality-of-life and to also reduce overall health care costs. In addition, the project objectives include developing a curriculum to train health professionals in the use of medical informatics and telecommunications, to demonstrated the application of these advanced technologies to help primary-care providers assist patients with their diabetes in a “home” setting, to assist those residents who have limited English language skills, to also develop standards for the application of telemedicine and medical informatics and to develop a model for the cost-effective delivery of primary and related care in both a fee-for-service environment and in a managed-care setting. The Secretary must also submit interim reports and a final report on the project, which will evaluate the impact of the use of telemedicine and medical informatics on improving access of Medicare beneficiaries to health care services, on reducing the costs of such services and on improving the quality of life of the beneficiaries. The total amount of payments that can be made under the project for the four-year period may not exceed \$30 million dollars. Clearly, excepted from this legislation are the costs for any support equipment. Also not included is the purchase or installation of transmission equipment, costs for the establishment or operation of a telecommunications common carrier network, and costs of construction. Notwithstanding the exceptions, the Act has been supported by the health industry because it is the most sweeping piece of legislation “with the broadest potential impact that we’ve seen in a number of years.” *Opportunities, But Not Guarantees, for Rural Hospitals in Federal Budget Act*, No. 11, VOL. 13, Nov. 1, 1997.

73. The FDA does not regulate the delivery of health care services nor the transmission of information related to care between physician and patient. 21 U.S.C. Sec. 301–381. *See* CENTER FOR DEVICES AND RADIOLOGICAL HEALTH FOOD AND DRUG ADMINISTRATION (July 11, 1996) available at <<http://www.fda.gov/cdrh/telemed.html>>.

74. The total impact of all these changes will not manifest itself immediately, but, just last year FDA had more activity in addressing the hardware and software of medical devices than ever before.

### B. State Telemedicine Laws

The federal regulatory scheme provides the framework to view the national boundaries of telemedicine application. The actual building of telemedicine programs and applications is both being legislated and built at the state level. On the state front, telemedicine activity has taken place in some form in every state with the possible exception of Rhode Island.<sup>75</sup> Many states have recently established and coordinated efforts. For example, in California and Kansas professional self-regulation and the governmental regulation of licensure and professional requirements are intertwined. For many reasons, licensure requirements have been designed by the states and are, in fact, delegated to the states as part and parcel of the states' police power. Part of this is historical in nature, part of this is because of the recent trend to decentralize government power to the states, and much of it relates to the growth of the medical profession and the manner in which it has developed. The licensure requirements and credentialing processes are based upon standards that have been developed by the medical professionals. Although under the auspices of the state government police power, the "policing" of the practice of medicine is in the physician's control. Medical boards, the licensing bodies, and even disciplinary panels are usually made up of medical professionals.

## III. REGULATING THE QUALITY OF CARE: LICENSURE, MEDICAL MALPRACTICE AND THE DOCTRINE OF INFORMED CONSENT

### A. Regulation by Licensure

Licensure is a state-based patient protection system.<sup>76</sup> Since telemedicine poses, by its very nature, the probability that medicine will be

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75. As of this writing, there are no major projects or legislation underway in Rhode Island.

76. Regulation of the practice of medicine is relatively new, but its origins date back to the age of Hippocrates. To the Hippocratic physician, the "injunctions and [enjoiners] were intended to safeguard the art and guard the reputation of the profession and its practitioners." [96]. It was a matter more of professional protection against non-professionals and protecting the "patient" from a person not "taught" by the professional scholar. Early on, this duty of licensing, passed from professor or scholar to student and was a matter more of ethics, to ensure that the pattern of performance was upheld, than the legal requirements. In fact, during Hippocrates' time, there were no state regulations or laws that addressed licensing. The Hippocratic oath is really a body or legacy of ethics and its purpose is to provide a "certain standard of decorum, a certain, etiquette, mainly to uphold a certain standard of performance, and serves to distinguish the expert from the charlatan."

practiced across state lines, state cooperation or federal regulation must be considered.

### 1. Current Licensure Laws

Throughout this country's history, states have been the gatekeepers of medical licensure.<sup>77</sup> Today, every state in the United States has laws and/or regulations that set forth strict requirements to be met before any physician, nurse, dentist or other "health professional" may hold themselves out, and legally practice, that profession within the borders of that particular state.<sup>78</sup> State licensing statutes require a physician to be li-

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77. Medical licensure history in the United States goes back some 150 years. The goal of licensure is to protect the patient by limiting the entry into the medical profession to those professionals who have met minimal requirements set forth by the state's professional regulating body. In 1889, the Supreme Court affirmed the need for medical licensure as well as an affirmation of its purpose: A unanimous Supreme Court ruled that the State had an interest, far superior to Dr. Dent's, in protecting its constituents: "Few professions require more careful preparation by one who seeks to enter it than that of medicine. Every one may have occasion to consult him [the physician], but comparatively few can judge of the qualifications of learning and skill which he possesses. Reliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications." *Dent v. State of West Virginia*, 129 U.S. 114, 117-18 (1889).

78. See Code of Alabama § 34-24-51 (Practice without license or certificate, Sec. 34-24-74 (Temporary privilege to practice in state); 34-24-50 ("Practice of medicine or osteopathy" defined; Ala. Code § 34-24-500 (Mar. 1, 1998) (authorizing the Medical Licensure Commission to issue special purpose licenses to practice medicine or osteopathy across state lines.") See also H.B.592(authorizing the Board of Optometry to issue a special purpose license to practice optometry across state lines providing an exemption from the licensure requirements for "irregular and infrequent" practice across state lines) (enacted June 11, 1998); Alaska Stat. § 08.64.170 (License to practice medicine, podiatry or osteopathy (does not address telemedicine or consultations outside of state); Arizona Rev. Statutes § 32-1455; 1421 (Exemption from licensing requirements under limited circumstances); See also § 41-108 (telemedicine provisions applicable only to practice of telemedicine within the state of Arizona); Arkansas Stat. Ann. § 17-95-401 (license requirements), § 17-95-203 (exemptions); California Bus. & Prof. Code §§ 2052, 2053; Chapter 864 of the California Laws (SB1665) (California Telemedicine Development Act of 1996); Colo. Rev. Stat. § 12-36-129 (exemptions for limited and "occasional" services only); Colorado Rev. Stat. § 12-36-106 (license not required for occasional medical services by a physician licensed and residing in another state); Conn. Gen. Stat. 20-9 (Act addresses telemedicine licensure providing exemptions for nonresident physicians who, while located outside Connecticut, consult on an irregular basis with a Connecticut physician or with a medical school within Connecticut; also provides from exemption for emergency situations; 24 Del. Code § 1702 (consultation exemption); DC Code § 2-3305.1-2 (emergency and consultation exemption); Florida Stat. § 458.327(requires licensure of physicians who provide electronic-communications diagnostic-imaging or treatment services but exempts nonresident physicians who consult through electronic communication on an irregular basis); Ga. Code Ann. § 43-34-31.1 (exemption for medical specialists for consultations and episodic consultations and physicians for consultations for emergencies, without the expectation of compensation, provide services to a medical school approved by the board, are guests of an approved medical school to assist for the sole purpose of proving professional education); Hawaii Rev. Stat. § 453-2 (exceptions for emergency situations and limited telemedicine consultations); See also 1997 HI S.B. 512 (Exceptions for telemedical practice);

censed in the state in which the physician is practicing medicine. When a physician in a state renders telemedical services to a patient in the same state, there is usually no additional requirement for a license. But once the practice of telemedicine extends beyond the state line, licensing

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Idaho Code § 54-1804 (emergency and consultative exceptions); 225 ILCS 60/3-4 (emergency exception); § 225 ILCS 60/49.4 (Telemedicine licensing provisions); Burns Ind. Code Ann. §§ 25-22.5-8-1, 2 (includes in the definition of the practice of medicine transmissions through electronic communications, but provides exemptions for second opinions from outside the state); Iowa Code § 147.2 (1996); Iowa Code § 8D.1-14; Kansas Stat. Ann. § 65-2803; Kentucky Rev. Stat. § 311.560; La. Rev. Stat. Ann. § 1271; 22 Maine Rev. Stat. Ann. § 85-2803; Maryland Health Occupations Code Ann. § 14-301 (14.302, Exceptions for consultations); Mass. Ann. Laws. Ch. 112 § 6; Minn. Stat. § 147.081, § 147.09 (consultation exemption); Miss. Code Ann. § 73-25-1 (license generally); 73-25-34 (requires an individual hold a Mississippi medical license to practice telemedicine); R.R.S. Neb. § 71-102 (general license) 71-1,103 (emergency and temporary practice rights exception); Nev. Rev. Stat. Ann. § 630.160 (license general including Sec. 630.020(3) (practice of medicine includes diagnosis and treatment of illness "using equipment that transfers information concerning the medical condition of the patient electronically, telephonically or by fiber optics."); N.H. RSA 329-24, 21 (consultation exception); N.J. Stat. § 45-9-6 (strict exceptions for temporary practice from the State Board); N.M. Stat. Ann. § 63-6-20 (emergency exception); NY CLS Educ. § 6522 (limited exception); N.C. Gen. Stat. § 90-18 ("A person who resides in any state and who, by use of any electronic or other mediums, performs any of the acts described in this subsection shall be regarded as practicing medicine or surgery.") 1997 NC S.B. 760 (license requirement as well as medical malpractice provision for those patients who may bring a medical malpractice claim in North Carolina courts against a nonresident physician who practices medicine or surgery by use of any electronic or other media in North Carolina); N.D. Cent. Code, § 43-17-34, 42 (limited exemption for out of state physicians who do not have offices within the State); ORC Ann. § 4731.41 (Anderson); Pending H.B. 193 (Mar. 1, 1998)(would require an individual providing medical services in the state, including through electronic communication, to be licensed by the Ohio State Medical Board); 59 Okl. Stat. §§ 491, 492(C)(2)(b) (practice of medicine includes "performance by a person outside of this state, through an ongoing regular arrangement, of diagnostic or treatment services through electronic communications for any patient whose condition is being diagnosed or treated within this state.") ORS § 677.080; 63 P.S. § 422.10 and § 422.34 (extraterritorial license, adjoining state exception); R.I. Gen. Laws § 5-37-12 (H.B. 7588 and H.B. 8228 pending addressing telemedicine licensure issues); S.C. Code Ann. § 40-47-60; S.D. Codified Laws §§ 2-2, 36-4-41 (practice of medicine includes diagnostic or treatment services through electronic means to a person located in this state); Tenn. Code Ann. §§ 63-6-201, 63-6-201; Board of Medical Examiners/Division of Health Re. TAC0880-2-16; Tex. Rev. Civ. Stat. Art. 4495b § 3.06(i); Utah Code Ann. §§ 58-1-307, 58-1-501; 26 V.S.A. § 1311 et seq. S.B. 245 (would include in the practice of medicine across state lines the rendering of diagnostic or treatment services to a Vermont patient by a person located outside Vermont by electronic or other means); Va. Code Ann. § 54.1-2901 et seq; Rev. Code Wash. (ARCW) §§ 18.71.021, 18.71030 (1997); Wash. H.B. 1216 (would require a nonresident physician providing tele-electronic care to a Washington resident to be sponsored by a physician licensed to practice and residing in Washington); W.Va. Code. § 30-3-13; Wis. Sta. § 448.03(consultation exception); Wyo. Stat. § 33-26-301 (consultation exception). See TELEMEDICINE, EMERGING ISSUES, *supra* note 34, Appendix for information concerning other statutes and bills relating to telemedicine practice; See 150 TELEMEDLAW, 1998 COMPENDIUM OF TELEMEDICINE LAWS, SELECTED STATUTE EXCERPTS AND ARTICLE CITATIONS RELATING TO TELEMEDICINE. This area of the law is changing very rapidly and many states are in the process of changing their licensing laws to include the practice of medicine, especially telemedicine, across state lines.

issues become more complex. There are several permutations to this “regulatory locus” problem: the patient may be located in a state different from the state in which the physician is located, the physician may be in the same state as the patient but consult with a physician located out of state, or the patient, physician and consulting physician may all be in different states.<sup>79</sup>

Within the last five years, states have begun to enact laws that specifically address telemedicine licensure. States adopt a variety of approaches. First, telemedicine laws sanction liberal interstate practice of medicine. Second, telemedicine practice might employ existing statutory frameworks that provide limited exceptions, including consultation with out-of-state practitioners. Finally, other states prohibit the practice of medicine by a telepractitioner outside the states borders.

Only four states do not provide for out-of-state consultation exceptions.<sup>80</sup> The prerequisite for the “consulting exemption” is that the physician located within the state is the treating physician. In many instances, the limitation imposed on the exemption assures that the outside consultant will not have the authority over the care of the patient being treated within the state.<sup>81</sup> To assist physicians in seeking medical exper-

79. All of the states have enacted laws that govern the practice of medicine and most state statutes delegate their authority to regulate to the states’ Board of Medical Examiners. The history of licensure couple with the police power reserved to the states by the United States Constitution to adopt laws to protect the health, safety and general welfare of their citizens, supports this single state licensure system. See TELEMEDICINE: EMERGING LEGAL ISSUES, *supra*, note 34 at 3; see also Kathleen M. Vyborny, *Legal and Political Issues Facing Telemedicine*, 5 ANN. HEALTH L. 61, 66 (1996).

80. As a result of distance medicine, the “where” is becoming the critical issue. In the past, “where”, in the practice of medicine, has been clear. With the introduction of the first telephone call between doctor and patient, or doctor and consulting doctor, all of this had the potential to change. With advances in technology, coupled with the movement of society and increased specialization, these changes went into high gear. Today, state licensing statutes require a physician to be licensed in the state in which the physician “practices medicine.” Consequently, if a physician licensed in state A delivers telemedical services to a patient in A, there are usually no additional licensing requirements. But when the physician in A practices telemedicine across state lines, then the legal issues become more complex. See TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* at 3.

81. TELEHEALTH AND TELEMEDICINE, *supra* note 8, at 53, for example, legislation has recently passed the California legislature (SE 1665) defining the consulting relationship to assure that the outside consultant will not have ultimate authority of the treating physician of his patient located within the California borders. However, “[t]he law is silent on the types of communication covered by the consultation exemption. Thus consultations, including telemedical consultations, may be obtained by California licensed physicians for California patients as long as the consulting doctor is licensed in his or her state of residency” (26). Thus, doctors and patients may have access to the medical authorities of their choice, regardless of their location and California license status and a Californian may achieve this access by calling, writing, e-mailing, or telemedically consulting with any physician in the United States as long as the consulting physician is licensed in his or her state of residency.

tise from other physicians out of state, most states have created exceptions to the general rule and permit some form of consulting exception. Until recently, most state statutes did not offer “protection for an out-of-state clinician unless a consultation is requested by or otherwise involves an in-state clinician.”<sup>82</sup> In Massachusetts, for example, the licensing requirements do not apply to “a physician or surgeon resident in another state who is a legal practitioner therein, when in actual consultation with a legal practitioner of the [C]ommonwealth.”<sup>83</sup> This exception to the rule has limitations, as interpreted and thus, the “consultation” exception only applies if the out-of-state physician provides a Massachusetts’ patient with a teleconsultation, and, if the out-of-state physician “is consulting with a Massachusetts physician of the same specialty.”<sup>84</sup>

Instead of providing more “license” to encourage telemedicine practice, many states’ physician licensing boards have placed even more restrictions on consultations, making routine telemedical consultations impractical if not impossible.<sup>85</sup> By limiting the number of consultations an out of state physician may provide without first obtaining a license

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82. *Id.*

83. Mass. Gen. Laws. Ch. 112, § 7. See discussion in TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, at 11 citing a second exception for “a physician authorized to practice medicine in another state, when he [or she] is called as the family physician to attend a person temporarily abiding in the [C]ommonwealth.” *Id.* Only Louisiana, Maine, Missouri, and New Mexico do not provide by statute for some type of consultation exception. Many states, have time and significant restrictions on the “consultation” exception. As discussed in TELEMEDICINE: EMERGING LEGAL ISSUES, Alabama provides a strict time restriction on the number of days an out-of-state physician, not licensed in Alabama, may be called into the state for consultation. The physician may “practice medicine without a license for no more than 10 calendar days in a calendar year.: Ala. Code § 32-24-74.

84. Massachusetts has carved out a consultation exception. See Mass. Gen. Law ch. 112, § 7. The Massachusetts licensing requirements will not apply to “a physician or surgeon resident in another state who is a legal practitioner therein, when in actual consultation with a legal practitioner of the [C]ommonwealth.” Note, however, that the Massachusetts Board of Registration has “stated unofficially that the Board understands ‘consultation’ to mean a consult between physicians with the same specialty.” See TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, at 4, 11. The effect is a physician from another state may teleconsult with a Massachusetts physician if and only if in the same specialty. On June 1, 1998, Colorado instituted changes to its state’s licensure statute adding “telemedicine” to the statutory definition of the “practice of medicine.” Similar to exceptions to the practice of medicine provided in other state licensure reforms, Colorado provides an exception for a physician lawfully practicing medicine in another state or territory who renders services in Colorado “whether or not such physician is in Colorado” but the services are limited to those occasional “consultations” or cases. The Act also exempts from the licensure requirements certain out-of-state laboratory testing functions. 1998 Colorado Senate Bill 36 (effective July 1, 1998). See also Ariz. Rev. Stat. Ann. § 36-4-41 (1997); Conn. Gen. Stat. Ann. § 20-9 (1997); Ind. Code Ann. § 25-22.5-1-1.1 (1996); Nev. Rev. Stat. Ann. § 630.020 (1997); Okla. Stat. Ann. § 492(C)(3)(b) (1997); S.D. Codified Laws Ann. § 36-4-41 (1997); Tex. Rev. Civ. Stat. Ann. art 4495b (1997).

85. See Ala. Code § 34-24-72, note 144 *supra* note 33.



from the state, by limiting the number of days or type of consultation that may occur, or limiting the state or the locality of the state in which the consultation may occur, states have closed the door on the practical application of "telemedicine."<sup>86</sup>

Strategies to address telemedicine vary from state to state, but most states that have addressed the issue of telemedicine have also addressed the issue of what telemedicine means to their definition of the "practice of medicine." At the end of 1997, at least 15 states<sup>87</sup> had addressed the need to amend or enact new legislation, one state had written an administrative rule addressing out-of-state licensure and another had the Attorney General issue an opinion on the subject.<sup>88</sup> To alleviate the burdens on physicians created by the licensure process, most states have carved out exceptions to the rule requiring a "license" to practice medicine.<sup>89</sup>

Some states, recognizing they may be losing some of their physicians to other states on a regular or consultative basis, have taken the position that they would, in effect, burden access to other state's practi-

86. In fact, real "telemedicine" is not concerned with the locality of the in state physician at all and could result in a patient in California being treated directly by a doctor from New Jersey.

87. At end of 1996, only 11 states had enacted laws. The laws may vary but the certainty is the recognition that this issue of licensure and interstate practice of medicine is more and more commonplace. See 1997 Oklahoma House Bill 2868, which became effective July 1, 1998 creating a Telemedicine Advisory Council whose purpose is, *inter alia*, to study the barriers as well as to make recommendations. See also 1997 New Hampshire Senate Bill 383 creating a special committee (enacted June 1, 1998). See TELEMEDLAW, *supra* note 83, <<http://www.legamed.com>>.

88. Laws varied and include a broad-based and usually liberally-interpreted exemption from licensing requirements for "medical consultations," a license issued specifically to out-of-state telemedical practitioners, exemptions for "irregular consultations and unplanned or emergency consultations. Most of the laws provided that the in-state practitioner, consulting with the out-of-state consultant, retain ultimate treating authority.

89. For example, Massachusetts has carved out a consultation exception. See Mass. Gen. Laws ch. 112 § 7. The Massachusetts licensing requirements will not apply to "a physician or surgeon resident in another state who is a legal practitioner therein, when in actual consultation with a legal practitioner of the [C]ommonwealth." Note, however, that the Massachusetts Board of Registration has "stated unofficially that the Board understands 'consultation' to mean a consult between physicians within the same *specialty*.'" See TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, at 4. The effect is a physician from another state may teleconsult with a Massachusetts physician if and only if in the same specialty. On June 1, 1998, Colorado instituted changes to its state's licensure statute adding "telemedicine" to the statutory definition of the "practice of medicine." Similar to exceptions to the practice of medicine provided in other state licensure reforms, Colorado provides an exception for a physician lawfully practicing medicine in another state or territory who renders services in Colorado "whether or not such physician is in Colorado" but the services are limited to those occasional "consultations" or cases. The Act also exempts from the licensure requirements certain out-of-state laboratory testing functions. 1998 Colorado Senate Bill 36 (effective July 1, 1998).

tioners.<sup>90</sup> Other states, such as North Dakota, have mandated the study of the use of telemedicine and what is needed for licensing changes.<sup>91</sup> Still other states, such as Illinois, have directed its state health department to study the feasibility of using telemedicine for both rural areas and patients that are homebound.<sup>92</sup> There are a few states that have not fully determined a stance on the licensure issue but have had conferences and/or bills proposed regarding their policy.<sup>93</sup>

In a minority of states, legislatures have restricted consultations, making routine telemedical consultations impossible.<sup>94</sup> These states limit the number of consultations that can occur without obtaining a local

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90. See California. Gen. Code § 37.

91. This approach makes sense. As noted in the Institute of Medicine's study on telemedicine, *supra*, many times the place in which telemedical practice occurs is of no consequence. Many of the grants for telemedicine, even the private studies, are conducted within the state's fences. The most experimental studies may be conducted by federal agencies, so state licensure laws are not applicable to a physician practicing medicine for a federal agency.

92. In conjunction with the practice of medicine, telemedicine obviously impacts what is or is not encompassed within each state borders' definition of the "practice of medicine." Since states have taken a variety of approaches to licensure, there is no single definition. In fact, at least one state provides specifically for osteopathic consultants (Oklahoma). Oklahoma H.B. 2868 established a Telemedicine Advisory Council to research the barriers to the development of telemedicine.

With the growth of alternative medicines, many states are beginning to look into legislation that will permit physicians to use alternative treatments, such as chiropractic and homeopathy. With the broadening of the practice of naturopathy medicine, it is conceivable out-of-state consultations could be sought as well.

93. The Medical and Chirurgical Faculty of Maryland, "Med Chi", has looked at this issue and a bill introduced in the Maryland State Senate would have required physicians to have a "special purpose license" to practice interstate telemedicine for patients in Maryland. In order to obtain this license, the physician would have had to apply to the State Board of Physician Quality Assurance, be licensed in another state and have a good record. The bill was withdrawn until the issue could be studied in further detail. Paul Briggs, *THE DAILY RECORD* (Baltimore, Md.) Nov. 5, 1997

94. See Ala. Code § 34-24-74. By limiting the number of consultations that the out-of-state physician may provide without first obtaining a license from the state or by limiting the number of days or months or type of consultation that may occur, or limiting the state or locality of the state in which the consultation may occur, states have closed the door on the practical application of "telemedicine." In fact, real telemedicine is not concerned with the locality of the in state physician at all and could result in a patient in California being treated directly by a doctor from New Jersey. In fact, the arguments for continuing the current state-directed licensing systems are met with furor with some calling licensing by the states a smokescreen. "Licensing has been hotly debated in many quarters, and some believe that this furor is a smokescreen. The underlying issue may be the economic interests of local doctors who don't want competitors beamed into their region." Dr. Sanders, a telemedicine advocate, believes that they may worry too much. "If they're good doctors, and they clearly demonstrate their concern for their patients' welfare, people will continue to come to them." Patrick Burns, *Changing times and the business case for 'telestuff', Innovative Telemedicine Solutions*, HEALTH MANAGEMENT TECHNOLOGY, No. 8, Vol. 18 (July 1997).

medical license, or limit the number of days that consultations occur, or limit the consultations to physicians practicing in bordering states. In a few states, the consultation exemption has been eliminated and the laws now require that any consultation occur only with a physician licensed by that state.<sup>95</sup> A number of states have reduced the existing burdens of individual state licensure by expediting the licensure process. South Dakota and Tennessee have allowed for reciprocity for the practice of telemedicine providing the other state's requirements are not less stringent than theirs. New Mexico has allowed telemedicine licensure by endorsement if a physician otherwise meets the requirements of New Mexico's laws.<sup>96</sup> Finally, Alabama and Tennessee have adopted restricted or special licenses.

State licensure has worked well for many years to regulate physicians. This system delegates to the states the power to adapt their regulations to the needs of their constituents, and gives wide latitude to make changes that will best serve their local needs. On the other hand, to the patient who is in need of a specialist located in another state, to the telepractitioner that cannot obtain a consultation because state laws prohibit the practice of medicine within its boundaries by those not licensed in the state, or to the hospital located on the border of a state with specialized needs located in its sister state, state laws can impede the telepractitioner's practice—in terms of time, expense and licensure requirements.<sup>97</sup>

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95. This type of restrictive regulation is in the name of controlling quality of medical services within the states' jurisdictional borders. But proponents of a national license believe that these type of state licensure restrictions "will prevent the spread of much needed medical services." Bass, Berry & Sims, *Telemedicine Expected to Grow*, TENNESSEE HEALTH LAW UPDATE (Jan. 1997). The argument has been raised that these restrictions unduly interfere with interstate commerce and if the state statute and regulation are not rationally related to furthering a legitimate state interest they may not be upheld by the United States Supreme Court. The Court could strike down legislation that is found to be based not on quality concerns but rather on economic protectionism. This type of statute, "which singles out interstate telemedicine consultations and not other types of consultations," could be vulnerable to a challenge. *Id.*

96. The practice referred to as "endorsement" requires submission of multiple documents, including educational histories, personal records, and certifications. Additionally, the specifications for the "practice of medicine" differ among the states, with many states requiring additional examinations. See Code of Alabama § 34-24-74 (Practice without license or certificate; temporary privilege to practice in State).

97. In addition to the costs associated with the application fees, the process itself is costly from a time perspective and involves massive paperwork. Interestingly, to date, there is not a proposal for a uniform state licensure application, which would at least minimize the length of time. See <<http://www.telemetoday.com/new/Statelaw.htm>>; Linda Gobis, *An Overview of State Laws and Approaches to Minimize Licensure Barriers*; <<http://www.telemetoday.com/new/Statelaw.htm>>. Additionally, the impact of state laws on the telepractitioner practicing internationally has not felt its full effect. International practice, not

## 2. National Initiatives: Professional Organizations, Institutions, and Commissions

Notwithstanding the government's interest in promoting telemedicine, many state licensing laws for physicians inhibit telemedicine's full realization.<sup>98</sup> Commissions and professional associations, recognizing that licensure is a key area that needs to be addressed, have proposed a variety of suggestions to remove licensure as a barrier to the practice of telemedicine.<sup>99</sup> Private organizations reflect the tensions between established regulatory systems and emerging reforms, disagreeing over which body—federal or state—deserves primary regulatory power in this area. A Telemedicine Report to Congress suggested that although there is a strong presumption against state preemption, states would have to give way to paramount Federal legislation.<sup>100</sup> As a California Commission suggested, the state adopted a license that permits consultants to practice within the State of California, but the ultimate decision making power rests with the patient's California doctor.<sup>101</sup> The Western Governors' Association has recommended a task force to draft a Uniform State Code for Telemedicine Licensure that would be similar in principle to the Uniform Commercial Code.<sup>102</sup>

The medical societies that have addressed telemedicine issues hold fast to the concept of self-regulation, and although professional organizations have come to a variety of proposed solutions, none espouses a national licensure scheme as proposed by the Telemedicine Task Force.<sup>103</sup>

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the focus of this article, is well underway. See David R. Johnson and David Post, *Surveying Law and Borders—The Rise of Law in Cyberspace*, 38 STAN. L. REV. 1367m 1382 (May 1996).

98. See Christopher Guttman-McGabe, *Telemedicine's Imperiled Future? Funding, Reimbursement, Licensing and Privacy Hurdles Face a Developing Technology*, 14 J. CONTEMP. H.L. & POLICY 161, 169 (1997).

99. A number of private commissions and task forces have made proposals at the request of governmental bodies looking into this issue.

100. See TELEMEDICINE REPORT TO CONGRESS, <<http://ntia.doc.gov/reports/telemed>>; see also TELEMEDICINE REPORT TO CONGRESS EXECUTIVE SUMMARY, 73 N.D. L. REV. 131 (1997).

101. The California Task Force vocally suggested that it had no time to wait for the Congress of the United States to resolve this legal issue. TELEMEDICINE, *supra* note 8 at 30.

102. This task force would be composed of interested parties and should consider issues such as the definition(s) of telemedicine, simplified licensing of individuals, licensure of networks, and requirements and grants of credit for continuing medical education. The task force could "explore the possibility of expanded interstate reciprocity in licensing and credentialing as an alternative to a model code." *The Western Governors' Association Telemedicine Action Reports*, 73 N.D. L. REV. 35, 55 (1997).

103. The Telemedicine Task Force, favoring a uniform interstate licensure system that is state-based, recognizes that it may not be feasible to accomplish this in the near future and suggests, in the alternative, a national licensing system. The Task Force, nonetheless, would leave the disciplinary authority with the states because the states are more "accountable to

The American Medical Association has examined the interstate<sup>104</sup> licensure issue, and recommends that all physicians be fully licensed in every state where their patients are located and/or where they practice medicine.<sup>105</sup> Likewise, the American College of Radiologists recommends that telemedicine physicians maintain residential licenses in addition to remote state licenses.<sup>106</sup> However, the Federation of State Medical Boards, which in the past had opposed national type legislation, has drafted model legislation that if adopted by states would move a step in between and create a special license for physicians. This approach would eliminate the necessity for a license in every state where the physician might practice telemedicine. In 1996, in response to telemedicine issues, the Federation of State Medical Boards developed this Model Act to regulate medicine across states lines. The Act, as proposed, requires physicians practicing medicine across state lines to obtain a special license issued by a state medical board. The license would be limited to those practicing medicine across state lines, and would be required for regular or frequent telemedicine practitioners. It would exempt a physician who engaged in practice across state lines in an emergency.

### 3. Current Legislative Activity

Most states that have not enacted statutes directed at telemedicine do have telemedicine bills pending under the following rubrics: individual state, interstate, model act and national licensure proposals. This nomen-

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their citizens." *Id.* at 130. The Center for Telemedicine Law, (CTL), a non-profit organization that addresses legal issues that may be impediments to the development of telemedicine, also argues for a uniform interstate licensure. See *Trends & Timelines Telemedicine*, AMERICAN POLITICAL NETWORK, Feb. 14, 1997, at 2.

104. BNA HEALTH CARE DAILY, July 2, 1996.

105. See also articles on licensure including Bass, Berry & Sims, *Telemedicine Expected to Grow In*, Tennessee Health Law Update, Vol. 3, Issue 4, 48 (Jan., 1997). Although not yet voted on by the American Bar Association's (ABA's) House of Delegates, and therefore not representing ABA policy as such, the Young Lawyers Division of the ABA has considered the issue of interstate telemedical practice and has favorably voted on language which would urge Congress to permit the practice of telemedicine across state lines "Notwithstanding any state law to the contrary, a physician licensed to practice medicine or surgery in any state is permitted . . ." TELEMEDLAW, *supra* note 83.

106. The AMA has, "simultaneously, encouraged all national specialty societies to work with these state societies to develop comprehensive practice standards and guidelines to address the clinical and technological aspects of telemedicine . . ." The AMA would also support legislation requiring that medical care organizations that establish ongoing arrangements for medical care delivery from remote sites require practitioners at those sites to meet the same credentialing standards and participate equally in appropriate quality review as those at the site of delivery. The AMA would encourage hospitals and other medical care organizations to develop a medical staff membership category that "would allow telemedicine and physicians regularly providing medical care to be granted and maintain medical staff membership." BNA Health Care Daily (December 11, 1996).

clature, although somewhat forced, provides a spectrum to look not only at the variety of approaches to regulating the quality of care, but the policy issues driving those approaches.

#### a. Individual State Licensure<sup>107</sup>

Most states, recognizing that special licensing issues are required to further telemedicine, bring telemedicine within their existing "practice of medicine" definitions. California and Mississippi, for example, have expanded their definitions while maintaining exclusive control of medical regulation.<sup>108</sup> California's approach, granting its Medical Board the authority to develop a registration program that would allow out-of-state physicians to provide telemedicine services to California residents, provides a broadened acceptance of the telemedical practice, and simultaneously, addresses quality control over its patients. Most of the laws and legislative proposals require a special license providing for telemedical services, but make exceptions for consultations, educational demonstrations, lectures and emergencies. The California approach, however, is atypical as most states continue to regulate only those physicians practicing within their borders. In fact, the individual state license is the approach endorsed by the American Medical Association (AMA). The AMA's House of Delegates has urged that physicians be licensed in every state where their patients are located.<sup>109</sup>

#### b. Interstate Licensure

The interstate licensure model has been proposed by one state compendium, the Western Governors' Association. It takes a number of forms: a multistate licensure system, mutual recognition, a uniform interstate licensure system, or interstate compact. State licensing bodies would provide consistent licensure requirements and allow physicians to qualify for practice in other states without duplicative examinations and

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107. Included in the license in every state position is also the "license plus," and the "license with consultation exception." The license in every state position, supported by the American Medical Association House of Delegates, requires that the physician be licensed in every state where the patient is located. The "license plus" model is adopted by California. The state sponsors "registration" programs that would permit out-of-state physicians, licensed in the state in which they reside, to practice telemedicine, providing that the license comply with additional requirements, such as education and training requirements. See Barry B. Cepelewicz, *Malpractice Over the Phone?* THE CONNECTICUT LAW TRIBUNE (September 15, 1997). There is also the "license with consultation exception," viz. "the Model Act."

108. Cal. Bus. & Prof. Code § 2052.5; Miss. Code § 73-25-34, (requiring physicians to hold a Mississippi medical license to practice telemedicine in Mississippi, but broadly defining "telemedicine").

109. *The Western Governors' Association Telemedicine Action Report*, *supra* note 102 at 55.

repetitive application costs. As proposed by the Center for Telemedicine Law White Paper, this system would define which law will govern the conduct of a physician, who practices across state lines, and who holds a license in both states. The physician would not be subject to the requirements of separate and inconsistent state laws. Or, as proposed by the National Council of State Boards of Nursing, registered nurses licensed in one state will be able to practice in any state that adopts the compact, provided they follow the laws and regulations of the state in which they are practicing. Under this system, the licenses are recognized in multiple states, facilitating telepractice, but each individual state has the authority to set its own educational, behavioral and competency requirements. This approach has the advantage of placing the responsibility on the physician to comply with the state laws, and vests each state with the authority to enforce its laws. However, for the telepractitioner specialist needed in many states, or for the telepractitioner practicing in numerous jurisdictions, interstate licensure could be burdensome.<sup>110</sup>

### c. The Model Act Approach

In April of 1996, the House of Delegates of the Federation of State Medical Boards ("FSMB") proposed model legislation known as the "Model Act."<sup>111</sup> The Model Act suggests a "special purpose license to practice medicine across state lines upon application for the same from a person holding a full and unrestricted license to practice medicine in any and all states . . . in which such individual is licensed, provided there has not been previous disciplinary or other action against the applicant by the state or jurisdiction." Although no state has endorsed the Model Act in total, several state medical boards have endorsed provisions of the Model Act,<sup>112</sup> and some states have, unsuccessfully, proposed implementation of the Model Act.<sup>113</sup> The Model Act has been criticized by the Western Governors Association, the Mayo Foundation, and the American Medical Association because its provisions are too broad.<sup>114</sup>

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110. The Telemedicine Task Force favors the "uniform" interstate license first and, alternatively, a national license.

111. The Model Act was drafted by a task force organized by FSMB.

112. See Ala. Code § 34-24-500 to 508; Tenn. Code Ann. § 63-6-209 (1997); 22 Tex. Ad. Code § 174.1 to 174.14.

113. Wisconsin, North Dakota, Maryland and Oregon proposed implementation of the Model Act but the state legislatures failed to pass the legislation. See also discussion in TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, at 6.

114. See Paul M. Orbuch, *A Western States' Effort To Address Telemedicine Policy Barriers*, 73 N.D. L. REV. 35 (1997), suggesting that if a state were to adopt the Model Act, it "would likely have the effect of increasing barriers to interstate telemedicine." *Id.*

#### d. National Licensure

A national licensure system would eliminate state licensures and replace them with a national-level licensure.<sup>115</sup> Arguably, Congress has the authority to regulate this type of activity since it has a substantial effect on interstate commerce.<sup>116</sup> Although there has been much discussion regarding a national license, and many scholars, especially telemedicine proponents, favor such national licensure, there is no evidence that sufficient support exists for such a scheme. In fact, the Western Governors are "loath to cede this authority to Washington, D.C., when state leadership and cooperation among other interested parties could help to alleviate the licensure burden placed on physicians and patients in a telemedicine context."<sup>117</sup> There are a number of arguments that compel moving to a national licensure system, and equally, a number of arguments that disfavor moving to such a system. Each of these will be examined from a quality of care perspective, with the focus on what ultimately will serve the best interests of the patient.

First, a national licensing system would remove the current barrier that states use to keep out-of-state physicians from entering their state.<sup>118</sup> Second, state licensure limits networking because such requirements limit interstate networking capability.<sup>119</sup> Third, educational and professional competency requirements for an initial state medical license are

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115. This is under study by the federal government. Obviously, major preemption issues would have to be addressed since the power of a state to regulate within its borders in the area of health care has been, with few exceptions, left to that state.

116. *United States v. Lopez*, 514 U.S. 549, 559 (1995). Many providers believe a national licensure system, with federal standards, is the best solution to concerns. Advocates of a national standard will have to overcome the current bias against federal preemption of states' rights. Moreover, the federal government has neither the legislative cohesiveness nor the will to take on the issues of a national licensure. By keeping the present gatekeeper, viz. the states, in place we continue to provide the latitude for states to continue acting as laboratories for innovation. In fact, the state reforms have many common elements. Licensure statutes are moving toward a model state approach, yet with each state retaining its options to respond to the needs of its constituents.

117. Orbuch at 46.

118. The fear is that physicians not licensed in the state will treat patients and thus take the business from the physicians who are already licensed to practice. Fearing telemedicine as a threat to their local specialists, some states have restricted their consultation exceptions. California, however, is more concerned that other states will use their physicians: physicians California claims it needs for its patients. The California approach is, by far, a far healthier approach to the issue. See TELEHEALTH, *supra* note 8.

119. The licensure issue may also impact how telemedicine networks utilize nurses and other non-physician assistants. Every state has its own definition as to what constitutes the 'practice of medicine,' and should the activities of the non-physician assistant fall under the 'practice of medicine,' licensure may become an issue. Barry B. Cepelewicz, *Malpractice Over the Phone?* THE CONNECTICUT LAW TRIBUNE (September 15, 1997).



now more standardized.<sup>120</sup> Every state requires that licensed practitioners graduate from an accredited medical school and pass a national test, the United States Medical Licensing Exam.<sup>121</sup> Fourth, there is now the National Practitioner Data Bank that collects, on a nationwide basis, information about physicians, including licensure matters.<sup>122</sup> Fifth, there is a track record of proving a national system will work, as the federal government funds a great part of the telemedical practice and has been using national licensure for many years.<sup>123</sup> Sixth, national licensure should not pose problems because the federal government clearly has the authority to regulate the medical professions, and has exercised this authority by setting standards in many other areas of health care.<sup>124</sup> Seventh, there now exist coordination efforts of telemedicine programs by the Joint Working Group on Telemedicine (JWGT),<sup>125</sup> including the JWGT's urge to consider a national licensure system.<sup>126</sup> Last, such a system would require uniform standards, as well as a centralized system coordinating physicians data, and would permit physicians to practice in any state without the necessity of obtaining a license in every separate state.<sup>127</sup>

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120. Interestingly, the Federation of State Medical Boards and the American Medical Association, although disagreeing on a national licensure system, did approve a national accreditation program to provide national standards for medical care. Physician Credentialing, BNA HEALTH L. R. (June 27, 1996); Physician Credentialing, BNA HEALTH L. REP., Dec. 12, 1997 at 1.

121. See generally Center for Telemedicine Law, *Telemedicine and Interstate Licensure: Findings and Recommendations of the CTL Licensure Task Force*, 73 N.D. L. REV. 109 (1997) at p. 5; See also Gobis, *supra* note 106, at 4.

122. 32 U.S.C. 11101 et seq. (1996).

123. The government employs a national licensure system in that physicians who work for the federal government are licensed in a particular state, but may practice in many jurisdictions. The Veterans Administration, Indian Health Service and Public Health Service have all adopted a national licensure system

124. See generally, Clinical Laboratory Improvement Act, 42 U.S.C. 263a (1996); Mammography Quality Standards Act, 42 U.S.C. 2636 (1996); Occupational Safety and Health Act, 29 U.S.C. 651 et. seq. (1996). Congress preempted state laws that prohibit the development of any interstate telecommunication service. 47 U.S.C. § 253(d) (1997).

125. As part of the sweeping Telecommunications Reform Act of 1996 (P.L. 104-104), Congress asked the Secretary of Commerce, in consultation with the Secretary of Health and Human Services and other departments and agencies, to submit a report on the use of advanced telecommunications services for health care purposes. The legislation required a summary of the activities of the Joint Working Group on Telemedicine ("JWGT") – a Federal interagency working group – as well as findings from federally-funded telemedicine studies and demonstrations. Congress requested that the report examine questions related to patient safety, the efficacy and quality of services provided and other issues. S. 652, 104th Cong., 1st Sess. (1996), Telecommunications Reform Act (Section 709); <<http://www.nita.doc.gov/reports/telemed/intro.htm>>; See generally L. Gobis, *supra* note 106, at 4-5.

126. *Id.*

127. A number of commentators have argued for a national licensure. See Gobis, *supra* note 106, "An interstate or national licensure system would better serve individual physicians

A national system, however appealing in theory, may not be the best practical solution or even the best solution for assuring patients obtain the best quality of care possible. First, a national license does not have the support of all professional groups—this alone is a difficult obstacle to overcome.<sup>128</sup> Second, telemedicine is young. Consensus does not exist on what exactly should be licensed, and by whom.<sup>129</sup> Third, regulation could cause more harm than good.<sup>130</sup> Fourth, licensure exists to protect the patient by keeping the gates closed to anyone who failed to meet the minimum qualifications necessary for entry. States have historically done an excellent job at policing, and there is no data to suggest a national system would work as well as the existing state systems.<sup>131</sup> Last, as our political climate warms to a national licensure system, progress is

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and the practice of medicine nationwide. It would also place U.S. physicians in a better position to practice telemedicine internationally." *Id.* at 5.

128. The American Medical Association rejected a proposal for an interstate licensure and holds fast to the policy that the states and their medical boards should develop licensure requirements. The Western Governors' Association, in its Telemedicine Action Report, is looking more for a Uniform State Code for Telemedicine, rather than a national approach. The Western Governors' Task Force is looking at definitions of telemedicine, what might be a more simplified licensing of individuals, network licensure, and the like. See Paul Orbach, *A Western States' Effort to Address Telemedicine Policy Barriers*, 73 N.D. L. REV. 55 (1997).

129. Telemedicine is in its infancy and, therefore, unless we adopt a very broad definition, we find ourselves in the position of manufacturing definitions that may not stand the test of time. Additionally, assuming the process begins immediately, it would take the government many years to develop an appropriate definition. This assumes, of course, strong sponsorship and agreement on who and which governmental entities are the principle speakers. Examining the record of just the Federal Communications notice of intent for rulemaking indicates just how slow and bureaucratic this approach would be.

130. Today, states are exercising their powers and have been creative in addressing the needs of their constituents. Without actual, or even perceived, harm in the current approach, physicians and politicians alike address the issue of licensure in the best interest of their constituents. The sheer number of states considering the impact of their current laws and regulations on telemedicine demonstrates that the issue is being considered and addressed. Thus, absent a compelling argument, what is lacking today that a national licensure scheme would supply?

131. Patients have come to rely upon the license of the physician, and this may be one of the last bastions of trust: the doctor or practitioner from which a patient seeks treatment has met the stringent requirements set by the state's regulating body. Doctors' qualifications matter more now than ever before. As of July 1, the American Board of Internal Medicine has decided that anyone contacting the Board to confirm the status of internists will be told by the Board that either the physician is certified or not certified. Therefore, if a doctor authorizes the Board to give out information, the panel will also confirm that an application for board certification is pending, or the Board will divulge the year when the candidate last took the exam. Apparently, it is reported that since doctors feel their qualifications count more now than ever before to managed-care companies and patients, some internists reportedly tried to beef up their credentials: internists "who haven't passed their Board exam often hedge by saying that they are 'board eligible.' But confusion over what that term actually means has prompted the [Board] to stop recognizing it—the last medical credentialing panel to do so." Jan Greene and Anne M. Nordhaus-Bike, *HOSPITALS AND HEALTH NETWORKS* 71(5): 12, 13, 16–17 (March 5, 1997).

better ensured through voluntary state entry than by federal preemption and regulation. In fact, as states adopt telemedicine statutes and amend their licensing laws to reflect telemedicine practices, states incrementally move toward a model uniform approach. The energy put into flexible state approaches will protect patients, continuously adapt to fit the needs of the constituents, and simultaneously move toward the best "model" approaches.

### B. *Regulating Quality: Serving the Best Interests of the Patient*

The threat of a malpractice action is another related legal issue which impacts telemedicine's future use and the quality of health services provided to the patient.<sup>132</sup> Telemedicine offers tremendous opportunities to improve both the quality and quantity of healthcare, but may also exacerbate the potential for liability that would arise in more traditional settings.<sup>133</sup> Telemedicine practice challenges the already complicated issues and risks in traditional face-to-face medical settings. To protect the quality of this relationship, whether face to face or through high resolution video, fiber-optic cables, or other advanced imaging technology, we should look to the law of malpractice certainly as a deterrent but also as an indication of what protections should be put in place in the first instance to avoid potential questions of malpractice.<sup>134</sup>

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132. I focus on medical malpractice to raise issues attendant to telemedical practice. There are many other types of liabilities that could arise, including the mis-transmission of data or the product failure of the telemachinery, that could relate to but not fall within the physician's direct responsibility but that of the telemedical center, the hospital or the equipment manufacturer. The federal government does have a group that has been looking at the variety of these barriers. See *Senate Approves Bill Designed to Remove Barriers to Telemedicine*, 5 BNA HEALTH L. REP. 910 (June 13, 1996).

133. See TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, at 11.

134. Although telemedicine is new, much has been written on the issue of potential telemalpractice, mostly from the perspective of the physician. Malpractice is seen as a barrier to physician's willingness to engage in telemedicine, or as an inevitable outcome of delivering services via telecommunications. See generally Phyllis Forrester Granade, *Medical Malpractice Issues Related to the Use of Telemedicine—An Analysis of the Ways in Which Telecommunications Affects the Principles of Medical Malpractice*, 73 N.D. L. REV. 65 (1997); TELEHEALTH & TELEMEDICINE, *supra* note 8. California Telehealth/Telemedicine Coordination Project (Jan., 1997); Physician Insurers Association of American, TELEMEDICINE, A MEDICAL LIABILITY WHITE PAPER, PIAA (1998); Lynette A. Herscha, Note, *Is There a Doctor in the House? Licensing and Malpractice Issues Involved in Telemedicine*, 2 B.U.J. SCI & TECH. 8 (1996). This author views the issues relating to potential malpractice actions as warning signals or red flags that should be addressed, by physician, insurance companies, and patients alike, to avoid situations where telemedicine might be inappropriate. Lawyers will always prove creative, regardless of the technology, but telemedicine is an area where lawyers can engage in prophylactic practice, and where policy decisions should be made in the best interest of providing care to a patient who would not otherwise be in a position to receive needed care.

The health care delivery system is in such turmoil that “default” regulation, i.e. liability actions, are also unresolved.<sup>135</sup> Outside of the federal government, telemedicine is in a nascent stage and, as such, no answers exist as to what “liability” may coincide with its use. More than 40 percent of telemedicine programs surveyed<sup>136</sup> have been providing teleconsultations for one year or less.<sup>137</sup> It usually takes at least 21 months following an alleged incident of an adverse outcome for a medical malpractice claim to be brought.<sup>138</sup> One of the reasons we may have so few reported medical malpractice cases relating to telemedical practice is that not enough time has elapsed for claims to have been filed.<sup>139</sup>

Malpractice liability is a potential concern in this relatively “new” health delivery model<sup>140</sup> and for that reason it is perceived as a major barrier to telemedicine’s growth.<sup>141</sup> But in the absence of any liability theory’s emergence, why are medical malpractice suits perceived as a significant barrier to telemedicine’s growth? Quite simply, telemedicine may affect the quality of care and, especially since it is new, the use

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135. Not only are the actions themselves unknown, but the theories upon which the actions will be based, are also unknown. Thus the telemedicine practice will inevitably breed issues and theories heretofore untested.

136. THE JOINT WORKING GROUP ON TELEMEDICINE, *supra* note 12 at 10.

137. *Id.* By the time this is written, this time frame will mean that the programs, to the extent they still exist, will have been providing teleconsults for over one year or a little more.

138. See Physician Insurers Association of America, *TELEMEDICINE, A MEDICAL LIABILITY WHITE PAPER*, *supra* note 143.

139. *Id.* Another reason is that the cases that have been brought have all been settled out of court. See David Bowerman, *Costs of a High Tech Cure*, <<http://www.msnbc.com/news.html>>.

140. Whether in the context of medical records or medical treatment, the issues of “virtual” medicine confront providers, patients and practitioners every day and are every day news. See Milt Freudenheim, *Medicine at the Click of a Mouse, On-Line Health Files Are Convenient, Are They Private?*, *NYT*, D. 1 (Aug. 12, 1998).

141. Many articles have focused on the impact medical malpractice suits have had, and will continue to have, on telemedicine. This author will not repeat all of the basis for such claims, but rather focus on the key issues that could arise and the threat liability poses to telemedicine application. See generally, Kathleen M. Vyborny, *Legal and Political Issues Facing Telemedicine*, 5 *Ann. Health L.* 61(1966); Lynette A. Herscha, *Note: Is There a Doctor in the House? Licensing and Malpractice Issues Involved in Telemedicine*, 2 *B.U. J. SCI. & TECH. L. R.* (Apr., 1996); *Telemedicine Poses Malpractice Risks for Physicians*, 112 *PUBLIC HEALTH REP.* 185-186 (May/June 1997); L. Sandburg, *Legal and Policy Issues Challenge Telemedicine*, *HEALTH MANAGEMENT TECHNOLOGY*, Vol. 16, No. 13 (December 1995) p. 30. There are “telemedicine” related liability actions, but perhaps not reported as such. “As far, there have been only a few malpractice cases involving telemedicine, all claiming misdiagnosis by teleradiologists. But no one has alleged that damage resulted from the use of a teleconsultation. One of the cases recently led to a \$1.3 million settlement by a Florida radiologist who missed a cerebral hemorrhage on a CT scan transmitted to him electronically at home in the middle of the night. Although he was an experienced physician who had never had a claim filed against him before, there was no suggestion that the use of telemedicine was related to the misdiagnosis.” Berkeley Rice, *Will Telemedicine Get You Sued?* *MEDICAL Economics*, No. 23, Vol. 74 (November 24, 1997).

itself may lead to malpractice liability suits. The uncertainty of its practice, coupled with the fact that care will take place over a distance, may increase the likelihood of malpractice suits.<sup>142</sup> Telemedicine might also augment the potential for missing a signal or symptom that would otherwise be observed in a face-to-face encounter. Skeptics of telemedicine suggest that advanced technology might even mask symptoms that would be noticed if the physician and patient were in the same room, and, thus lead to the increased possibility of misdiagnosis. Other concerns relate to the potential for a mistake in the transfer of information, for dissemination to a third party or loss of the information in the technological transfer. There is, however, no empirical evidence of malpractice claims increasing as a result of telemedical practice.<sup>143</sup> It may be that telemedicine practice will reduce the likelihood of malpractice by bringing care to the patient who might not otherwise have healthcare.<sup>144</sup> Moreover, pragmatic barriers develop: since telemedicine is new, the risks are unclear, and unclear risks cost more to insure.<sup>145</sup>

Another concern to be addressed is whether the practitioner has formed a physician-patient relationship via telemedicine. Medical malpractice cases generally recognize that a physician's duty to a patient is predicated on the existence of a physician-patient relationship. The telemedicine encounter would not change this underlying question, but may complicate the parameters of establishing whether a duty of care has clearly been established. Generally, courts have considered whether the physician has met the patient, examined the patient, reviewed the patient's records, knows the patient by name and was paid for services

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142. The concern regarding malpractice cuts to the heart of the telemedicine debate—telemedicine provides the lifeline to bring healthcare to patients who may not otherwise receive medical attention or the advice from a specialist. But this very lifeline, since it is remote, carries the risk that a signal might be missed or a symptom not actually seen that would otherwise be observed in a face-to-face encounter.

143. This is not unusual, especially since telemedicine itself would usually not be the basis for a suit. Indeed, a suit would be based on a "failure to provide the standard of care due and owing," or the "failure to discover." Just as likely as a suit might be brought for a medical service provided in the telemedical context, so too, could a suit be premised on the failure to provide "telemedical" services, if such services are available. This type of "failure to provide" or "failure to warn" will be difficult to pursue given the current managed-care climate and the laws that prohibit such suits.

144. This is especially so for physicians who would provide care to rural patients but may not because they face the uncertainty of their liability and malpractice insurance to cover this liability. Certainly, if this is a barrier, it could cause more harm in not treating the patient, since the patient, in such a rural area, may not get any treatment at all.

145. Questions include: Which telepractices will be covered by medical-malpractice insurance? What venue's insurance premium will apply? What is the volume of the telepractitioner?

rendered.<sup>146</sup> A number of courts, wrestling with this issue in the non-telemedical context, indicate that the physician-patient relationship will exist and evolve whether the meeting is in person, telephone or optic image.<sup>147</sup> Generally, courts will find a physician-patient relationship even if the physician has had only brief telephone contact with the patient. In *Bienz v. Central Suffolk Hospital*, a New York court held that it was a question of fact whether a physician-patient relationship existed, and refused deem a telephone call to a physician's office to initiate treatment insufficient to form a physician-patient relationship.<sup>148</sup> In a Texas case, the court found a physician patient relationship existed between a pathologist and a patient where the pathologist had examined a biopsy slide of the patient, but had never actually met the patient.<sup>149</sup> The latter situation is indicative of what courts could find in a telemedical context where the physician has established a relationship with the patient even though the two have not met face to face.

After establishing the existence of a physician-patient relationship, another question is whether the physician has met the applicable standard of care during the course of treating the patient. Assuming a virtual relationship exists, there will be no liability if the physician or consulting physician has met the applicable standard of care.<sup>150</sup> In the telemedical context, the standard of care owed to the patient must begin with an analysis akin to medical malpractice questions in the non-telemedical context. Medical practice standards of care are "not normally established by either judge or jury."<sup>151</sup> The medical profession establishes the standards of practice; and the courts enforce the standards in a medical malpractice setting.<sup>152</sup> The recognized standards for

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146. The "paid for services" might become complicated as physicians figure out how to charge for consulting services. This could be further complicated because, at present, Health care Financing Administration (HCFA), has set stringent requirements on reimbursement for telemedical services. See also Granade, *supra* note 143, at 69.

147. See TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, citing *Bienz v. Central Suffolk Hosp.*, 557 N.Y.S. 2d 139 (N.Y. App. Div. 1990); *Dougherty v. Gifford*, 826 S.W. 2d 668 (Tex. Ct. App. 1992)..

148. *Bienz*, *supra* note 147, cited and discussed in TELEMEDICINE: EMERGING LEGAL ISSUES, *supra* note 34, at 12.

149. *Dougherty*, *supra* note 147.

150. See generally Phyllis F. Granade, *Malpractice Issues Affecting the Implementation of Telemedicine*, TELEMEDICINE SOURCEBOOK, 361-62, asserting that courts will find that a physician-patient relationship exists in a telemedical consultation if: 1) if the consultant has met the patient, or knows the patient's name; 2) if the consultant examined the patient's record; 3) if the consultant examined the patient; (or) 4) if the consultant accepts a fee for his services.

151. Barry R. Furrow, Thomas L. Greanery, et al., HEALTH LAW, p. 152 (3rd ed. 1997).

152. Standards of practice in the medical profession develop over a period of time, and usually through the flow of reports in medical literature, at professional meetings and through peer discussions. Over time, clinical policy develops into "standard practice" which provides

determining a physician's negligence have been the "national standard" and the local, regional or "community standard." This latter standard or custom of practice by those in the physician's specialty is usually established through expert testimony. The standard of care, by which the conduct of the physician is measured, requires the trier of fact to find that the injury to the patient was caused by a failure to exercise the "required degree of care, skill and diligence" under the circumstances.<sup>153</sup> More and more, courts employ a "national" standard, so the impact of the exact locality of the physician and patient should not impact the outcome. The question, more likely than not, will focus on the physician's knowledge, skill and treatment regime regardless of location. Thus, telemedicine's advent compels jurisdictions toward a national standard of care. For some time, information and consultation have been available via a telephone line, and information regarding where the specialists might be found is always available on the Internet.<sup>154</sup> Any reason to revert to the "local" rule is further diminished since specialists are usually board certified by national tests, rather than local. In *Robbins v. Footer*, the court found that a nationally certified specialist would be held to a "national" standard of care grounded upon the omnipresent nature of telecommunications.<sup>155</sup> As information becomes more available through medical databases and the Internet, the average physician likely will be held to a higher standard of knowledge. Although no court has held that a physician has a duty to check a national database, use telemedical contacts, or engage in a telemedical consultation, the ability to have "expert" advice instantly available will raise the bar of existing "duty" standards. Predictably, access to such databases will diminish the role of the "locality" rule, augment the use of the "national" standard, and, most likely, establish a higher standard of care bar so that physicians will be required or expected to find readily-available information through existing databases and the use of accessible experts and data. Although not decided in the telemedical context, this standard will allow evi-

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guidelines for judging the conduct of physicians vis-à-vis a particular patient. These standards can be developed on a national as well as a local, or regional, basis and courts have applied both as standard practice.

153. *Bardessomo v. Michele*, 478 P.2d 480, 484 (Cal. 1970).

154. See Claudia Glenn Dowling, *Death on the Mountain*, LIFE, August 1996, at 32; Israel Kloss, *Telemedicine Brings D.C. Specialists to World*, THE WASHINGTON TIMES, Nov. 17, 1996, at D8; George Gilder, *Ethersphere*, FORBES, Oct. 10, 1994, at 132.

155. 553 F.2d 123 (D.C. Cir. 1997); but see Ala. Code § 6-5-484(a) (XXXX 19XX) where the standard of care is defined for physicians "in the same general neighborhood, and in the same general line of practice, ordinarily have and exercise in a like case."

dence demonstrating the resources under which the particular physician operates. In *Hall v. Hillbun*,<sup>156</sup> the court stated:

The duty of care . . . takes two forms: (a) a duty to render a quality of care consonant with the level of medical and practical knowledge the physician may reasonably be expected to possess and the medical judgment he may be expected to exercise, and (b) a duty based upon the adept use of such medical facilities, services, equipment and options as are reasonably available.<sup>157</sup>

Courts following *Hall* will allow the trier of fact to consider the resources available to the physician, including the facilities, staff and other equipment available in the environment in which the physician practices. For instance, the rural or country physician traditionally was not expected to have the same access to facilities, knowledge or equipment as the city physician.<sup>158</sup> With instant access to information through technology and the availability of distance medicine, the country physician may be able to have access to a host of resources otherwise unavailable.

As telemedicine develops further, the appropriate standard of care is an area that could be better defined by the development of practice guidelines.<sup>159</sup> Defining guidelines will assist physician, patient and regulator alike. A national spokesperson on telemedicine has suggested that of the various legal barriers to the furtherance of telemedical delivery systems, there are "several vexing legal issues that may impede wide adoption of telemedicine by the medical profession" and suggests, with respect to the litigation process, that the set of issues may be "more amenable to amelioration, if not prevention."<sup>160</sup> Sanders suggests that "the most effective approach is the development of practice guidelines for telemedicine, including standard clinical protocols and professional norms of conduct governing clinical encounters."<sup>161</sup>

Whether the risk for potential lawsuits would increase or decrease, standards or professional codes of telepractice would assist both physician

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156. 466 So. 2d 856 (Miss. 1985).

157. *Id.* at 872-873.

158. See RESTATEMENT (SECOND) OF TORTS, § 299A, cmt. g (1977). ("Allowance must be made also for the type of community in which the actor carries on his practice. A country doctor cannot be expected to have the equipment, facilities, experience, knowledge or opportunity to obtain it, afforded him by a large city").

159. Several states have legislated the use of practice guidelines and provided immunity from tort in exchange for the physician's adhering to such guidelines. See Medical Liability Demonstration Project, Me. Laws § 2971-78 (1978); Smith, *Maine's Liability Demonstration Project, Relating Liability to Practice Parameters*, 18 State Health Legislation Report 1 (1980).

160. Sanders, 6 J. PHARMACY & L.I., at 10.

161. *Id.*



and patient alike. Actions that telepractitioners could agree to take before practicing "telemedicine at a distance" would inure to the best interest of the patient and, prophylactically, reduce the likelihood of any later lawsuits. Toward this end, there should be full disclosure of the telemedical transaction to the patient. From the patient's standpoint, guidelines addressing what constitutes a "telepractice" would both address concerns the patient may have and, at the same time, provide a solid basis to avoid, as much as possible, any misunderstandings and resulting potential liability.

These guidelines or telemedical codes of professional conduct specifically should address communication between physicians, clarify the roles of the consulting and treating doctors, and provide for disclosures of any conflicts of interest. Additionally, such codes of professional conduct should provide for agreements regarding reimbursement and payment, as well as detailed conditions addressing confidentiality of physician-patient relationship, security, informed-consent requirements and the substantive proposed teletreatment process and options. Since application of the standard of care will depend upon not only the physician's duty to his patient, but many attendant issues relating to the coordination of consulting physicians, ancillary equipment and the proper communication among the treating practitioners, guidelines or codes of professional practice will provide a checklist for physicians to follow. Hopefully, these guidelines will not only help the physicians provide certain basic, minimum information to the patient, but also will reduce practice variation in the telemedical context. Such practice guidelines would provide a base upon which physicians would be able to share "best practices," thus continually improving the process of the practice of distance medicine and concomitantly reducing the margin of error in the practice.<sup>162</sup>

Yet another concern involves the location where an action may be brought. In the traditional face-to-face physician-patient relationship, the forum in which malpractice actions arise was the court of the state in which the diagnosis and treatment occurred. In a situation where the treating physician, the consulting physician and the patient are located in different states, there will be multiple forums in which a malpractice action may be brought. As telemedicine becomes more and more commonplace, this area could develop through litigation in the various potential forums—allowing the relevant courts to answer this choice of law question. In this traditional approach, the courts develop the law on a fact-

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162. See Furrow, *supra* note 162, at 364 (citing Edward Felsenthal, *Cookbook Care: Maine Limits Liability for Doctors Who Meet Treatment Guidelines*, WALL ST. J., May 3, 1993 at A1).

sensitive basis. Today, physicians who practice telemedicine could be subject to the jurisdiction of a patient's state. Physicians usually will have had the "minimum contacts" with the state in which their patient is located unless the court finds that the physician's presence was only "casual" or "isolated."<sup>163</sup> Conflict-of-law principles generally have provided that jurisdiction will be in the state in which the injury occurred and the state that has the greatest connection to the injury.<sup>164</sup> Plaintiffs usually have sought their own local court systems for the simple reason that their courts are convenient and familiar to them. In the telemedical context, it can be foreseen that a plaintiff, having a choice of forums in which to file an action, could shop around and bring a suit in which the awards are most likely to be the highest.<sup>165</sup> In discussing the issues of "multiple forums," the best interests of the patient have received little attention, such as when physicians should be subject to the jurisdiction of their patients' home states. The focus in the future must center on the patient. A number of reasons compel this position. First, physicians who practice telemedicine should be deemed to have the requisite "minimum contacts" with the state in which the telemedical consultation has taken place.<sup>166</sup> Second, jurisdiction over such a case usually will be found in the state in which the injury occurred and the state that has the greatest connection to the injury.<sup>167</sup> Third, the growing sentiment by many states is that their police powers may need to be stronger to protect the health and safety of their residents. States have approached this new arena in a variety of ways, and some states have defined statutorily what will be the jurisdictional reach if such telepractice takes place.<sup>168</sup> To the extent that these choice-of-law issues are anticipated, states could choose to

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163. *International Shoe v. Washington*, 326 U.S. 310, 316-17 (1945).

164. Many states, notably California, have an "inconvenient forum" doctrine that provides a court may refuse to exercise its jurisdiction in a case if it "would more conveniently, efficiently, and fairly [be] tried in the locality in which it arose, and it would be oppressive or inconvenient, or an unwarranted extra burden on the courts of the forum, to try it there." 2 B.E. WITKIN, CALIFORNIA PROCEDURE 461-64 (3d ed. 1985).

165. See TELEHEALTH & TELEMEDICINE, *supra* note 8, at 74.

166. See *International Shoe Co. v. Washington*, 326 U.S. 310, 316.

167. See RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 146 (Proposed Official Draft No.2, 1968) ("in an action for personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship"); see also 2 B.E. WITKIN, CALIFORNIA PROCEDURE § 303 at 711-712 (3d ed. 1985) (setting forth California's "inconvenient forum" doctrine that allows a court to refuse to exercise its jurisdiction over a foreign cause of action if, "the cause would be more conveniently, efficiently and fairly tried in the locality in which it arose").

168. See Ill. Comp. Stat. § 60/49.5 (1999). "An out-of-state person providing a service . . . to a patient residing in Illinois through the practice of telemedicine submits himself or herself to the jurisdiction of the courts of this state." *Id.*

legislate what will be deemed "minimum contacts" in the telemedical context. Such legislation would put both physician, providers, insurers and patients on notice.

### *C. Informed Consent*

A more feasible approach, however, involves providing informed consent because telemedicine is still new, it is often considered optional treatment rather than the first course of treatment. Whether it is optional or primary, it is unclear under what circumstances telemedicine will be used. Clearly, the patient will need to be advised of alternatives. Providing the patient with sufficient information regarding treatment options will enable the patient to make an informed decision. A patient cannot make a decision unless he understands what is involved in the procedure, how the procedure will benefit him, the risks and/or consequences associated with the treatment and the likelihood of these risks and/or consequences occurring.

The doctrine of informed consent is the duty to provide the patient with sufficient information regarding treatment and options that allows the patient to make an "informed decision regarding" the care. This doctrine was first legally recognized in 1914 and has been reaffirmed over the years.<sup>169</sup> Informed consent, grounded in both statutory and case law,<sup>170</sup> encompasses knowing not only what, when, and how the procedure will be accomplished, but the alternatives to the treatment.<sup>171</sup>

Telemedicine does not alter the physician's general duty to inform the patient about the intended care, but it actually may require a more regimented approach in advising the patient. As such, the necessity for informed consent may be of a higher order in a telemedical practice because some telemedical applications are still considered experimental or

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169. See Wisc. Stat. § 448.30t (19XX); *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979).

170. See *Salgo v. Leland Stanford Jr. University Board of Trustees*, 317 P.2d 170 (Cal. Ct. App. 1957) (creating the terminology "informed consent"); Fay A. Rozovsky, *CONSENT TO TREATMENT: A PRACTICAL GUIDE* (1990).

171. See *Gemme v. Goldberg*, 626 A.2d 318, 326 (Conn. App. 1980) (requiring physicians to advise their patients of the course of treatment and also the alternatives to the treatment planned, including the failure to treat and treatment that may be experimental and thus more risky); *Truman v. Thomas*, 165 Cal. Rptr. 308, 613 P.2d 902 (Cal. 1980); *Holt v. Nelson*, 523 P.2d 211 (Wash. App. 1974) (advising physicians that if they are not capable of providing the required treatment, performing the procedure or evaluating the risk, the patient should be advised as well). In the telemedical context, physicians may be well advised to inform their patients the potential risks inherent in not exploring telemedical treatment, especially if the physician is able to consult with another distant physician located at a distance from the patient.

riskier than an in-person consultation or procedure.<sup>172</sup> On the other hand, the telemedical approach may provide the vehicle to obtain services and medical approaches that otherwise would not be available locally. There is no question<sup>173</sup> that communicating information regarding telemedical application will require, at a minimum, informing the patient of the diagnosis, the nature and purpose of the treatment, the risks and outcomes, and disclosure of the treating physician's skills and the skills available by another physician through the use of telemedicine, especially if the patient may be able to obtain treatment by a physician who has more expertise than available locally.<sup>174</sup> It is critical for the patient to understand any differences between the prognosis if treated locally and teleconsultation. Equally important, the patient should understand the consequences of not pursuing teletreatment. Even if a physician believes that the patient will be best served by a telemedical consultation or treatment, this is not a decision for the physician, hospital or the insurance company. The decision to use telemedicine, like any other treatment, should require the patient's consent. A right of refusal allows patients to control their own health care.

Since telemedicine may be perceived as a new method of providing treatment to patients, it is equally critical that the use of telemedicine be discussed and documented thoroughly.<sup>175</sup> In fact, California's telemedicine law mandates such a course of action.<sup>176</sup> The California approach is

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172. See *Canterbury v. Spence*, 464 F.2d 772, 787-88 (D.C. Cir. 1972). See *Scott v. Bradford*, *supra* note 172. Compare *Fischer v. Wilmington General Hospital*, 149 A.2d 749 (Del. Super. Ct. 1959) with *Cobbs v. Grant*, 104 Cal. Rptr. 505, 502 P.2d 1 (Cal. 1972).

173. The Physician Insurers Association of America ("PIAA"), in its White Paper on telemedicine and malpractice, suggests that since telemedicine encounters may still be "looked upon as experimental" it "may" require consent under any/all circumstances. Since the communication is critical to the patient, there is an ethical, as well as a legal, question involving informed consent. See PIAA, *Telemedicine, A MEDICAL LIABILITY WHITE PAPER*, *supra*, note 143, at 15.

174. See *Webb v. T.D., D.C.*, 951 P.2d 1008 (Mont. 1997) (imposing a duty on physicians who examine patients for third parties. The Court held that physicians must use care to discover and advise their patients of harmful conditions. Although this case was not decided in the telemedical context, but rather relates to an examination requested by the State Compensation Insurance Fund, the Court held that a direct physician-patient duty arises from the third-party contractual relationship and thus may ultimately impact telemedicine encounters. It underscores the importance of treating physicians providing informed consent their patients.)

175. The PIAA suggests that the referring and the consulting physicians should discuss the need for a consent form and that they should consider whether a form is needed based on the "procedure, risks, jurisdiction and patient's understanding of the encounter." Also, each physician should document the extent to which a "written and verbal explanation of the encounter is given to the patient." See PIAA, *supra* note 143, at 16.

176. The California legislature mandated that the health care practitioner who has "ultimate authority" over the patient's care is required to obtain both verbal and written informed consent from the patient. The following are included in the requirements for obtaining consent: informing the patient that he or she retains the option to "withhold or withdraw"

a piece of legislation that has been passed or is being considered in many states.<sup>177</sup> The California statute requires both written and verbal communication prior to the delivery of any telemedical care. In informing the patient, the physician should be certain to set forth that the treatment or consultation will be done via telecommunication. If the application is still considered experimental, either because the technology is new or because the procedure has only been performed face-to-face, then the physician should set forth any limitations, including any equipment limitations, risks of the treatment, and potential consequences.<sup>178</sup>

Just as in any face-to-face treatment, the physician should explain any alternate diagnostic options. Above all, the physician should discuss the confidentiality of the procedure. If persons other than the physician will be present, the physician should explain who they are and their roles in the treatment. Finally, the physician should identify the primary physician, the treating physician and the consulting physician.

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consent at any time, a description of the potential risks, consequences, and benefits of telemedicine, that all existing confidentiality protections apply, that the patient has access to all medical information transmitted during the telemedicine consultation, that there will not be, without the patients consent, dissemination of any "patient identifiable images or information" from the telemedicine interaction, that the patient will sign a written consent form, that this consent form will become part of the patient's medical record; and that failure to conform to this requirement will constitute "unprofessional conduct." The section applies when the patient is directly involved in the telemedicine interaction but not when one health care practitioner consults with another health care practitioner, and the section shall not apply in an "emergency situation," when the patient is unable to give consent or when the patient is under the jurisdiction of the Department of Correction. Cal. Bus. & Prof. Code § 2290.5.

177. *See, e.g.*, OKLA. STAT. tit. 36 § 6801-4 (19XX), requiring physicians to obtain written informed consent from the patients before the delivery of telemedical services. The requirements are very specific and include a statement that the individual retains the option to withhold or withdraw consent at any time, a description of risks, consequences, and benefits, and that patient access to all information is guaranteed. Furthermore, a statement that any dissemination to a person external to the telemedicine relation will not take place without the written permission of the patient.

178. In the Joint Task Force's Recommendations, the core principles stress that (1) the health care system or practitioner "cannot use telehealth as a vehicle for providing services that are not otherwise legally or professionally authorized"; and, (2) "All clients directly involved in a telehealth encounter must be informed about the process, attendant risks and benefits, and their rights and responsibilities, and must provide adequate informed consent." Of all the federal legislation pending addressing telemedicine and telehealth, there is little focus on the notion of "informed consent." Thus, this issue is one the states should anticipate addressing in their telemedicine legislative proposals. *See* Telemedicine Report To Congress, <<http://ntia.doc.gov/reports/telemmed>> (last visited May 3, 1999); *Telemedicine Report to Congress Executive Summary*, 73 N.D. L. REV. 151 (1997).

## IV. REGULATING ACCESS AND STANDARDS

As reflected by malpractice actions, there are no clearly demarcated lines between quality, access and costs.<sup>179</sup> Like the issue of quality, access must be viewed from a state and national viewpoint because there is no single controlling organization monitoring the progress and regulation of telemedicine. Three federal laws, passed within the last few years, impact telemedicine's future path. Two of these laws, the Telecommunications Reform Act of 1996<sup>180</sup> and the FDA Reform Act of 1996<sup>181</sup> govern entry to the marketplace. The FCC Act of 1996 promises to regulate access to information through telecommunication lines.<sup>182</sup> The FDA Act of 1996 regulates access by regulation of devices into the marketplace. The third, the Balanced Budget Act of 1997, provides the funds to ease telemedicine's path. All three of these federal laws combine to improve the public good and to assist telemedicine's entry to the health care system.<sup>183</sup>

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179. All three issues interrelate, and, at time, cross into each others' territories. Superimposing telemedicine's issues on these three areas admittedly adds another dimension, but also helps focus on the interrelationship of the underlying health care delivery system and the legal-root guards that protect the patients from new delivery systems.

180. 47 U.S.C. § 254 (1996).

181. 21 U.S.C. § 321. The corresponding regulations are found at 21 C.F.R. § 800.

182. Arguably, the telecommunications Act of 1996, 47 U.S.C. § 254 (1996), could be viewed as a complex funding issue or "cost" of telemedicine issue. The issue is more complicated and points out the interdependency of the issues of quality, access and cost. Without access to telecommunication lines, telemedicine is not available, and the quality of care, available to those with telecommunication access, is not available to those without. Equally so, telecommunication lines that make telemedicine accessible must be open; without the lines, there is no service. For the purposes of this discussion, the FCC Act of 1996 is viewed more as an "access" issue, than a simple "funding" or "cost" issue. First, mere money will not address the problem. Lines must be run and open. Both federal and state laws and regulations will apply. Second, neither the federal government alone, nor the states alone, provide the access—this is a private market, publicly regulated arena. Third, the question of who and where the communication lines are open and the timing of the connections drawn will affect the access of the patients to the availability of the telemedical services. Thus, the cost of telemedicine will definitely be affected by the opening up of the lines, but is entirely dependent upon having access to the service in the first instance.

183. There are other federal agencies that potentially could regulate telemedicine, including the Consumer Product Safety Commission, the Occupational Health and Safety Administration, and with limited jurisdictional responsibility, the Federal Trade Commission (hereinafter "FTC."). Today, the main federal actors regulation, the Federal Communications Commission (hereinafter "FCC"), the Food, Drug and Cosmetic Administration (hereinafter "FDA") and Health and Human Services (hereinafter "HHS") play distinct, but inter-related roles. In many respects, the lack of any telemedicine strategy reflects the fact that no one agency has the lead, yet each agency addresses the issues that fall under its umbrella. I am not suggesting an overhaul of the federal system to address telemedicine, but rather that the agencies coordinate and work in concert. It could prove ultimately, that one of these agencies should have the regulatory lead; in this respect, it should be the FDA.

### A. Regulating Access: The FCC and "Universal" Access

The first law, the Telecommunications Reform Act of 1996, promises access to information for all citizens, regardless of their geographic location.<sup>184</sup> Telemedical activities in areas where the need was often the greatest was impossible because communication access in rural and other underserved areas was not established. Basic telephone connections simply did not exist.<sup>185</sup> Historically, communication costs in rural and other underserved areas were set by telecommunications providers, often easily accomplished because of the lack of competition for those markets. Large segments of the population, including rural and low-income households, were and still are unable to afford local access to a network, rendering them medically disenfranchised.<sup>186</sup> Even if the providers offered discounts to health care practitioners, they could not because state and federal utility laws prevented them—the threat, of course, being pricing discrimination. With the passage of the Telecommunications Reform Act of 1996, carriers must now provide telecommunications services to health care providers serving rural areas at rates that are comparable to those imposed in urban areas.<sup>187</sup>

The purpose of the Telecommunications Act of 1996 is to provide universal access.<sup>188</sup> The legislation accomplishes this by increasing com-

184. President Clinton, on Feb. 8, 1996, signed into law the first major overhaul of the Communications Act of 1934. This landmark action shifts communications policy responsibility to the FCC and the states, and moves the regulating away from the courts and other regulatory agencies. The FCC, together with Medicare and Medicaid programs and state initiatives will play a critical role in the growth of telemedicine. Unlike Medicare and Medicaid, which will eventually provide funding for telemedicine transactions, the FCC is critical in mandating the one avenue closed today: access to communication lines.

185. In a study examining the reasons patients failed to receive needed medical care at urban hospitals, and delays in receiving such care, it was found that 20% of respondents cited a lack of phone service. Kimberly J. Rask, et. al., *Obstacles Predicting Lack of A Regular Provider and Delays in Seeking Care for Patients at an Urban Public Hospital*, JAMA 1931 (1994).

186. See Ed Rose, *The Haves and the Have-Nots: Access to Information Technologies*, COMM. WORLD, Nov. 1994, at 23.

187. Telecommunications regulation is both an access and cost problem, since it is estimated that one-half of the cost of operating telemedicine programs is the cost of the telecommunications support. Consequently, the cost issue is a serious potential barrier to telemedicine's growth, but without "access" in the first instance, cost is an academic discussion. The Telecommunications Reform Act states the policy driving the resulting actions: universal access.

188. The Communications Act of 1934, 47 U.S.C. 151 states a goal "to make available, so far as possible, to all the people of the United States a rapid, efficient, nationwide. . . wire and radio communication service with adequate facilities at reasonable charges." This goal has come to be known as universal access or universal service. Section 254 of the 1996 Act does not define "universal service." Rather, the Act requires the FCC, together with representatives of state regulatory bodies, to create a joint board charged with making recommendations to the FCC regarding the definition of universal service. Telecommunica-

petition through deregulation, and establishing a universal service fund that would subsidize rural and other disadvantaged telecommunication users. In the long run, the free market should work to increase competition, lower costs, and provide better service and more consumer choices. This revived market, free and open to competition, should result in local and long-distance phone companies, and wireless, satellite and cable companies competing in each others' playing fields.<sup>189</sup>

For the purposes of this discussion, the key importance of the 1996 Telecommunications law is that it provides, *inter alia*, universal communications services at affordable rates for rural, high-cost, or low-income areas.<sup>190</sup> In order to bring the widespread availability of basic communications services at affordable prices, the Act requires the FCC to ensure that rural health care providers have access to essential telecommunications systems to deliver services at rates comparable to those offered in urban areas.<sup>191</sup> It was the first time universal service benefits had ever been specifically targeted to rural health care providers.<sup>192</sup> The guiding principles are quality service at just and reasonable rates, services for rural and isolated consumers at rates comparable to those in urban areas, and access to telecommunications services for rural health care providers. The major aim of the Act was to enhance health care in America.<sup>193</sup> The telecommunications providers in rural areas, according to the Act, must be compensated via a fund designed to promote universal access to modern telecommunications.<sup>194</sup> The challenge was, and four

tions Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (codified in scattered sections of 47 U.S.C.A. (1997).

189. The belief in the free-market approach is reinforced—notwithstanding changes in FCC Commissioners, *see* Speech, before the Congressional Economic Leadership Institute Luncheon, June 17, 1998, [http://www.fcc.gov/daily\\_releases](http://www.fcc.gov/daily_releases) [as delivered] p. 1-4 (223) and prior remarks of previous Chairman Reed Hundt [as prepared for deliver] Promoting Standards in Telehealth forum (July 17, 1997), at p. 3, <http://www.fcc.gov/speeches/hundt> (225).

190. The history and chronology of the 1996 Telecommunications Act is (a) well beyond the scope of this article and (b) still in the making. *See* Proposed Rules, Federal Communications Commission 47 CFR Parts 36 and 69, Federal-State Joint Board on Universal Service, Thursday, Mar. 14, 1996, 61 FR 10499-01, 1996 WL 108610.

191. 47 U.S.C. § 254 (1996).

192. Congress, recognizing that rural health care suffers because of distance – a distance that can be overcome by telemedicine – set up a system to address the 60 million people, approximately one quarter of the U.S. population, who live in rural areas. The FCC rules will directly link the 12,000 non-profit and public health care providers who serve rural Americans to specialists – special medical care that would ordinarily be hours or even days away. *See* REMARKS OF CHAIRMAN REED HUNDT, TRANSATLANTIC TELEMEDICINE SUMMIT, May 20, 1997, <<http://www.fcc.gov/speeches/hundt>>.

193. *See* 47 U.S.C. § 254 (1996).

194. The rates that are charged must be comparable with the rates for similar services in the state's urban areas, but the discount is not to be paid by the telecommunications industry, but by federal funding through the universal support fund that the carriers must contribute to.



years after its passage still remains, to compensate rural health care providers for much higher telephone line charges,<sup>195</sup> due to the distance, than their urban counterparts<sup>196</sup> and remove the enormous access barriers associated with the growth of telemedicine.<sup>197</sup> Health care via telemedicine should not be hampered by excessive telecommunications rates in rural areas, by lack of equipment standards, or by regulatory and legal barriers imposed by the FCC.<sup>198</sup> This is no small matter since communications costs in underserved areas could end up costing four to five times the rates charged in urban settings.<sup>199</sup>

Procedurally, the FCC and the States share responsibility for the Act's implementation.<sup>200</sup> The FCC is charged with addressing any

In other words, there is a Congressional mandate to equalize the rates charged so that urban and rural are treated more the same than not. *Id.*

195. Even if telecommunications providers wanted to provide discounted rates to health care providers, they were not permitted to do so because federal and state utility laws prevented telecommunications providers from offering discounted rates to health care practitioners. This action would have constituted pricing discrimination. Under the utility rules existing, a single telecommunications rate was applied equally to all customers in a given area, whether the customer was a non-profit or for profit entity. Hezel Associates, *TELEMEDICINE 1997-1998* (1998) at 10.

196. *Id.* The premise of the Act is that increased competition would lead to innovations and improvements in urban areas. Because of the manner in which Congress is structured, the rural states prevailed in providing subsidies in this new environment to certain "high-cost" areas.

197. See S. Cong. Rep. No. 104-230, 131, 132 (1996) for Congress' intent to make telemedicine "affordable."

198. On Apr. 12, 1996, shortly after the passage of the Act, then Chairman Reed Hundt announced the Commission's intention to form a Telemedicine Advisory Committee to assist the FCC with implementation of the service. "Telecommunications will play an increasingly important role in the development and delivery of health care in American . . . [W]e need to make sure there are no barriers that would prevent progress in improving the health of rural and urban areas. . ." PRESS RELEASE, Apr. 12, 1996, COMMISSION ANNOUNCES INTENTION TO FORM TELEMEDICINE ADVISORY COMMITTEE TO ASSIST IMPLEMENTATION OF THE TELECOMMUNICATIONS ACT, <<http://www.fcc.gov>>. The lack of standards and the resulting incompatibility of telehealth systems is clearly an obstacle to the growth of telemedicine, and therefore, the FCC sponsored a forum to promote telehealth equipment standards. See *id.*; Remarks of Chairman Reed Hundt, Promoting Standards in Telehealth Forum, July 17, 1997, <<http://www.fcc.gov/speeches>>. In the January 1997 Telemedicine Report to the Congress, issued jointly by the Departments of Commerce and Health and Human Services, the development of standards is recognized as a key important step. See also February 1997 GAO Report, *Recommending the Promotion of Telemedicine System Designs*.

199. FCC Advisory Committee, 1998. In fact, prior to the 1996 Act, even if the communications providers were to promote discounted rates to health care customers, they were prohibited from discounting because this would have constituted pricing discrimination. It had therefore been impossible, without violating the law, for a company to apply, according to profit or non-profit status, different rates to different categories of customers in an area.

200. Thus, the states have the obligation to review and make recommendations to their state public-utility laws governing competition, pricing and pricing standards. States should consider changes that will encourage lowering prices for telemedicine services that will im-

federal or state preemption disputes arising under the Act.<sup>201</sup> The States also have a significant role: their duty is to address local competition and intrastate universal service.<sup>202</sup> The Joint Advisory Committee Task Force is to figure out how to implement the Act, a significant responsibility. The FCC's role is to assure that there is a general policy as well as specific implementation of equitable distribution of reasonably priced, quality services that are affordable to the populace.<sup>203</sup>

The Act required the FCC to issue regulations as well as to appoint a Joint Advisory Committee Task Force to make recommendations to the FCC.<sup>204</sup> The Advisory Committee made its recommendations, and in

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prove rural public health. States should also consider changes that “would encourage investment and extend services to under and unserved areas.” Orbuch at 58.

201. Section 252 of the Act requires the FCC to preempt any “[s]tate or local statute or regulation, or other [state] or local legal requirement . . . which may prohibit or have the effect of prohibiting the ability of any entity to provide any interstate or intrastate telecommunications service.”

202. The States' role is to mediate or arbitrate disputes between the local exchange businesses and any new entrants to the market.

203. The universal service principles of 254(b) are: Quality services should be available at just, reasonable, and affordable rates, access to telecommunications and information services should be provided in all areas of the United States; consumers in all areas, including low-income consumers and those in rural areas should have access including exchange services and advanced telecommunications and information services which are reasonably comparable to services provided in urban areas and available at like rates; equitable and non-discriminatory contribution to the preservation and advancement of universal services; a specific, and predictable and sufficient regulatory mechanisms, federal and state, to advance universal service; access to advanced services for schools, health care, and libraries, and whatever other principles as the Joint Board and the Communication determine are necessary and appropriate for the protection of the public interest, convenience, and necessity and are consistent with the Act. Moreover, and of critical importance, is that the FCC is authorized to stimulate faster deployment of services, just as long as the FCC facilitates more competition.

204. The Advisory Committee on Telecommunications strongly encouraged the Universal Service fund to reimburse the telecommunications carrier for taking the product to the rural community and to provide a discounted rate to the rural healthcare professional. The Advisory Committee recommended the following: telecommunications services should be available to healthcare providers at rates that are comparable to those in urban areas, the “market basket” of “essential telemedicine applications should be reviewed and updated . . . at least every two years,” that the “market basket” include the following, “healthcare provider to healthcare provider consultation,” “healthcare provider to patient consultation,” “rural physicians and other health care providers” participate in continuing medical education, “rural healthcare providers should have access to current medical information through the Internet, “rural emergency departments should get 24 hour a day support from on-call physicians/specialists at urban centers or a local physician's office, a comprehensive set of specialty services and emergency departments and trauma centers in urban areas should be able to interact with paramedics directly at the scene in case of emergencies. For a complete review of the recommendations. See FCC Telecommunications and Health. . . Findings and Recommendations at <<http://www.arentfox.com/telemed.reports/fccfindings.html/#overview>>. See also, FCC Telecommunications and Health care Advisory Committee Findings and Recommendations, provided by R. Waters (on file with the author).

May, 1997, the FCC's Universal Service Report and Order was issued,<sup>205</sup> providing major financial support for telemedicine.<sup>206</sup> The Universal Service Order required telecommunications companies to provide rural health care providers comparable access to telecommunications services to those of urban areas.<sup>207</sup> The health care provisions established a \$400 million per year<sup>208</sup> subsidy to rural health care providers to bring them up to par with their urban counterparts. Last, the Order provided that carriers furnishing telecommunications services to health care providers will be entitled to treat the amount of service provided against their universal service obligation and receive a reimbursement for any amount that exceeds the obligation. Those providing non-telecommunications services will be entitled to a direct reimbursement for the eligible amount. These moneys will be available to provide toll-free access to the Internet, and to pay for the long-distance charges that rural healthcare providers using

205. 47 C.F.R. §§ 36, 54 and 69 (effective July 17, 1997, except for Subpart E of Part 54 which will become effective on Jan. 1, 1998). The rules adopted in the Order are "intended to promote affordable access to telecommunications and information services to low income consumers and consumers residing in high cost, rural, and insular regions of the nation." *Id.* at 32862-01 (June 17, 1997) (containing a summary of the Commission's Report and Order adopted May 7, 1997 and released May 8, 1997). *See also* 61 FR 10499-01 (Mar. 14, 1996) (Notice of Proposed Rulemaking and Order establishing the Joint Board). The 1996 Act sets forth seven principles that guide the Commission in establishing policies for the preservation of universal service. "These principles include quality services at just, reasonable, and affordable rates; access to advance services; access in rural and high cost areas; equitable and nondiscriminatory contributions from all providers of telecommunications services; specific and predictable support-mechanisms; and access to advanced telecommunications services for schools, health care providers and libraries." FCC News, COMMISSION IMPLEMENTS TELECOM ACT'S UNIVERSAL SERVICE PROVISIONS, REPORT No. CC 97-24 (May 7, 1997).

206. *See* 47 U.S.C. § 254 (1996) (providing the Act's mandate relating to universal access to telecommunications).

207. *FCC Announces \$400 Million Universal Service Program for Telemedicine*, CTL LEGAL AND REGULATORY UPDATE: 3, p. 212 (June 1997).

208. Note that the \$400 million is additive to the 1996 Telecommunications funding. The "cost" of all of this is another story, but just to provide a snapshot of what is being spent with respect to this Act, figures range from 2.25 billion dollars a year to 12.8 billion dollars in the year 2002. The bottom line is that Congress has no proverbial bottom line—there is, as far as this author can ascertain, no limit on the amount the Commission can dispense in universal service funds just as long as the money is spent in the name of the "public." 47 U.S.C.A. § 254(h)(7) (1997). In May of 1997, the FCC issued the First Order adding \$400 million dollars per year for rural health care providers. The total, including the funds for schools and libraries is now 2.65 billion dollars per year. The Second Order was issued in July, 1997 and iterated universal service costs and how the administration of the funds would be addressed. Report and Order and Second Order on Reconsideration, 62 Fed. Reg. 41, 294 (1997). Examining the comparatively short period of time since the enactment of the Act, one thing is obvious, the cost issue is no small potatoes. Another thing is clear, the regulator is regulating in piece-meal fashion, and there is uncertainly what the real cost is or may be. And yet a third factor is certain, universal isn't universal if it only addresses a part of the total universe. *See also* *FCC Announces \$400 Million Universal Service Program for Telemedicine*, CTL LEGAL AND REGULATORY UPDATE: 3 (June 1997).

telemedicine applications will incur. The telemedicine projects will be eligible for subsidies; the funding will come from the federal “universal service fund” provided by the telephone companies and their customers.<sup>209</sup> The Order recommended that two corporations be created to administer the universal program: the Rural Health Care Corporation (RHCC)<sup>210</sup> and the Schools and Libraries Corporations. Additionally, the FCC established a number of committees and boards to advise and administer the support of the new program.<sup>211</sup>

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209. A pool of some 2.25 billion dollars a year will pay for Internet services and \$400 million will help implement on-line “telemedicine” services. The government has dubbed the discounted rates “E-rates.”

210. There is a web site, operated by the Rural Health care Corporation, which is expressly dedicated to Universal Service for rural health care providers. The Universal Service “candidates” are asked to look there to learn more about their eligibility, calculate the actual amount of their discount and to actually apply online. See <<http://www.rhccfund.org>>. The web site explains what universal service is, how it works, how to make an application for universal service, how it intends to be implemented and explains the “pending issue: which is still pending as of the date of this article: e.g. that while universal service discounts “are still expected, the number of rural health care providers that will benefit is in question.” It is debated whether the wording under Section 254(h)(1)(A) of the Act will limit the number of telecommunication providers that will be eligible to provide discounted services. “As a result, any reduction in participating telecommunication providers would also reduce the number of health care providers that could benefit from Universal Service discounts.” *Id.* (227) As of July 9, 1998 more than 1,250 applications from not-for-profit rural providers in 45 states have requested discounts on telecommunications services for providing clinical care. *Telemedicine: Applications for Telemedicine Service Discounts in Rural Area Promoted*. BNA HCD July 9, 1998 (228).

211. The number of organizations involved, the number of people involved, and the interrelationship of the federal government agencies is large, especially since the terms Congress used were not exactly specific, leaving a lot of room for dialogue over the charge of these committees, the meaning of the words involved, and, by the very nature of the beast, the jurisdiction of the committees as they met to discuss what their “advice” would be. The bottom line is that originally, Jan. 1, 1998, was set as the “beginning of the Universal service, but the administrative structure was not in place and as of July 14, 1998, there was a 75 day window—beginning on May 1, 1998 and ending on July 14, 1998, for determination of “eligibility.” Currently pending is the issue of who is “eligible” to be included as a “long-distance” carrier or inter-exchange carrier. As of this writing, the FCC has not resolved this issue, although the FCC has clearly recognized that it has a major issue to resolve.

Immediately after the order was issued it was praised,<sup>212</sup> criticized,<sup>213</sup> questioned<sup>214</sup> and challenged.<sup>215</sup> For example, it was enthusiastically

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212. With respect to whether this is the “right” direction or not, some authors, in examining the effect of the 1996 law pointed out that the law was a significant step toward where we, as a society should be focused. For instance, in an examination of the Act, the loss of competition “could well be less than the welfare loss from the delaying of consumers’ access to new information services. . . . Delaying the development of a fiber optic network because of antitrust concerns would result in billions of dollars lost from such projected future services as telemedicine. Telemedicine will use local fiber optic networks to connect distant and expensive specialists to local hospitals by transmitting patient images for diagnosis. By using a two-way interactive live television system, specialists could effectively watch and give advice during live surgical procedures. Interactive video communications could also take place between homebound patients and their primary-care physician. . . .” Moreover, some have argued against regulating the new interactive broadband services and that it would be “counterproductive” to take that approach that the services “are not likely to be necessities of life of the sort that government has traditionally regulated.” Although the authors express support for the new uses of the interactive networks, including telemedicine applications, they caution that there will be “little evidence of the market demand for new interactive services until firms actually build the networks and experiment with new service offerings.” *Id.* at 1212. The authors mention that while it is possible that interactive broadband applications will generate network externalities, the benefit to society from the use of telemedicine applications may go up, “first at increasing and then at diminishing marginal rates of access and usage, as additional hospitals and research laboratories subscribe to the broadband network.” *Id.* at 1213. But this doesn’t necessary mean that there will be any market imperfection that will arise. They recommend that if the government felt compelled to do something in the name of attaining a socially optimal scale, the best approach, via a public policy route, would be a “direct subsidization of the broadband applications at issue, rather than an attempt to regulate entry, pricing, investment, or service quality.” *Id.* at 1214. See generally, Julie M. Kearney, *Telemedicine: Ringing in a New Era of Health-Care Delivery*, 5 COMM. LAW CONCEPTS 289 (Summer 1997).

213. In an address on telemedicine shortly after the FCC Order was issued, the Governor of North Dakota, Edward T. Schafer, expressed concern over the terminology of the word “comparable” as relating to the rates. “In writing the policies and definitions to implement the legislation [The Telecommunications Act of 1996], the Federal Communications Commission (FCC) and the Federal-State Joint Board on Universal Service (Board) used language and terms that decrease the efficiency and flexibility of the available funds. This action does not seem in step with the clear intent of the law. For example, the Board recommended that the health care providers serving people who reside in rural areas must also be physically located in rural areas, which immediately disqualifies most telemedicine providers.” Gov. Edward T. Schafer, *Closing Key Note Address: Telemedicine: An Emerging Technology with Exciting Opportunities for North Dakota*, 73 N.D. L. REV. 199, 204 (1997).

214. The question arises much more regarding definitions and how these conflicting mandates will work than anything else. For instance, the law provides shockingly little guidance as to what “universal service” means, what is “access”, who can receive the service, and what this “universal service” will cost. In fact, there is an inherent oxymoron in the telemedicine and communications debate, because not only does telemedicine operate at a distance from the ultimate consumer, but telemedicine, to the “have-nots” may be the only medicine the “have-nots” receive. How will exactly the market provide an existing claimed communication privilege when the very issue of why the consumer does not have the service, in this case medicine, is usually the cost factor. According to our nation’s past track record, entrepreneurs usually rush to the marketplace where the consumer will pay for the service, not where the consumer only has the remnants of federal funding that may or may not always be in place. In fact, two years after the passage of the Act, the FCC has yet to release any funds for the purposes of providing “universal service.”

215. Indeed, it has been challenged by many, and litigated—especially with respect to the education related issues—by even more. Most of the litigation centers over the constitu-

cheered by the health care community. Questions, however, were also raised, concerning the extent of the \$400 million subsidy,<sup>216</sup> and whether the restriction on the availability of discounts and subsidies to non-public, for-profit entities include physicians and specialty clinics that try to operate on a for-profit basis. What did it mean for the "new type of health care organization, such as Columbia" that is for-profit?<sup>217</sup> Why did the FCC limit the bandwidth to T1 speeds of 1.54 Mbps?<sup>218</sup> And a specific problem, raised by some of the states is the provider's ability to actually obtain telecommunication services at discounted rates. Under the Act, the telecommunications carrier is obligated to provide its services to a rural health care carrier at a discounted rate if the provider makes a bona fide request for services that are needed for providing health care services to a rural community. This poses a problem in some states because the service requires the use of facilities owned by long-distance carriers that do not fall within the definition of an eligible telecommunications carrier; therefore, they are not entitled to receive reimbursement for providing the discounted service to rural health care providers. The FCC has recognized that it needs to address this as a problem, because, in many remote areas, patients will not be able to benefit from the very mechanism Congress established for them.<sup>219</sup>

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tionality of the school-financing schemes. The appeals of the universal service report and order have been assigned to the Fifth Circuit Court of Appeals, *See* 7 Comm. Reg. 109 (1997) and *Telephony, Comm. Daily*, Aug. 8, 1997.

216. Dave Swartz, *FCC Universal Service Report*, *Telemedicine Today*, p. 16 (May/June 1997).

217. *Id.* The FCC did accept a number of the recommendations that had been advanced by the Advisory Committee, e.g. granting but not exceeding 1.544 mbps to health care providers, defining broadly "health care services," to include medical applications that go beyond patient care, diagnosis, and treatment, and including general administrative services, including public health-related services, and instruction. FCC REPORT, MAY 1997.

218. *Id.* Dr. Swartz questioned this and thought it made little sense, "since the need for bandwidth is going to change as new applications emerge." Dr. Swartz speculated that this was a way to ration the \$400 million. Moreover, are thirty hours available for reduced access charges for Internet service to a rural hospital adequate? Thirty minutes *seems* inadequate, considering that it takes a few minutes just to get acclimated. Additionally, there was no support for continuing education. As a tape on the Kansas City Telemedicine Project indicates, one of the least controversial and most useful applications of telemedicine is for continuing education of physicians located in rural areas. (Tape from the University of Kansas Medical Center on file with the author). The continuing education is made available for higher education institutions and "[m]ost telemedicine programs use a significant percentage of their aggregate bandwidth for continuing educational programs rather than for telemedicine. Although the FCC takes a broad view and refers to the educational part as "telehealth," does this include the "distance learning programs" for physicians and providers of care or was the intent of the FCC for Internet access for public information and "actual telemedicine services.?" *Id.* at 17.

219. SPEECH, William E. Kennard, CHAIRMAN, FEDERAL COMMUNICATIONS COMMISSION, BEFORE THE SUBCOMMITTEE ON COMMUNICATIONS, COMMITTEE ON COMMERCE,

There are at least two major impediments that rural health care officials recognize could deter providers' applications. First, they must be aware of the program; second, the provider must have a computer, software and capital sufficient to support participation. But even more significant, if the provider is using either AT&T, MCI or Sprint, the provider cannot receive a discount because these companies do not provide local service and are not eligible telecommunication carriers.<sup>220</sup>

The FCC Act's solution to increasing access was fraught with problems.<sup>221</sup> In early February, 1998, GAO reported that the FCC broke the law in ordering the creation of the Universal Service Fund Administrative entities. GAO found that the entities administering the "E-rate" and telemedicine portions of the Universal Service Fund did not have the authority to establish the two separate entities. In making this finding, the GAO also found that despite the FCC's illegal action, the FCC, and not Congress, has direct oversight authority for the administrative spending of the corporations. The corporations, the Schools and Libraries Corporation and the Rural Health Corporation, were both created to implement the legislative mandate to connect schoolchildren to the Internet and bring the latest medical advances to those underserved rural areas that were in need.<sup>222</sup> Congress directed the FCC to combine RHCC with the Schools and Library Corporation and Universal Services

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SCIENCE AND TRANSPORTATION, UNITED STATES SENATE, FIELD HEARING ON UNIVERSAL SERVICE, ANCHORAGE, ALASKA, JULY 1, 1998, <<http://www.fcc.gov/daily>> (assuring that the FCC "will solve this problem").

220. *Telemedicine: Applications For Telemedicine Service Discounts In Rural Areas Promoted*, BNA HCD (July 9, 1998).

221. Although addressing "telemedicine" issues directly, even before the FCC Chairman suggested that the "conversations commence," the "court" conversations had already begun. In a decision handed down by the Court of Appeals of Kansas in Aug. 1997, the Court reversed and remanded a Kansas Corporation Commission Order that examined whether the Kansas Act and the KCC's orders implementing the Act violated or are inconsistent with the Federal Act. The court concluded the KCC's final Orders were not in compliance with the Federal Act and set the KCC's orders aside. *See Citizens' Utility Board v. The State Corporation Commission of the State of Kansas, et. al. v. The State Corporation Commission of the State of Kansas*, 24 Kan. App. 2d 222, 943 P.2d 494, (1997 Kan. App.), modified, 264 Kan. 363 (1998 Kan. App.). The Court held that interpretation of the Kansas Act is a question of law, and the constitutionality of the statute would be presumed and all doubts would be resolved in favor of the validity of the statute. Additionally, the court found that "the challenged portions of the Kansas Act do not prescribe the conduct of individual citizens or regulate the public at large . . ." but rather the statute applies "to a highly specialized, closely regulated industry."

222. The report, issued by GAO on the FCC's implementation of the E-rate" and telemedicine universal service provisions of the Telecommunications Act of 1996 was issued in response to a request made by Senator Ted Stevens (R. Alaska) in late November, 1997, asking whether the FCC had indeed the authority to establish the two separate entities. On Feb. 10, GAO's General Counsel said that the two Corporations "act as the agents of the Commission." *See State & Loc. Comm. Rep. WL Database, COMNEWS, 1998 WL 8062141.*

Administrative Corporation under the umbrella of the universal-service fund.

This new development immediately placed the 1996 Telecommunications Act once more in the political spotlight. Sides were taken, with the chairman of the Senate Commerce, Science, and Transportation Committee calling the findings "serious," and promising to "work to ensure that the FCC revises the schools and libraries and rural health care programs and that the agency abides by the spirit and intent of the law."<sup>223</sup> The original sponsors of the Amendment that became the E-rate and telemedicine provisions didn't see the GAO finding as a "threat to the program," and viewed it as "more of a logistical problem."<sup>224</sup>

But this "small" problem opened the door for a re-examination of the issues. Amid the criticism that the FCC is overemphasizing "E-rate" and telemedicine programs, discussion began to take place to introduce a bipartisan bill that would require some "hard new thinking on how we fund universal service."<sup>225</sup> The FCC continued its support to the universal service programs, and FCC Chairman William E. Kennard said he planned to "have a conversation with wireless carriers to make sure they're paying their fair share to support universal service."<sup>226</sup> Toward that end, the Rural Health Care Corporation, the Corporation charged with administering the funds, continues to accept applications.<sup>227</sup>

Moreover, a fatal flaw in the 1996 Telecommunications Act is arguably Congressional nonfeasance in addressing only a fraction of the universe, e.g. those in rural areas, as opposed to the medical "have nots" in urban areas as well. This is not a small omission. Universal service that applies only to a fraction of the population, and may not be affordable to even those covered by the Act, is not "universal." It appears that the implementing provisions fall far short of the original intent of the

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223. *Id.* See also, SPEECH, INTRODUCTORY AND WELCOMING REMARKS BY CHAIRMAN HUNDT AT THE UNIVERSAL SERVICE ADMINISTRATIVE COMPANY INAUGURAL MEETING, Sept. 22, 1997, <<http://www.fcc.gov>>.

224. *Id.*

225. Sen. John McCain (R. Ariz) announced plans to introduce a new bill. This prompted a spokesman for Sen. Olympia Snowe (R. Maine) who sponsored the Telecom Act Amendment that contained the E-rate and telemedicine provisions to tell [McCain] that he "would be very concerned, if not opposed, to any arbitrary efforts to reduce the amount of funding" for those programs. Apparently, there may more that just this issue back in the spotlight as now there may be a number of draft bills "dealing with universal service 'flying around out there . . .'" 3/12/98 Telco Competition Re. (Pg. Unavail. Online) 1998 WL 8888791.

226. FCC Chairman William E. Kennard told an audience at a Washington conference on access to telecom service, "where the questions and conversations were reported to reveal concern that discounts many had begun to count on might not materialize." State & Loc. Comm. Rep. (Pg. Unavail. Online), WL Database COMNEWS, 1998 WL 806213.

227. See <<http://www.rhccfund.org>>.



1934 Telecommunications Act.<sup>228</sup> From an implementation standpoint, state activity will be critical and states will need to take the initiative, will need to begin planning for telemedicine and will need to anticipate interstate systems. Unfortunately, only one interstate planning group, the Western Governors Association,<sup>229</sup> has formed a regional group to address interstate telemedical issues.<sup>230</sup>

As indicated by the above, the promises of the 1996 Act are great, but the execution, to date, proves less so. The missing thrust has been a force that compels the players to act in the best interest of their patients. Telemedicine has the potential to bring access to health care for people of every economic background in all locations, but the ideal of this legislation is ensnared in politics and money. The above regulatory gyrations reflect the fact that universal "access" is more a legislative dream than a reality. The FCC, is regulating in piecemeal fashion and no one appears to have the big picture of how access will be provided, who will provide the access, how much it will cost, and who will pay.<sup>231</sup> Moreover, "universal" cannot be universal if it addresses only a part of the ultimate vision. If, therefore, the cost to be calculated is not "universal," it would be impossible to know the actual cost of universal care. It is axiomatic, that with a matter so weighty, in addition to the "vision" of "universal service," a plan needs to be put in place to move

228. See generally, Allen S. Hammond, *Universal Service in the Digital Age: The Telecommunications Act of 1996: Codifying the Digital Divide*, 50 FED. COM L.J. 179 (December 1997).

229. By September there were a number of announcements to build new network systems for the purpose of delivering health care services. Vermont's largest health care provider received preliminary permission to build a new 30 million dollar video computer network, linking primary-care doctors with the Fletcher Allen Health care in Burlington, Vermont. This system is promised to delivery medical care, through the telemedicine project, permitting consultations on procedures between "every doctor" in Vermont and state authorities "all for the cost of a telephone call." *Fletcher Allen Gets Go-Ahead for Medical Network*, STATES NEWS BRIEFS, Lexis-Nexis States News Services, Sept. 17, 1996. The Eastern Montana Telemedicine Network links physicians with Deaconess mental health professionals. See Pat Bellinghausen, *Deaconess Gears Remodeling to Patients' Needs*, BILLINGS GAZETTE, Sept. 16, 1996.

230. As individual states focus on telemedicine planning it will be important for states to prepare for technical compatibility across state lines. "Leadership in supporting interstate planning thus far has resided in the Western Governors Association, and unless a greater number of regional consortia are formed the future success of interstate telemedicine initiatives remains unclear." *Telemedicine 1997-1998*, *supra* at 11.

231. In fact, one of the major impediments is that the rural telecom rate-cut effort got off to a rocky start from the outset. The program may have suffered an early setback due to an FCC ruling that scaled back collection from telecommunications companies to fund the program. The FCC states that it was not retrenching from the commitment to fund the program, but many telemedicine users expressed concern that it was the first step in rolling back the program. F. Goerdert, *Rural Telecom Rate-Cut Effort Gets Off to a Rocky Start*, HEALTH DATA MANAGEMENT 6(2): 14-16 (February 1998).

forward toward realizing "universal access." The current vision omits a portion of the universe, e.g. the medically underserved population, including those in urban areas as well as rural areas. The question of how to unravel these problems could be addressed through comprehensive governmental regulations, which set forth in-detail the telemedical tasks to be accomplished. There is another approach, however. Rather than legislate, the FCC should set specific goals. That is, the FCC should clearly define universal service, set forth how the country should approach that clear definition, and establish milestones to mark and measure progress. In addition to the enormous amount of money on the table, the real harm is the ultimate effect (or non-effect) falls on the medically underserved. To this end, the Western Governors' Association Telemedicine Policy Review Group listed "universal service" as one of its top four areas that should be addressed for telemedicine to successfully grow.<sup>232</sup>

The key to moving universal service from a vision to reality must be a combination of clear Federal regulation and allowances for free market price regulation and service distribution.<sup>233</sup> Not only will the marketplace seek the optimum route for delivery, but it will tailor solutions to each community.<sup>234</sup> Additionally, freeing the market will result in better

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232. The WGA Telemedicine Policy Review Group issued a Telemedicine Action Update in June 1998 as a follow-up to its 1995 report, which set forth the barriers to telemedicine's growth. Those barriers at the time, prior to the 1996 Act, included *infrastructure* planning and development and telecommunications regulation. In its update, the first area that needs to be addressed is that the FCC, the Rural Health care Corporation, and state utility commissions need to speed the flow of universal service support funds to rural health care providers. "The Action Update provides a wake-up call for the political leadership and others to redouble our efforts to tackle these issues," said North Dakota Gov. Edward Schafer, the lead governor for rural health issues. *Telemedicine: Western Group Pledges to Eliminate Barriers to Expansion of Telemedicine*, BNA, HEALTH CARE POLICY REPORT, VOL. 6, No. 30 (July 27, 1998) at 1227.

233. Before the 1996 Act was passed, Kellogg, Thomas and Huber argued that the central lesson of seven decades of American telecommunications regulation is that "government cannot ordain how the technologies of freedom shall evolve. Rather than continue that futile task at this late day, regulators should let the walls come tumbling down and permit the consumers on whose behalf they regulate to savor the benefits of competition and technological innovation." *Telecommunications in Jericho: Federal Communications Law*, 81 CALIF. LAW R. 1209 at 1239 (1995). See generally, Ilene Knabe Gotts and Alan D. Rutenberg, *Navigating the Global Information Superhighway: A Bumpy Road Lies Ahead*, 8 HARV. JOUR. L. & TEC. 275 (Spring 1995) at 339. In fact, the states have incredible power to encourage their physicians, their communities and patient constituents to unite "to create organizations of telemedicine consumers that can yield economies of scale in purchasing, greater influence in policy making, and interoperability in technology across systems. Orbach, *supra* at 59.

234. *Id.* The comments expressed by Senator Conrad in introducing a symposium on telemedicine. The Honorable Kent Conrad, *Introduction*, 73 N.D. L. REV. 1 at 5. Senator Conrad suggested that his proposal will enable various "technological approaches" and not

technologies and cheaper delivery systems, architectures the FCC seemingly cannot imagine. The proper role for the regulator, then is a discrete, albeit a difficult, role: to define what is meant by universal access, to provide the supporting funding mechanisms through reimbursement or tax incentives,<sup>235</sup> and to regulate violations of federal laws.<sup>236</sup> As patients, especially the home-bound patient, increasingly require medicine and treatment delivery, distances should be virtual and should not override the needs of the patient.<sup>237</sup>

### B. Regulating "Teledevices"

There is one federal regulatory agency that has done an excellent job in acting as the gatekeeper to access—the Food and Drug Administration. In this area of access regulation, the FDA has been a proactive protector of the patient's best interest.<sup>238</sup> The Food, Drug and Cosmetic Act regulates certain software and hardware intended for use in telemedicine applications.<sup>239</sup> The FDA must clear certain telemedicine devices for marketing, ensure proper and accurate labeling, and regulate manufacturing specifications which guarantee quality control.<sup>240</sup> As gatekeeper to obtaining regulatory access to the telemarketplace, FDA's guidelines set forth the Agency's position regarding what is, and what is not, a telemedical device (e.g., a telephone used in teleconsultation is not a medical device but hardware used to assist remote evaluations of radiological results is a teledevice). The FDA has spent considerable time addressing this issue, but the guidelines are vague and rely upon "intent

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impose specific mandates upon communities, enabling the communities to determine approaches that work best for them.

235. The Joint Committee, recommended that "determining a cost-effective manner of delivering necessary health care related telecommunications services to rural Americans will be the future job of the FCC." Orbuch, *supra* at 41.

236. See generally Howard L. Steele Jr., *The Web that Binds Us All: The Future Legal Environment of the Internet*, 19 HOUS. J. INT'L. 495 (Winter 1997).

237. During early discussions of the charge of the Task Force to provide recommendations to the FCC, the issue of rural versus non-rural, or urban, was raised, but left unanswered. *Id.* <<http://www.fcc.gov/reports/telemed>>.

238. The specific areas the FDA includes in the definition of telemedicine are: direct clinical, preventive, diagnostic, and therapeutic services and treatment; consultative and follow-up services, remote monitoring including, the remote-reading and interpretation of results of patient's procedures; rehabilitative services and patient education.

239. 21 U.S.C. § 201(h). Prior to 1976, the FDA regulated drugs, but not medical devices. In order to regulate a medical device, the FDA had to first classify it as a drug and then the device could be regulated. With the passage of the Medical Device Amendments of 1976, 21 U.S.C. 340c–360k, the FDA had authority to regulate medical devices directly. The Safe Medical Devices Act of 1990 supplemented the 1976 Amendments. 21 U.S.C. and 42 U.S.C. et seq.

240. *Id.* See 21 U.S.C. 321(h) for definition of a "device."

for use” as the primary consideration in determining if a telemedical device is FDA regulated. The FDA should have a formal notice of proposed rulemaking so manufacturers will have clear regulations that will specify what devices are more likely than not to be subject to FDA approval. This notice of proposed rulemaking should spark debate over the definition of a teledevice as well as providing the FDA with information regarding what is being developed in the marketplace, what questions the manufactures of these devices have, and what ambiguities could pose problems in the future for physician, manufacturer and patient alike.

Within the FDA, The Center for Devices and Radiological Health (CDRH)<sup>241</sup> has regulatory oversight of clinical telemedicine<sup>242</sup> and is responsible for restricting access and ensuring the safety and effectiveness of the medical devices used in telemedical practice.<sup>243</sup> The CDRH’s oversight includes regulation of the commercialization of health care delivery technologies,<sup>244</sup> including setting standards for mammography equipment, practices and personnel.<sup>245</sup> The FDA’s regulation of

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241. *Id.* Center for Devices and Radiological Health, Food and Drug Administration, Telemedicine-Related Activities (1996), available in <<http://www.fda.gov/cdrh/telemed.html>> (the FDA and CDRH employ the Internet to provide information to the public. The CDRH has established a Web Page, which provides Federal Register reports, pma submission information, assistance to small business, and safety device alerts).

242. On Feb. 3, 1998, the Food and Drug Administration announced that it was proposing a new rule that would require drug and medical device companies seeking FDA approval “to disclose if anyone involved in clinical research on the products had a financial interest in them.” FDA Lead Deputy Commissioner Michael Friedman said, “this regulation will help assure that the process is thoroughly open and aboveboard.” The new rules will require doctors to disclose whether they have a financial interest in the devices of the product they are distributing. *Politics & Policy FDA: Researchers to Disclose Ties to Rx Companies*, available on WESTLAW, American Political Network (February 3, 1998). Interestingly, the financial disclosure requirement in health-related matters is getting closer and closer to that required by the Securities Exchange Commission requirements.

243. The FDA has defined the term “telemedicine” as the delivery and provision of health care and consultations services to individual patients and the transmission of information related to care, over distance, using telecommunications technologies. Center for Devices and Radiological Health, Telemedicine Related Activities (July 11, 1996). The CDRH has the responsibility for the regulation of medical devices including the radiation-emitting electronic products used for telemedicine. The principle areas of responsibility include: premarket review, postmarket surveillance, quality systems, standards and science.

244. “[T]he use of advance telecommunications technology to deliver health care brings with it a host of concerns about safety and effectiveness,” FDA, Safety and Standards, in Department of Commerce, National Telecommunications and Information Administration, Telemedicine Report to Congress, 63 (Jan. 21, 1987).

245. As such, the FDA does not regulate the “delivery of health care services” or even the transmission of information between physicians and patients, but it does address those issues that relate to technology and concerns about safety and effectiveness.” *FDA, Safety and Standards, Department of Commerce, National Telecommunications and Information Administration, Telemedicine Report to Congress*, 63 (January 21, 1997).

telemedicine systems ensures that telemedicine systems are properly evaluated and validated so as not to pose a substantial risk to patients. The medical images transmitted by telemedicine systems must be transmitted with sufficient detail and resolution to permit accurate diagnoses. For example, the FDA has regulatory oversight of the Mammography Quality Standards Act (MQSA) of 1992. This oversight includes the regulation of personnel, equipment, practices, and procedures in use in facilities that are conducting mammography. There is also a separate division that is responsible for interpreting and developing standards so that they will be specifically applicable “to telemammography as that becomes a viable modality.”<sup>246</sup>

The FD&CA defines a medical device to include “instruments, apparatus, implements, machines used in direct, clinical, preventive, diagnostic and therapeutic services, consultative and follow-up service, remote monitoring, and rehabilitative services.”<sup>247</sup> In issuing the policy enforcing the Act, CDRH has taken the position that any device that is used in patient education, provided it is in the context of delivering health care to individuals, is also included when “education” is medical device labeling information.<sup>248</sup> Medical devices, to the CRDH, include

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246. *Id.* at 8. CDRH outlined in its White Paper, *infra*, its jurisdictional sweep relating to telemedicine and telemedical activities. The areas include premarket review of telemedicine devices, including device determination, software policy development, mammography quality standards and telemammography, technology transfer, and post-market surveillance. Standards development, including health care informatics standards, electromagnetic compatibility in telemedicine, nomenclature standardization, quality systems, and lastly, telemedicine related research. Additionally, CDRH delineated a number of “critical initiatives” in enforcing its “crucial role” in the “emergency of viable telemedicine systems” including pre-market and post-market approval and surveillance, standards development and scientific research.

247. *See* 21 U.S.C. § 321(h). “The term ‘device’ . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The CDRH has taken the position that any telemedicine activities relating to (1) through (3) above are “obviously” subject to the Center’s medical device regulatory authority. Moreover, the CDRH has stated that those activities in (3) are “integral to that authority when the ‘education’ is medical device labeling information. CDRH WHITE PAPER, at <<http://www.fda.gov/cdrh/telem.html>>. Courts have found that in determining whether a device qualifies as a medical device for FDA regulatory oversight, the courts “must give broad deference to the FDA’s reasonable interpretation of the statutory scheme that it is entrusted to administer.” *Clinical Reference Lab., Inc.* 791 F. Supp 1499 (D. Kan. 1992). No contact with the patient is necessary for the FDA to regulate a device as a medical device within the meaning of the Act.

248. *Id.*

the hardware that produce medical images, and the software and equipment used to transmit, store, process, display and copy. The FDA will look to what the manufacturer claims in making the product, how the product is advertised and whether the product has a specific medical purpose. For telemedicine practice, the FDA's position of whether or not a device is "intended" for the use in the diagnosis, treatment or prevention of disease may not be subject, at present, to a legal litmus test.<sup>249</sup> For instance, although it is clear that the telephone is not subject to FDA regulations,<sup>250</sup> hardware supporting remote CT scans is considered a medical device.<sup>251</sup> The definition of "device" under the statute includes "components" of devices and consequently, whether a component is subject to the provision will depend on the same reasoning as applied to complete devices.<sup>252</sup> Software associated with diagnostic or medical applications may be classified as a device depending on its intended use.

Assuming the FDA classifies an item as a "device," the FDA then classifies the device into one of three categories. The classification is based on the degree of regulation needed to ensure safety and effectiveness, including the level of risk to the health and safety of the patients.<sup>253</sup> Class I devices, such as tongue depressors, do not present an unreasonable risk of injury or illness and require only general controls;<sup>254</sup> Class II devices, such as hearing aids, are subject to additional regulations, because general controls alone are not sufficient to provide assurance of safety and effectiveness;<sup>255</sup> Class III devices, such as the HIV device, are subject to pre-market approval (PMA) requiring the manufacturer to file an application with the FDA demonstrating the device is safe and

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249. *Id.* S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935); *Id. Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. § 321(h)*, 41 GEO. WASH. L. R. 806 (March 1993).

250. If a telephone is used in a teleconsultation, the telephone is not subject to FDA regulations; telephones are neither advertised nor marketed as "diagnostic tools;" the telephone manufacturer does not have the "intent" to market a medical device.

251. *See* 21 U.S.C.S. § 321(h); MRIs are also "medical devices;" 1987 FDC Reports, The Gray Sheet (Feb. 9, 1987) *Id. See generally* 1 O'Reilly, Food and Drug Administration at 13.03; 41 GEO. WASH. L. R. 806 (March 1993); PHARMACEUTICAL APPROVALS MONTHLY VOL. 3; No. 5, p. 42 (May 1, 1998).

252. The statutory definition of the term "device" will extend the FDA's jurisdiction over many "nonmedical" articles as well as the traditional items such as sutures, syringes, and x-ray machines. Courts have given an expansive reading to the Act holding that urine and saliva specimen containers used by a laboratory in HIV testing were "devices" within the meaning of 21 U.S.C. § 321(h) since the products were serving a diagnostic purpose of identifying a disease.

253. 21 U.S.C.A. § 360(c) (1995).

254. 21 U.S.C.A. § 360(a)(1)(A) (1995); 21 C.F.R. § 880.6230 (1995).

255. 21 U.S.C.A. § 360(a)(1)(B) (1995); 21 C.F.R. § 874.330 (1995).

effective.<sup>256</sup> PMA review could take a long time because it requires the manufacturer to submit a detailed application with information addressing the device's design, components, properties, principles of operation, manufacturing process and performance standards.<sup>257</sup> To act in the patient's best interest, the CDRH, primarily through its subdivision, the Division of Reproductive Abdominal, Ear, Nose, and Throat and Radiological Devices (DRAERD) has established certain categories that would be exempt from the burdensome requirements. The FDA subjects certain devices to review under a pre-market notification (510(k)) or a pre-market approval application (PMA), after the device has been used so that the FDA will be aware of any significant, or potential, problems.<sup>258</sup> The FDA therefore exempted general purpose devices from the rigorous requirements of the Act.

To date, FDA has regulated various devices including telemammography,<sup>259</sup> pacemakers,<sup>260</sup> hearing aids,<sup>261</sup> intraocular lens,<sup>262</sup> and rubber prophylactics.<sup>263</sup> The FDA has cleared many teledevices. The device that perhaps captured the most attention during the process of FDA approval was Home Access Express—an at-home HIV test.<sup>264</sup> However, the statute's ambiguity presents a problem as it may not be clear to the manufacturer that the "device" marketed under the FDA's regulatory

256. 21 U.S.C.A. § 360(c) (1995). 21 U.S.C.A. 360c(a)(2)(C); 21 C.F.R. § 870.3925 (1995).

257. The purpose of the PMA is to ensure efficient and thorough device review so that the approved device is safe and effective. 21 U.S.C.A. § 360e(d)(2)(A) (1995); 21 C.F.R. § 814.2 (1995).

258. 21 U.S.C. §§ 360e(b)(2)(A), 360e(1)(B) (1995).

259. Early in 1996, as the telemedicine field was being debated, medical imaging was noted as one of the "most intense focuses of telemedicine." See *Telemedicine, Clinical, Technical Standards Called Inadequate to Advance Field*, BNA HEALTH CARE DAILY (July 18, 1997) (115).

260. *Martin v. Teletronics Pacing Sys., Inc.* 70 F.3d 39 (6th Cir. 1995).

261. *Massachusetts v. Hayes*, 691 F.2d 57 (1st Cir. 1982).

262. *United States v. Torigian Labs*, 577 F. Supp. 1514 (E.D.N.Y. 1984), *aff'd*, 751 F.2d 373 (2d Cir. 1984).

263. *United States v. Crown Rubber Sundries, Co.*, 67 F.Supp. 92 (N.D. Ohio 1946).

264. On Sept. 8, 1997, Abbott Labs announced that it will market tests to be developed by Home Access. Hoffman Estates based Home Access also announced that it would be conducting research in the areas of genetics, cancer drugs, reproductive health and nutrition "to determine which diagnostic tests have the most use and potential for the home telemedicine market." Interesting, the firm is purportedly the only company that markets the FDA-approved at-home diagnostic tests "with counseling services"—the Home Access and Home Access Express HIV test systems. The firm announced that it expects the tests it is developing, which act much like the Home Access test, e.g., the patient can perform the test at home and then "anonymously obtain the results by phone." WESTLAW DATABASE FDC-FDC REPORTS INC. THE TAN SHEET, Sept. 8, 1997, VOLUME 5, ISSUE 36.

authority.<sup>265</sup> If there is a doubt regarding whether the “device” is within the parameter of the FDA’s authority, the FDA has the authority to make a decision subject to judicial review testing the intent of the manufacturer in bringing the product to market.<sup>266</sup>

Until the FDA promulgates detailed standards, questions will remain regarding what is, and what is not, a “teledevice.” For instance, a software system that tracks blood donations is a “device.”<sup>267</sup> Expert programs that evaluate x-rays, databases of medical literature that assist physicians in determining prescriptions may be a device.<sup>268</sup> Even a one-of-a-kind device, such as a custom-designed laser, may not be exempt from FDA’s jurisdictional reach.<sup>269</sup>

Although the FDA’s authority to restrict access and its jurisdictional sweep remain unsettled,<sup>270</sup> the FDA clearly intends to regulate telemedical software.<sup>271</sup> The FDA’s interpretation of its jurisdictional sweep will be key in addressing future telemedical issues.<sup>272</sup> In a series of dialogues,

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265. Other devices granted 510(k) clearance include: Instromedix’s Life Signs (TM), a system that enables doctors and nurses to monitor a patient’s condition outside the hospital, the first automatic alarm system displaying an ECG waveform on a wireless receiver. *Id. also* RhythmStat (TM), XL, which monitors cardiac arrhythmia via conventional or cellular phone systems.

266. This ambiguity could pose a problem for manufacturers of telemedical devices because they may not know that their product is subject to FDA regulation, may wait a long time for their product to be cleared for manufacture, or may need to make adjustments, thus prolonging getting the product to the market and simultaneously causing more expense in getting the product to the market. I am more concerned that the product be evaluated so the patient will be protected, and thus my focus is on clearer definitions to provide guidance to manufacturers of telemedicine products. FDA’s decision will be given significant weight by a court. *See, e.g.,* United States v. 22 Rectangular or Cylindrical Finished Devices, 714 F. Supp. 1159, 1165 (D. Utah 1989); United States v. 25 Cases, 942 F. 2d 1179 (7th Cir. 1991).

267. The concept of treating blood establishment computer software products as medical devices is not new. As far back as Sept. 1994, FDA indicated its intention to regulate computer software at blood establishments as “medical devices” because “they identify unsuitable blood and blood components for transfusions.” 59 Fed. Reg. 44, 991 (1994). In 1995, the FDA ordered a recall of a blood management program. G. Pascal Zachary, *FDA Orders Recall of Informedics, Inc. Software for Blood*, Wall St. J., April 12, 1995, at B3.

268. *Id.* Alexander Volokh, *Software Pirates*, Reason, Nov. 1, 1997 at 38.

269. In the case of a one-of-a-kind “customer” designed “laser,” the FDA decided that it wasn’t yet convinced of the product’s safety or efficacy. Some claim that the FDA is stretching its tentacles into forbidden territory: medical practice.

270. To date no one seems to have questioned FDA’s authority to regulate this field, although there is strong federal interest. The “object sought to be obtained by the federal law and the characters of obligations imposed . . . reveals the same purpose.” *Recie v. Santa Fe Elevator Corp.*, 381 U.S. 218 at 230. *See generally* Paul Sherman, *Use of Federal Statutes in State Negligence Per Se Actions*, 13 WHITTIER L. REV. 831 (117).

271. For a history of FDA’s regulation of the telemedicine devices, *Id.* Peter S. Reichertz, *FDA Regulation of Telemedicine*, *infra* note 304.

272. FDA’s basis for regulation of software is in the definition of “device” as set forth in section 201(h) of the (codified as amended 21 U.S.C. § 321 (1994)). A device is “An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or related article,



draft policies,<sup>273</sup> publications, revisions of draft possibility,<sup>274</sup> announcements, and public workshops,<sup>275</sup> the FDA, through the CDRH continues, albeit slowly, to review the issues.<sup>276</sup> In general the FDA intends to regulate software when it is intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease.<sup>277</sup> The FDA has acknowledged that products that are not “intended” to be used for a medical purpose are not medical devices, and therefore are not within the FDA jurisdictional ambit—even if the device may be employed in medical use.<sup>278</sup> Therefore, not all software used in medical facilities is within FDA regulatory control.

Problems with the status quo involve the FDA’s attempts at proactive regulation without clear regulatory guidelines.<sup>279</sup> Without clear guidelines, we depend upon the strength of the FDA to regulate the manufacturer seeking approval of a new product or software for use in telemedical applications. To date, however, the FDA has not held formal hearings.

Today, stand-alone medical software is subject to regulation on a case by case basis. The FDA drafted policies in 1987 and 1989 that classified software as a medical device; but the FDA has yet to issue a

including any component, part, or accessory, which is (1) recognized in the National Formulary, or in the United States Pharmacopoeia . . . (2) intended for use in the diagnosis of disease, or other conditions, or in the cure, mitigation, treatment or prevention of disease. . . or (3) intended to affect the structure or function of the body.” *Id.* As such a device is defined broadly, and could encompass some software products, at least, software that would fit under the term “contrivance” in the Act.

273. A draft policy was developed in 1987, 52 Fed. Reg. 36,104 (Sept. 25, 1987).

274. CDRC, FDA POLICY FOR REGULATION OF COMPUTER PRODUCTS, DRAFT (1989).

275. CDRH Software Policy Workshop, Bethesda, MD, Sept. 3–4, 1996 (transcript and summary available at Food and Drug Admin., CDRH Software Policy Workshop <<http://www/fda.gov/cdrh/swpolpg.html>>).

276. *Id.* FOOD AND DRUG ADMIN. REGULATORY REQUIREMENTS FOR MEDICAL DEVICES 2–24 to –26 (FDA Pub. No. 92-4165) (1992); FOOD AND DRUG ADMIN, EVERYTHING YOU ALWAYS WANTED TO KNOW ABOUT MEDICAL DEVICE REQUIREMENT. . . . 20 (FDA Pub. No. 92-4173) (1992).

277. *Id.*

278. In fact, efforts to develop a software policy have been ongoing since 1985, when then-FDA Commissioner Frank Young stated that FDA would take the least regulatory action possible that was consistent with the requirements of public health and safety. *See Medical Device Software: Highest Level of FDA Regulation Will Be 510(k), M-D-D-I Re. THE GRAY SHEET*,” Sept. 22, 1986, at 4–5. Since then, the FDA issued a draft policy, revised the draft, and ultimately decided that it was difficult to decide when the exemption should be applied. 61 Fed. Reg. 36,886–7 (July 15, 1996). Finally, it announced it may redraft its draft policy. FDA has held public hearings, and ongoing discussions with industry, but to date there has been no final decision regarding medical software. *Id.* Industry and Washington Memos, M-D-D-I Rep. (“The Gray Sheet,” Dec. 23, 1996, at I&W 4–5.) For a history of FDA’s regulatory approach to medical hardware and software, *Id.*

279. As such, the FDA exercises a case-by-case approach to determining the status of the device.

proposed or final rule. Because software undergoes frequent upgrades, a step-by-step approval process could require continual FDA action—proving difficult for developers and the FDA. This regulatory dilemma has potentially two outcomes. On one hand, if regulatory review must occur each time the software is adapted, potentially powerful tools could be denied to patients and their physicians. On the other hand, if the FDA exercises too little regulatory review, substantial risks would be shouldered by the patient.<sup>280</sup> In a 1996 report, the Council on Competitiveness noted a lack of common standards and languages for communications and computing activities, and suggested a review of national information infrastructure technologies. To promote the use of new technologies in the health care arena, the Council's report recommended that the FDA should not regulate "stand alone medical decision-support except when it 'both introduces substantial risks to patients and is to become a commercial product.'"<sup>281</sup> With the market expanding so rapidly, some additional action should be taken to protect the best interest of the patient. The average patient may be able to determine the results of a home pregnancy test, or a home ovulation test, but what about the coumadin home analysis?<sup>282</sup>

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280. Software that falls within the definition of a medical device, and would not be exempt from review, is subject to the 510(k) or a PMA. The problem is that FDA regulations require a new FDA approval whenever a significant change in the product occurs that could affect the safety or effectiveness of the device. Software usually undergoes continual updating and therefore could be subject to a new review, each time the update occurs. This would carry a burden "that would have a chilling effect on the medical software industry." Reichertz, *supra* note 271, at 9. FDA has periodically come up with suggestions to address this dilemma, such as a software quality audit, 61 Fed. Reg. at 36886, or a certification process which would reduce unnecessary paperwork for the agency and the manufacturers, but there is no final solution to this problem.

281. REPORT HIGHWAY TO HEALTH: TRANSFORMING US HEALTHCARE IN THE INFORMATION AGE, COUNCIL ON COMPETITIVENESS, Mar. 14, 1996; LEXIS F-D-C REPORTS, THE GRAY SHEET 22(16); *See also* BNA 4 HCPR 12 d49, (Mar. 18, 1996) (suggesting that the NII, the national information infrastructure, can be "harnessed in conjunction with market forces to address these competing tensions and ease our health care predicament").

282. Many of the devices arriving on the market are entering simultaneously with legislation directing that the services be provided. For instance, beginning Jan. 1998, Medicare started paying for Pap smears, mammograms for women over 40 and in the year 2000, Medicare will be paying for annual prostate-specific antigen tests and digital rectal exams for men over 50. Three days prior to HHS' announcement, a new product signaled its soon entry to the market. The new system is designed to "overcome many of the clinical limitations found when screening for, identifying, and managing the treatment of cervical abnormalities.) It will use state-of-the-art digital technology for cervical visualization and documentation and will include a hand held computer imaging device to be used in cervical screening, a computer that will store patient records and analyze digital images using wireless transmission technology, in short, telemedicine. *See Cooper Companies' Unit to Introduce New System of Products to Assist in the Diagnosis of Cervical Cancer; Innovative Digital Technology that Tracks Disease Progress Simplifies Diagnosis*, BUSINESS WIRE (Dec. 8, 1997) Lexis Nexis News Library. In Wisconsin, a bill is pending which will require HMOs to cover FDA approved

We should learn from history that calamity, as a regulator, does not serve the best interest of the patient. Barely 60 years ago, the fledgling FDA did not have the authority to require new drugs be tested for safety.<sup>283</sup> After a small company in Tennessee exploited a market, within four weeks almost one-third of the patients receiving the new wonder drug elixir sulfamilamide died from diethylene glycol poisoning. The FDA, then, had no power to even seize the drug. Thirty years later, there was still no requirement that new drugs had to be labeled and tested to do what they were supposed to do. There was no FDA requirement at the time to label pharmaceuticals with specific instructions of when the drug should not be taken. Thalidomide, after all, did what it was supposed to do: put its patients to sleep.<sup>284</sup> After this tragedy, in which thalidomide caused over 1,000 birth defects in Europe, congressional hearings focused more attention on the shortcomings of the FD&CA. Congress unanimously passed the 1962 Drug Amendments,<sup>285</sup> requiring that not

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medical devices if the physician so orders. In Alabama, the state passed a mammography coverage bill. A software company has recently received FDA 510(k) clearance for a system which will allow caregivers to view patient information and respond to multiple alarms using a handheld wireless receiver, just as Congress is considering approving telemedicine applications reimbursement policies for the homebound. Data Critical Corporation, a wireless telemedicine and software company received FDA 510(k) clearance for its StarView(TM) System, which allows caregivers to view patient information and respond immediately to multiple alarms by the use of a handheld wireless receiver. BUSINESS WIRE, LEXIS-NEXIS TOPNWS (4-13-98). *See also First US Hospital Adopts FDA-Approved 24-hour Monitor,*" HEALTH DATA NETWORK NEWS (5-20-98).

283. Michael L. Millenson discusses the impact of technology and economics, the future opportunities as well as the previous failures. The issue of "regulation" and the role of the regulators is discussed in Chapter Five. This author has used some of the same examples. *See Millenson, DEMANDING MEDICAL EXCELLENCE, DOCTORS AND ACCOUNTABILITY IN THE INFORMATION AGE.* *See pp.* 103-06 (1997).

284. In the early 1960s, European women using the drug thalidomide gave birth to children who had serious birth defects. Thalidomide, a sleeping pill, caused these defects. Thalidomide was never formally approved in the United States, in part because the discoveries made by foreign scientists as part of the investigational process used by the FDA became available. But thalidomide's manufacturer, Merrell had distributed doses to many physicians who dispensed the drug to over 20,00 patients. *Id.* Merrell "had attempted to convince the FDA that Thalidomide was safe to market in the United States, but FDA suspicion and delay resulted in Merrell being giving only initial limited authorization for investigational use . . ." Marc Rodman, tracing the history reports that while Merrill was awaiting FDA approval, Merrell "engaged in what might charitably be called extremely lax behavior" in distributing 2.5 million Thalidomide pills to 20,000 patients, including 624 pregnant women, leading to at least ten deformed Thalidomide babies. Marc A. Rodwin, *Patient Accountability and Quality of Care: Lessons from Medical Consumerism and the Patients' Rights, Women's Health and Disability Rights Movements*, 20 AM. J. L. AND MED. 147 (1994). A year later, in 1962, the FDA "discovered that Merrell had misrepresented numerous animal studies as demonstrating the complete safety of MER/29, an anti-cholesterol drug, when in fact Merrell knew that most animals exposed to the drug developed cataracts and other side effects." *Id.*

285. Drug Amendments of 1962, Pub. L. No. 87-781, 102(b), 76 Stat. 780, 781 (codified as amended at 21 U.S.C. § 355(b) (1967)).

only must drugs be proven safe, but that, prior to marketing, all new drugs be proven effective for their intended use.<sup>286</sup> After thalidomide, pharmaceutical companies had to list adverse reactions and contraindications, spelling out when a drug such as thalidomide should not be taken as well as when it was safe to take it and by whom. Until 1976, medical devices were not regulated, unless FDA classified the devices first as a drug.

With the market expanding so rapidly, action needs to be taken to protect the best interests of the patient. The FDA is the appropriate body for such regulation. For the most part, the teledevices that are being marketed are in the patients' best interests since the average company usually contemplates sufficient time for appropriate FDA and other governmental approval. In fact, companies and markets are required to submit their plans to the FDA when the company begins to promote or market a product as having, even potential, medical applications. The FDA's good manufacturing practices require that the manufacturer or distributor submit to the FDA a pre-market notification.<sup>287</sup> Therefore, under most circumstances, by the time a product is hitting the market, the tests should not be speculative nor experimental. Absent clear and unequivocal information that a device or software will cause no harm to the patient, that device should be regulated and studied.<sup>288</sup> In addition, the FDA should aggressively regulate any new telemedical technologies. Although there may be much to gain by proceeding quickly to market, there could be more of a risk to the patient being treated at a distance instead of on-site. Where the patient is concerned, empirical evidence is essential to protect patients from risky or dangerous telemedical applications. In all instances, unless there is a serious countervailing social

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286. *Id.* The amendments inserted the words "and whether such drug is effective in use" following "is safe for use."

287. Telemedicine devices are subject to 510(k) evaluation and could be reviewed by CDRM's Division of Cardiovascular, Respiratory, and Neurology Devices, Division of Dental, Infection Control, Infection Control, General Hospital Devices, or the Division of Reproductive, Abdominal, Ear, Nose, and Throat and Radiological Devices. The last division are usually "picture archiving and communications systems," (PACS) which are devices utilized for the communication and storage of images.

288. It is what is occurring in the case of coumadin, a blood thinner given to prevent clotting and reduce the risk of a stroke used to control patients with chronic heart disease. Some have argued that coumadin represents an excellent rationale for home testing, but the quality control reporting and the several hours of testing of the patient make it difficult to use. Since there is no reimbursement for home use of physician office testing through teledevices, the use has not taken off notwithstanding the fact that it is being used in Germany by the patients who report into their doctors. Additionally, the device that could potentially perform this test costs \$1300 and the strips sell for \$6.00 each. The instrument costs \$2,000. Until the risks of patient self-monitoring for anti-coagulation are thoroughly tested, its use will not be approved.

reason to move forward with doubt, the needs of the patient, distanced from his physician, must be paramount.

*C. Regulating Access Excess: Protecting The Patient's Privacy, Confidentiality and Security Interests*

1. Privacy, Confidentiality and Telemedicine

Who is entitled to patient information, who must provide releases for that information, and who should have access to the information? In most respects all of these questions, and the attendant issues of privacy and confidentiality, are not unique to telemedicine. Telemedicine augments privacy concerns, however, because it promises to make common the transmission and storage of personal information. In the traditional patient-physician relationship, privacy and confidentiality were always an issue, but with telemedicine, the patient's records and medical history will be shared with the consulting physician, with two sets of staffs and possible technicians supporting the telemedicine system.<sup>289</sup> Although current mechanisms could be sufficient to hold every physician and medical provider accountable,<sup>290</sup> the traditional concepts of privacy and confidentiality are dramatically changed with telemedicine.

In the health care context, privacy has been protected by an ethical obligation of the health care provider to preserve the confidentiality of medical information, and as a legal right to privacy from the unwarranted use of personal-health information. Confidentiality "refers to a relationship (e.g. between patient and physician) that includes an expectation that personal information obtained as part of that relationship will be protected."<sup>291</sup> Both Reed Hundt, the former chairman of the

289. The Hippocratic Oath, states, "Whatever, in connection with my professional practice, or not in connection with it, I see or hear in the life of men, which ought not to be spoken abroad, I will not divulge, as reckoning that all such should be kept secret." The American Medical Association's Principles of Medical Ethics state: "Confidentiality. The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest degree . . . . The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law." *American Medical Ass'n., Current Opinions of the Judicial Council of the American Medical Association* (1984).

290. The potential for using information in a positive way is as great as the potential for using the information in a negative manner. But the issue is control: which controls need to be in place to restrict access to information and whether the current law offers adequate protection.

291. Privacy, confidentiality and security are almost used interchangeably in the telemedicine literature. In this article, privacy is used in the ethical and legal sense, what historically has bound physicians, with or without the constraints of a legal system, to preserve the privacy of their patient's health matters. Security and integrity will be used in the context of a system that will meet the standard for protecting the confidentiality of the records

Federal Communications Commission and Donna Shalala, the agency head of the Department of Health and Human Services, have openly criticized the lack of security and information standards relating to telemedicine, telemedicine systems, telemedicine information and the lack of systems to provide confidentiality and security safeguards in the use of telemedicine or telehealth technology and services.<sup>292</sup> Without appropriate privacy protections, telemedicine cannot be established as a viable treatment alternative.

A number of different confidentiality issues may arise as a result of telemedicine. There may be an improper disclosure, there may be either unauthorized access or an abuse of the information accessed, there may be identification of patients within the data aggregated, or there may be the problem of data integrity and authenticity.<sup>293</sup> Liability could arise in a number of different situations given the nature of the different types of breaches. Concerns exist relating to the ready accessibility to electronic patient information, the conveyance of video images, the presence of

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and assuring that information and programs are "changed only in a specified and authorized manner, that computer resources operate correctly, and that the data in them are not subject to unauthorized changes.: "Security" will refer to the manner in which the provider or gatekeeper of the information provides a system to secure the information to achieve the goal of confidentiality. Joseph N. Gitlin, *Teledradiology*, in *TELEMEDICINE: THEORY AND PRACTICE* (1997) at 167. It has been argued that "security in multi-user and distributed computer systems is difficult to achieve. Those who claim a right of access to health data are more numerous than ever, and include providers, insurers, employers, managed care providers, public agencies and the research community. "It is not clear whether confidentiality obligations of health care professionals need be met by companies providing telemedical support, but plaintiffs might so argue." Joseph McMenamin, *Telemedicine: Technology and the Law*, FOR THE DEFENSE (July 1997) at 10.

292. Prior to the passage of the Balanced Budget Amendment, which contained provisions which addressed tangentially, but did not address or define specifically, confidentiality and security issues, both Hundt and Shalala spoke out at a conference calling for telemedicine standards and protections. Interestingly, neither spoke to the issue of what the standards should be, where they should be set, by whom, in what forum, with the imprimatur of any body, but just that "industry" should be setting some standards. It was suggested that the aim is not to "suggest any particular set of standards, but to identify needs and encourage the organizations represented here to work toward the creation and adoption of . . . standards." John Breeden II, Agency heads call for telemedicine standards and protections; Government Computer News, Vol. 26, Vol. 16, p. 15 (Sept. 1, 1997).

Clearly, the quilt of state laws makes its point in the hodgepodge of laws addressing patient confidentiality and privacy. "The way we protect the privacy of our medical records is very erratic," she [Shalala] said. "And it's dangerous." *Id.* Shalala said people are already starting to abuse the fledgling telemedicine networks springing up in government and industry. She spoke about people who misuse telemedicine networks for pleasure or profit. For instance, a medical student was caught tapping into patient records to tip off malpractice attorneys, she said. And bored employees at a psychiatric clinic had acknowledged that they routinely read therapy session notes." She said such blatant abuses were evidence that security is lacking. Medical records are being managed "with fewer federal safeguards than video store records. . . ." *Id.*

293. See McMenamin, *Telemedicine: Technology and the Law*, *supra* note 291, at 10.

additional persons, the possible loss of control over the route of medical information, the integrity of electronic record keeping, and the potential for unauthorized access and disclosure of records. In many instances, leaked information on medical information could cause the loss of a job, the loss of reputation, and, potentially, the loss of health-insurance availability.

Traditionally, and with few exceptions, the issues of privacy and confidentiality, especially relating to the physician-patient relationship, are matters the federal government left to the states. Issues of patient consent, provider confidentiality, and overall security of telemedicine information encompass not only medical histories and records, but image transfers, electronic information stored in the computer, and the security of the data stored.

Unlike many other countries, the U.S. has the barest threads of common law and no encompassing federal statute, nor any visible, or feasible mechanism to address the complicated issues raised by the burgeoning area of telemedicine and telehealth.<sup>294</sup> The issue hasn't been addressed for lack of notice, or lack of debate, but rather more of a paralysis of what should be done and who should be in charge.<sup>295</sup> Debates rage over whether federal regulation of telemedical privacy is appropriate, whether an optional uniform model statute would work, and whether privacy is further threatened by the potential implications of international telemedical practice.<sup>296</sup> Whether in the name of federalism or states' rights, virtually no consensus has been reached on what should be done.<sup>297</sup> Most state laws do not address issues of privacy and confidentiality of medical records within a single statute, but rather states affirm a right to privacy and confidentiality through a web of statutes, regulations and policies. In many states, as in a web, there are gaps and sometimes overlapping laws.<sup>298</sup>

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294. Although the international use of telemedicine is beyond the scope of this paper, there are clearly international implications of telemedical practice and there are obligations of those who are responsible for data processing. There are also a number of rights for individuals. *Id.* B. Stanberry, *The Legal and Ethical Aspects of Telemedicine. 2: Data Protection, Security and European Law*, *JOURNAL OF TELEMEDICINE & TELE CARE* 4(1): 18-24 (1998).

295. See Robert M. Gellman, *Symposium: Article: Can Privacy be Regulated Effectively on a National Level?* (noting the mess the lack of uniform legislation has on health records). *Id.* at 135.

296. The comparison to what other, even less sophisticated countries are doing in this regard, is an important issue, and one not to be taken lightly. However, this issue needs to be addressed literally bit by bit, and some consensus needs to be addressed within the U.S. before we jump to a solution which will bind us internationally as well. This is not to concede that the matter should be drawn out, only to concede that it must be taken in logical fashion.

297. Gellman, *supra* note 295, at 139.

298. It is beyond the scope of this article to examine each state's laws in this area, but it should be noted that the area is, at best, complex.

Other substantive areas, in what would on their face appear to be of less concern in life's value chain, have had more success in addressing privacy and confidentiality provisions, e. g. video copying<sup>299</sup> and credit reporting.<sup>300</sup> Congress has passed a number of laws which protect our financial privacy interests.<sup>301</sup> To date, no one has successfully led a charge to garner consensus on a national level to enact one uniform federal law that would comprehensively address privacy issues relating to our health.<sup>302</sup> Interestingly, we have a right to inspect, our financial history,<sup>303</sup> but there is neither a right nor an obligation to a health information, records or history.<sup>304</sup>

## 2. Federal Protections

Unlike many other countries,<sup>305</sup> the United States has no national law that protects data. The current law, enacted well over 20 years ago, applies to information that is in the possession of the government.<sup>306</sup> Under the Health Insurance Portability and Accountability Act of 1996

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299. Video Privacy Protection Act of 1998, 18 U.S.C. § 2710 (1994).

300. Fair Credit Reporting Act of 1970, 15 U.S.C. § 1681 (1994).

301. Right to Financial Privacy Act of 1978, 12 U.S.C. §§ 3401–3422 (1994); Fair Credit Reporting Act of 1970, 15 U.S.C. § 1681 (1994).

302. With all of the concerns Americans express regarding their constitutional rights, and specifically the right to privacy, it is ironic that the one area that is not protected, on a federal level, is the privacy of our health information. See generally Bartley L. Barefoot, *Enacting a Health Information Confidentiality Law: Can Congress Beat the Deadline?* 77 N.C.L. Rev. 283 (Nov. 1998).

303. Fair Credit Reporting Act, 15 U.S.C. §§ 1681–1681t (1984). We also have a right to privacy of cable television subscriber information, Cable Communications Policy Act of 1984, 47 U.S.C. § 551 (1994).

304. Daniel Mendelson and Eileen Miller Salinsky offer perspectives why information, which plays such an important part in performance measurement and quality settings, has moved more slowly than other industries in the “electronic market,” and see privacy concerns as a major block. “Concerns about privacy, however, have become a major impediment to developing the king of comparative value information envisioned by virtually all of the health care reform plans of the early 1990s.” See Daniel N. Mendelson & Eileen Miller Salinsky, *Health Information Systems and the Role of State Government: A taxonomy and evaluation of State Government Efforts on the Health Information Frontier*, HEALTH AFFAIRS (May–June 1997). See generally Robert M. Gellman, *Can Privacy Be Regulated Effectively on a National Level? Thoughts on the Possible Need for International Privacy Rules*, 41 VILL. L. REV. 129, 136 (1996).

305. European Union members have agreed to a common scheme to protect the privacy of personal data. Directive 95/46/EC of the European Parliament and of the Council of Oct. 24, 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, Art. 32, 1995 O.J. (L281) 31.

306. The Privacy Act of 1994, 5 U.S.C. § 552a (1994) prohibits federal agencies, including federal hospitals, from disclosing information in its system of records without obtaining the consent of the person “to whom the record pertains.” 5 U.S.C.A. Sec. 502a(b). *Id.*



(HIPAA), some relief in this arena is promised.<sup>307</sup> HIPAA "requires that any health plan, health care clearinghouse or health care provider who transmits health information in electronic form must maintain reasonable and appropriate administrative, technical and physical safeguards to ensure the integrity and confidentiality of information, protect against any reasonably anticipated threats to the security of information, and prevent unauthorized use or disclosure of information."<sup>308</sup> If Congress fails to act, then the Clinton Administration's recommended standards, which cover both privacy and protection of individually identifiable health information, will go into effect.<sup>309</sup> HIPAA will also require the Secretary of the Department of Health and Human Services to promulgate rules regarding the electronic transfer of medical information, and it is anticipated that those rules would include the use of "unique identifiers and electronic signatures."<sup>310</sup> Until July, 1998, development of the system by the Department of HHS to create such a "unique health identifier" was making little headway, but when public hearings began to solicit comments on the proposed health care codes, the issue evoked mixed reactions, stirring contentious arguments from almost every front. Like salt on an old wound, the patient ID proposal's debate woke every health care sleeping giant from a summer's sleep. The standards will include security to protect health information. H.R. 4250 considered but rejected a delay in the program to give every citizen a computer identification number to track health care from cradle to grave.<sup>311</sup> The hearings on the national medical identifier raised privacy implications to the surface, re-erupting the debate and bringing to the forefront the privacy debate in

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307. 42 U.S.C.A. §§ 1320d to 1320d8 (1998) (hereinafter "HIPAA") is also referred to as the Administrative Simplification Provisions of P.L. 104-191(1996), and is commonly called "Kassenbaum-Kennedy" in reference to the two senators associated with this legislation. For a detailed discussion of the Administrative Simplification provisions of HIPAA.

308. See generally Office of Tech. Assessment, *Protecting Privacy in Computerized Medical Information* (1993); Barry B. Cepelewicz, *Malpractice Over the Phone?* The Connecticut Law Tribune (Sept. 15, 1997); Paul M. Schwartz, *The Protection of Privacy in Health care Reform*, 49 VAN. L. REV. 295 (1995).

309. 42 U.S.C.A. § 1320d-2 (1998); Historical and Statutory Notes, citing 264(c)(1), P.L. 104-191.

310. 42 U.S.C.A. §§ 1320d-2(a), (b) (1998). The provisions of the Act requiring the Secretary to set forth security standards are found at 42 U.S.C.A. § 1320-2(d)(1). Interestingly, the insurance risk industry has wondered "if such rules will block their ability to gather facts and assess risks." David M. Katz, *Health-Privacy Issue Hits Risk Managers; Healthcare Industry Risk Managers Struggle with Issue of Privacy for Medical Records*, NATIONAL UNDERWRITER LIFE & HEALTH-FINANCIAL SERVICES, ED. NO. 44, VOL. 101 (Nov. 3, 1997) at 45.

311. On Capital Hill, patient privacy is already a hot topic with six bills on the issue circulating in Congress. Provisions being debated include those that would allow patients to exempt themselves from the system and the age-old question of whether "federal privacy legislation should override stricter state laws."

general and, specifically, the impact of the medical-computerized world on the telemedical patient.<sup>312</sup> The national identifier, like telemedicine, is the center of the maelstrom but certainly just an symptom of the complex overall problem.<sup>313</sup>

Under HIPAA, the Secretary of HHS is also required to adopt standards for certain transactions to enable health information to be exchanged electronically.<sup>314</sup> The National Committee on Vital and Health Statistics (NCVHS)<sup>315</sup> is complying with the law, and addressing issues, barriers, and challenges that face the health care issues, including questions regarding security issues in the implementation. The law requires that, within 24 months of adoption, all health plans, health care clearinghouses, and health care providers who choose to conduct transactions electronically must comply with the standards.<sup>316</sup>

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312. Lest there be any doubt, the taskforce's charge is to determine what kind of identifier will be adopted, and not whether there will be a unique health care identifier. *Id.* HC Policy Report, 7/27/98: "The identifier would streamline administrative costs and ease the electronic transfer of records, as well as establishing a national database that would help research." Many privacy advocates strongly disagreed with these provisions calling the provisions a threat to privacy. For instance, physicians, and especially psychiatrists, have opposed the Secretary setting standards for each individual expressing their concerns that the computerized access will make confidential health information subject to abuse. *See Health Data: Implementation of Unique Patient Identifier May be Cause for Concern About Abuse*, HCD Rep. (July 24, 1998).

313. On July 31, 1998, Vice President Gore announced a delay in implementing the unique patient identifier until Congress passes comprehensive privacy legislation. Gore said that although Congress is charged with creating privacy protection, the administration does not intend to wait for them to do the job alone. "No matter how technology grows and changes, your fundamental right to privacy will never change." *See Patient Identifier: Vice President Gore Announces Delay of Unique Patient Health Identifiers*, 7 BHLR 1259 (August 6, 1998). Despite the concerns raised, HHS plans to issue a notice of intent to appear in the federal register addressing these issues. *Health Data: Implementation of Unique Patient Identifier May Be Delayed Due to Concern About Abuse*, 7 HEALTH CARE POLICY (July 30, 1998), WL Database, BNA-HLR. It should be noted that the Senate Republican Patient's Bill of Rights (S. 2230) contains provisions extending the HIPAA deadline for implementation of the unique patient identifier.

314. 42 U.S.C.A. §§ 1320d-2(a), (b) (1998).

315. *Id.* Although the legislation did not specify which standards should be adopted by the Secretary of HHS, the task of providing recommendations to the Secretary was assigned to the NCVHS. The committee held hearings throughout 1997 and submitted a report recommending, *inter alia*, a proposal for a National Provider Identifier but stated in its Sept. 1997 report that it would be unwise to select and implement a unique health identifier for individuals without legislation that insured the confidentiality of patient data.

316. Specifically, HIPAA mandates that in any HIPAA related transaction, any health-care provider or health plan which transmits health information in electronic form maintain safeguards to (1)protect the confidentiality of the information, (2)protect against anticipated threats or hazards to the security of integrity of the information and (3)prevent unauthorized use or disclosure of the information. Interestingly, however, the law did not set any deadlines for standards for clinical information and this omission could slow telemedicine and other applications down considerably.

Today, the only other laws protecting patient privacy and confidentiality in the health care arena that could apply include the Privacy Act of 1974<sup>317</sup> and some federal laws which protect the identities and records of patients who seek treatment for drug and alcohol abuse.<sup>318</sup> The Privacy Act merely provides that federal departments and agencies that obtain confidential information from private individuals may use that information only for the purpose for which it was collected.<sup>319</sup> Thus, an immediate concern is simply that the federal government is not the exclusive user of telemedicine, and any information gained through private action will not be protected under the Privacy Act. The Privacy Act does restrict the federal government's ability to disclose private medical information, but most individuals do not submit their personal medical records to a federal governmental agency.<sup>320</sup> The Privacy Act does extend to health care facilities under federal operation and to medical record systems under contract with the federal government, but this leaves private entities and the private health care industry outside the Privacy Act umbrella. With the recent legislation and recognizing privacy concerns, HCFA has become sensitive to its own use of health information and has recently required that Region II HMOs and CMP, cease using the Internet to transmit or store any protected information. HCFA policy states that "acceptable encryption mechanisms are not currently available for the Internet to insure the degree of privacy, HCFA, plans, and contractors are required to maintain."<sup>321</sup>

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317. 5 U.S.C. § 522a(b).

318. 42 U.S.C. §§ 290dd-2, 290ee-2.

319. See *Telehealth & Telemedicine, Taking Distance Out of Caring*, CALIFORNIA TELEHEALTH/TELEMEDICINE COORDINATION PROJECT, Jan., 1997 at 61.

320. Neither a state nor a hospital which receives federal money is obligated under the Act.

321. In a recent article in *Telemedicine Today*, the author addresses this "new" HCFA policy which prohibits the transmission of "individually identifiable information" over the Internet or "any internal environment which is not secured from external users." The policy originated as a result of the memo sent by Ms. Gail Weinreb, Director of the Health Plans Branch of HCFA Region 2 in New York; HCFA has indicated that the memo does, in fact, represent national policy. T. Wheeler, *HCFA vs. The Internet: What Can They Be Thinking?* *TELEMEDICINE TODAY* 6(3): 18 (June 1998). On December 7, 1998 HCFA published its policy outlining data sharing conditions for HCFA, Medicare and Medicaid partners, and other parties allowed to use Privacy Act-protected information. The guidelines cover any transmission systems that utilize the Internet, and any transmissions that take place over those systems. Moreover, the guidelines cover any transmission systems that utilize the Internet and any transmissions that take place over those systems. The methods which are acceptable for protecting information transmitted over the Internet include allowing access only to authorized parties through authentication or identification and encryption of the information. 154 HCDR (August 11, 1998) at 2.

The above legislation and agency focus on health-information security is breathing life into an almost dead hope for federal privacy laws addressing the use and protection of health information.<sup>322</sup> On September 11, 1997, HHS released medical-record confidentiality recommendations to Congress. HHS urged Congress to treat parties that obtain health care information "under false pretenses" or that engage in "knowing and unlawful use or disclosure of health information" as felons. The proposal would make anyone who violates the statute face fines or imprisonment.<sup>323</sup> In addition, penalties would be "higher" in cases where the violations are "for profit or monetary gain." Civil monetary penalties could be levied against providers or plans that violated any part of the statute. Under this proposal, providers would not be permitted to condition treatment on a patient's giving consent for disclosure of health records, "unless the disclosure is necessary for a health care or payment purpose." Moreover, the plans would be prohibited from conditioning payments on consent to disclosure. The legislation would allow providers and or plans to disclose health information without patient authorization only in limited emergency health situations or when the public health was at stake.

A flurry of bills was introduced in the past few years addressing health information and privacy. H.R. 52, the Fair Health Information Practices Act of 1997 ("FHIPA") and S.B. 346, the Patient Protection

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322. The recent discussion of bringing a more unified approach to health-related issues under federal protection is a culmination of years of failed efforts to achieve a comprehensive legal scheme in a very critical area. The combination of the power of the Internet and the mass of health information available has made Americans more sensitive than ever to the dearth of laws that provide protection for any breaches of their assumed privacy. It is well beyond the scope of this article to track the history of the interplay between the state and federal governments, especially in the wake of the Clinton Presidency and the killing of many federal programs in favor of the strong muscling by the states to revitalize themselves into the laboratories of democracy. But where privacy and confidentiality issues are concerned, the states may be at a loss in regulating the electronic, informational highway that runs across their borders. Powers not specifically assigned to Washington are indeed reserved to the states (U.S. Constitution, Tenth Amendment), but even the states will need some help from the federal Government in addressing issues that can only be resolved by an interplay, at a minimum, between the federal and state governments, not to even mention the difficult job of addressing domestic and international issues. For this reason, the issues of privacy and confidentiality, medical records, whether paper or electronic, must be addressed on a national scale. There is too much at stake where the patient is concerned, even if the states may be more flexible in addressing the mechanics of health care for their constituents. See Garry Wills, *The War Between the States. . .and Washington*, THE NEW YORK TIMES MAGAZINE SEC. (July 5, 1998) (Magazine Sec. p.28). Note that until early in 1998, most of the privacy legislation suggested addressed the medical records law area.

323. The fact that the information is private is, in part, a misnomer, since under the Secretary's proposal, certain governmental authorities, both federal and state, would have access to the patient's information.

Act ("PPA") suggest further protection of health information and confidentiality of patients' records. H.R. 52 would permit the use of health information by a health trustee if the purpose is compatible with and directly related to the purpose for which the information was collected or received by the trustee or unless the trustee received disclosure authorization.<sup>324</sup> Other bills that simmered in Congress include the Medical Privacy in the Age of New Technology Act,<sup>325</sup> the Federal Privacy of Medical Information Act,<sup>326</sup> the Medical Records Confidentiality Act,<sup>327</sup> all suggesting various improvements in this area, but none successful in securing passage to date. These bills would mandate patient authorization for disclosure of information for the purposes of medical treatment or payment, permit patients to obtain, copy and correct their medical records, provide civil and criminal penalties for any unauthorized disclosure of patient records and require that records be kept of patient data that had been disclosed. Furthermore, the bills permit the states to set stricter privacy rules and permit patients to designate some information as specifically protected. During the summer of 1998 discussion on the issues of patient rights, patient confidentiality, medical-records confidentiality, unique patient identifiers, managed-care confidentiality, confidentiality of electronic records, reached a crescendo.<sup>328</sup> Interestingly, for the first time in U.S. history, there may not be a consensus on what should be in such a uniform federal policy, but there are more overlapping suggestions than ever before.<sup>329</sup> In fact, the proposals suggesting that we have a uniform federal law also proposed that, for the

324. FHIPA makes exceptions for (1) next of kin and directory information, (2) public health, (3) health research, (4) emergencies, (5) judicial and administrative purposes, (6) law enforcement and (7) subpoenas, warrants, and search warrants.

325. S. 1360, 104th Cong., 1st Sess (1995).

326. H.R. 3482, 104th Cong. 2d Sess (1996) *Id.* 9 UNIFORM LAWS ANN 479-529 (1988) and *Bringing Health care On-line*, *supra* note at 113-114.

327. H.R. 5935, 96th Cong. 1st Sess (1979). *See also*, *Leads to Increasing Use of Computerized Recordkeeping Legislative Proposals for Medical Privacy*, 276 JAMA 270 (1996).

328. *Health Data: Implementation of Unique Patient Identifier May Be Delayed Due to Concern About Abuse*, 7 BHLR 1201 (July 30, 1998).

329. Barefoot notes that the "basic building blocks of a federal health confidentiality law are not in dispute and cites to a 1973 report by the then U.S. Department of Health, Education, and Welfare recommending five 'fair information' principles that should form the basis of confidentiality guidelines for any kind of data: (1) no data system should be maintained in secret; (2) individuals should have means of determining what information is head about them and how it is used; (3) individuals should have means to amend incorrect information concerning themselves; (4) personal information should not be used for purposed other than those for which it was collected without the consent of the subject of the information; and (5) organizations that create, maintain, or disclose identifiable information must assure its reliability and take reasonable precautions to prevent its misuse." Barefoot, *supra* note 302, at 306, citing Secretary's Advisory Comm. on Automated Personal Data Sys. U.S. Dep't of Health, Educ., and Welfare, *Records, Computers, and Rights of Citizens* 41 (1971).

first time, federal law would preempt any state law that had not adopted a similar baseline for protection of public-health data.<sup>330</sup> In other words, there would be a federal law establishing a floor or minimum legal standards.<sup>331</sup> Those state laws that provided more stringent requirements than the federal “minimum” standards would be exempt from the federal confidentiality proposals.<sup>332</sup> Although no proposal has been legislated to date, states that afforded protection to their constituents equal or greater to a proposed uniform minimum standard would be free to legislate in this area. This freedom provides latitude for the states to enact more protective legislation, and to experiment in meeting the needs of their specific issues.

### 3. State laws

Various state laws offer an idiosyncratic hodgepodge of protection but no uniformity in content or protection for the confidentiality and privacy of health records. With few exceptions,<sup>333</sup> state laws are generally inadequate to provide protection. A number of states have enacted laws or regulations to protect individuals against the unauthorized disclosure of their private medical records by either physicians, health care professionals or other third parties.<sup>334</sup> These laws address concerns relating to the dissemination of the record, recordkeeping, accidental release, third party review, tampering and/or destruction of records and lack of any deterrence mechanisms.<sup>335</sup> Some states, such as California, have taken action to address health care providers that “utilize electronic record keeping systems only.”<sup>336</sup> The California Confidentiality Act provides a

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330. The NCVHS had suggested to HHS that the preemption question was the “most difficult conflict” in the national health arena. NCVHS Recommendations, *supra* at 16.

331. S. 1921, 105th Cong. 401(a)–(c) (1998); S. 1368, 105th Cong. 401(a) (1997); H.R. 1815, 105th Cong. 402(a) (1997).

332. S. 1368 401(a); H.R. 1815 402(a); S. 1360, 104th Cong. 401(a), (c)(1), (c)(3) (1995).

333. California has enacted comprehensive legislation protecting patient’s privacy and confidentiality of medical records.

334. Certainly, professional organizations have a code of professional standards that prohibit the unauthorized disclosure of medical records as an ethical matter. With the explosion of health care information as well as the dissemination via “tele” mechanics, the use of paper and pen is not the only area needing protection. As has been pointed out by a number of writers, and what is almost common sense to a child, once the information is shared via electronic means, other third parties, not bound by an ethical code, will have access to information and the ability, without legal restriction, to disclose that information.

335. TELEHEALTH & TELEMEDICINE, *supra* note 8, at 60.

336. Cal. Health & Saf. Code § 123149(a). The standard makes the same rules available to electronic record keeping as to the extent of hard copy records. “Any use of electronic record keeping to store patient records shall ensure the safety and integrity of those records at least to the extent of hard copy records.” Cal. Health & Saf. Code § 123149(b).

cause of action to any patient for improper disclosure of their medical record. In addition, California has enacted confidentiality protections for any patient information that is stored electronically as part of a telemedicine consultation or diagnosis.<sup>337</sup> Most states have legislation that addresses the use and dissemination of medical records, and many states do address confidentiality of specific class of medical information, including certain records relating to HIV status, drug and or alcohol abuse, minors' medical records, or mental health records.<sup>338</sup> But if a state telemedicine practitioner, covered by state confidentiality provisions, collaborates with out-of-state practitioners, the privacy laws of another state may apply and that other state's laws may only offer different and perhaps even minimal privacy protection.<sup>339</sup> Choice-of-law questions, although not unique to medical suits, become even more complicated in the telemedical situation. The complexity of all of these issues without the introduction of the telemedical patient is mind boggling. Adding other layers of legal issues, including the problems of what state law would apply, the law where the patient resides, the practitioner resides, the breach arose, makes for a classic moot-court problem but one which would be a nightmare for the unwary telemedical patient whose privacy had been breached. Telemedicine interjects the real-life fact pattern with which we all will soon live with: the patchwork of state confidentiality laws is "a legal, political and practical mess."<sup>340</sup> The availability of telemedical assistance does not solve the problem but do bring compelling reasons to move to a uniform federal system that will offer a "floor" of minimum protection for every American.

#### 4. Professional Codes of Ethics and Private Positions

Anticipating a problem with the ambiguity in the law regarding medical records maintained by computer, the American Medical Association's Council on Ethical and Judicial Affairs formulated standards

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337. The Telemedicine Development Act of 1996 modified the California law to address any patient information which is stored electronically as a part of a telemedicine consultation or diagnosis. "(a) It is the intent of the Legislature that all medical information transmitted during the delivery of health care via telemedicine become part of the patient's medical record maintained by the licensed health provider." Cal. Health & Saf. Code 123149.5. California addressed the problem of brokering health care information by enacting strict laws which regulate the extent of disclosure may be made to third parties. California's Confidentiality Act provides also for strict penalties and permits a patient to recover up to \$3,000 in compensatory damages, \$1,000 in attorneys' fees and the costs of litigation for a violation of the Act. *Id.*

338. *Id.* TELEMEDICINE, *supra* note 8, at 25, citing statutes.

339. Since there is no uniform federal law safeguarding the privacy of health records, the person aggrieved would not only have to look for protection on a number of forums, but would also have to depend on the various state protections provided through the common law.

340. Gellman, *supra* note 295, at 137.

for addressing the confidentiality of medical records that are maintained by computer. The AMA's Regulation 5.07 requires that the "utmost care and effort must be taken to protect the confidentiality of all medical records, including computerized records."<sup>341</sup> Nine guidelines were developed to assure physicians take the utmost care in maintaining their patient's confidentiality. These guidelines, ranging from authorization to make additions, to access to the records, would apply to any telemedicine application. Obviously, they are guidelines by a professional organization, and although arguably imposing an ethical duty, neither have the force and effect of law, nor do they cover those outside of the physician and medical-service organizations. The AMA opposes any kind of unique patient identifier "unless it can be proven that they are absolutely necessary."<sup>342</sup> Strong opposition to patient identifiers is grounded in the AMA's belief that the potential for abuse is enormous. The AMA has argued that before any such identifier system is put in place, stronger privacy protection must be in place.<sup>343</sup> The AMA and other public-health advocates are also concerned that having a federal law that preempted state laws would prohibit the states from enacting more stringent privacy legislation.<sup>344</sup>

## 5. Proposals

The issue of confidentiality of medical records, while not in dispute in a theoretical sense, is far from resolved in a practical sense. There is still no consensus concerning the issue of medical records' confidentiality and privacy.<sup>345</sup> Other areas of debate include, who is responsible, what should be protected, and how the confidentiality should be protected. Various positions have been espoused ranging from a strong sentiment that federal legislation is warranted and needed, that federal

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341. AMA, Council on Ethical and Judicial Affairs, Regulation 5.07.

342. *Id.*

343. Donald J. Palmisano, a member of the American Medical Association's Board of Trustees, is quoted that the AMA supports the work of Paul Calyton, of the National Research Council, who found that information within a person's medical record can be used to identify them without a separate unique identifier being established. Palmisano is quoted as saying that "A unique identifier makes it too easy for those who don't have access to the record to break in." 7 BHLR 1201.

344. *See* Medical Records Confidentiality Act of 1995, Hearings on S. 1360 Before the Senate Comm. on Labor and Human Resources, 104th Cong. 107 (1985) at 163–64 (American Psychiatric Association); *Id.* at 87–88 (American Psychological Association).

345. This statement does not apply to California where confidentiality and privacy are very much an issue. S.B. 922 addresses the transfer of medical data and telephone conversations between health care physicians and patients. Additionally, existing laws addressing patient access to medical information and copies of medical records, confidentiality of records will apply to telemedicine patients.



legislation would be desirable but is not feasible, that a uniform model act would be appropriate, and that this is a matter of state interest.<sup>346</sup> Simply, no united movement, representing the interests of the patient, exists. For the time being, patients must live with the status quo—each individual must rely on the ethics of the health care practitioner.

We are a country that takes pride on our information capabilities, and the protection of our citizen's rights, but the laws protecting the confidentiality of patients' medical records fall short of providing adequate coverage.<sup>347</sup> Federal laws and proposals, while proliferating, do not today fill in the cracks of the current melange of state laws addressing what is and what is not protected. This lack of coverage and uniformity in what coverage does exist offers patients, and especially telemedicine patients only "patchwork" protection—hit or miss "confidentiality" coverage—carries potentially a high price tag, with the patient carrying the burden that such protection is there. In response to the variety of state laws, the National Conference of Commissioners on Uniform State Laws proposed the Uniform Health Care Information Act. This Act would require health care providers to implement reasonable safeguards to ensure the security of all health care information, requires providers to notify patients that records are maintained and the patients may access their records, permits authorized representatives or parental guardians of the patient to have these rights, and permits disclosure if and only if the patient authorizes such disclosure, except under narrow exceptions.<sup>348</sup>

Protection of confidentiality and privacy in the telemedical context requires both technical and legal solutions.<sup>349</sup> Technical options could include universal identifiers, authentication, authorization procedures,

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346. In favor of federal legislation: California Telehealth/Telecoordination Project ("The most obvious solution is federal legislation to establish uniform national standards" that would establish uniform minimum standards of protection for medical records and telemedicine . . . e.g. the Fair Information Practices Act of 1994 and the Medical Records Confidentiality Act of 1995 (S. 1360) at 66). "The establishment and the effective preservation of key values is an absolute necessity if we want to improve our daily lives without paying too great a social cost for the development of a networked society." *Id.*

347. Mendelson and Salinsky, *supra* note 304, make a compelling argument that in the age of information, we have failed to use out technology so that consumers can compare and assess cost and quality of health care. "Some advocates of civil liberties contend that patients have a right to control any use of their medical records and that medical organizations should be required to secure consent each time they seek to use individual records."

348. Two states, Montana and Washington, have enacted this Act and other states are currently studying its provisions. *Id.* SP600 (Maine); H.B. 1498 (Massachusetts); HB 490 (New Hampshire); A.B. 1727 (New Jersey); A.B. 5217 (New York); H.B. 224 (Pennsylvania).

349. TELEHEALTH & TELEMEDICINE, *supra* note 8, at 61.

audit logs, firewalls and cryptography.<sup>350</sup> These options are attractive regardless of the legal framework chosen—whether federal preemptive law, individual state law or some combination of the two. Clearly, the issue of medical confidentiality is far broader than telemedicine but the patient's ability to employ telemedicine without sacrificing privacy of medical records and treatment depends on laws that will not only advance telemedicine but provide protection to the patient. Today, that protection does not exist. There still is no uniform national standard that protects the confidentiality of health information. Only 28 states allow patients access to their health information but even these statutes are not uniform in their approaches. There is a lack of what information is protected, what is "confidential," who is protected, what information is covered, and most statutes fail to address penalties for unauthorized disclosure of health information.<sup>351</sup> In the best of all worlds, legislation that would offer protection to any patient, including the telemedical patient, is far preferable than legislation targeted to the telemedical patient alone. But the debate must begin to offer solutions aimed at protecting the patient first. Congress should unequivocally establish patient protections establishing that the patient has a right to know what data is being used and entered into the telemedicine system; the patient has a right to know who is entering the data, the patient has a right to review the individual records for accuracy and that there is in place a national law establishing civil and criminal penalties for anyone who wrongfully releases confidential information or obtains data from individual medical records.

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350. Institute of Medicine, *supra* note 13. Security measures include: data encryption techniques that encode information so that it is not easily read without a code/book or decryption key; authentication procedure to ensure that messages are received from the stated source exactly as they were sent; authorization procedures that determine whether a user is permitted access to particular information; auditing and tracking programs that provide information about those who have gained access to a system; and so-called 'firewalls' that encompass a range of access control mechanisms that either block or permit access to one network from another." *Id.* at 197.

351. In 1994, the Institute of Medicine released a report, *Health Data in the Information Age: Use, Disclosure and Privacy*, recommending that federal preemptive legislative be enacted to establish uniform requirements for the preservation of confidentiality and protection of privacy rights for health data concerning individuals. In the Office of Technology Assessment (OTA) report, *Bringing Health care Online: The Role of Information Technologies*, the issues of privacy and confidentiality were identified as critically important areas in addressing health information. The report recommended that Congress establish federal legislation and regulations for privacy and confidentiality of medical information and for storage and transmission of medical information.

## V. REGULATING COSTS: WHAT SERVICE AT WHAT PRICE?

Telemedicine is no longer just a playground for dreamers, enthusiasts and pilot programs. It has become a strategic tool for hard-eyed hospital administrators and entrepreneurial practitioners, whose first questions are: Does it make sense economically? Does it improve efficiency enough to justify its cost? Will it help the bottom line?<sup>352</sup>

As of the year 2000, the United States has spent as much as 1.5 trillion dollars on health care costs, with as much as \$15 billion dollars on health care "systems."<sup>353</sup> Part of the problem in initiating any new system, practice or technology is money.<sup>354</sup> Telemedicine is no longer for dreamers, but the question remains whether it will reduce health care costs. Will it fulfill its promise of improving the quality of care, augmenting access to care and can it be both economically feasible and cost effective? The issue of paying for telemedicine is a complex and critical issue. Clearly, changes in our health care delivery system and in our demographics signal a strong future for telemedicine. The search for solutions, including managed care, where the focus is on cost containment, continues. With an aging population, there will be more patients, more home health care and nursing-care needs, and as medical science continues to prolong life and cure disease, there will be more chronic medical conditions needing treatment. Toward this end, there are policy questions concerning who should pay and for what and the more difficult questions relating to the cost effectiveness of telemedicine.

### A. Federal Funding

In 1997, the federal government, for the first time, approved limited reimbursement of federal funds for on-going medical consultations. The

352. See Ace Allen, *A Review of Cost Effectiveness Research*, TELEMEDICINE TODAY (Oct. 1998) at 18.

353. See Advanced Health Information Systems, *Telemedicine & the Law*, 1 Health Information Systems & Telemedicine <<http://www/ArentFox.com/telemed/articles>>; Health care Financing Administration, *National Health Expenditures and Per Capita Amounts, Percent Distribution, and Average Annual Percentage Growth By Source of Funds: Selected Years 1960-1990* <<http://www.hcfa.gov/stats/tab1kdf>>. The questions of who sponsors, who pays are critical. Reimbursement for telemedicine consultations alone will not support telemedicine.

354. See Sandy Campbell, *Opportunities, But No Guarantees, for Rural Hospitals in Federal Budget Act*, Health care Strategic Management, No. 11, Vol. 13 (Nov. 1, 1997). "Services follow funding streams . . . when you make reimbursement available for the application of a new technology, people are going to be looking at that as a new support for services." *Id.*

consultations are limited to those who perform telemedical consultations for rural Health Personnel Shortage Areas (HPSAs). Under the provisions, reimbursement will be established for all eligible Part B Medicare services at normal co-payment rates. Combined with the provisions in the Telecommunications Act of 1996 and subsequent actions by the FCC, this Congressional action represents two major public policy decisions that will facilitate better access to health care "for all Americans regardless of their geographic location or socioeconomic status."<sup>355</sup>

On November 2, 1998 HCFA finalized regulations on the new rural health care reimbursement program, providing payment for professional consultation by a physician.<sup>356</sup> HCFA interpreted the legislation, however, as not allowing the reimbursement of fees for store-forward consultations.<sup>357</sup> In effect, the provider or practitioner must actually be

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355. Congress Approves Telemedicine Reimbursement, *Health care Strategic Management*, N. 9, Vol. 13, (Sept. 1, 1997). Under the combination of these new provisions, more than 1250 applications from not-for-profit rural providers in 45 states have been submitted to the Rural Health care Corporation. These applications, requesting discounts on telecommunication services and "the advent of the [proposed] Medicare rule allowing reimbursement for telemedicine underscores the rapid rate that telemedicine is emerging as a health care mechanism . . ." (245) *Telemedicine: Applications for Telemedicine Service: Discounts in Rural Areas Promoted*, HEALTH CARE DAILY REPORT (July 9, 1998), WL DATABASE BNA-HCD.

356. On June 22, 1998, HCFA proposed regulations for rural reimbursement program. The proposed rule provides for payment for professional consultation by a physician and other practitioners via "interactive telecommunication systems" only. As discussed, HCFA has narrowly interpreted the new legislation and will not allow the reimbursement of fees for store-forward consultations. Therefore, the proposal will allow payment only if the physician or other practitioner furnishes a service for which payment would be made under Medicare to a beneficiary residing in a rural area that is specifically designated as a "health professional shortage area." The proposal itself contains many details and establishes the methodology HCFA intends to use to determine the amount of eligible payments for the consultation. See *Federal Register*, June 22, 1998, Vol. 63, (Nov. 2, 1998) at 58863-58912. The program will go into effect Jan. 1, 1999. Individuals interested in determining eligible areas can find a list of Health Professional Shortage Areas at <<http://158.72.105.163/databases/hpsa/hpsa.cfm>>.

357. See 63 Fed. Reg. Vol. 33,882 (June 22, 1998) (implementing parts of the Balanced Budget Act of 1997 to provide for payment for professional consultation by a physician and certain other practitioners via interactive telecommunication systems. Comments were due on Aug. 21, 1998). HCFA defined telemedicine as two kinds of technology, one being the two-way interactive video, used when a consultation involving the patient, the primary care give, and a specialist is necessary (teleconsultation); the other technology, called "store and forward," is used to transfer video images from one location to another, using a camera or similar devices. To qualify for Medicare payment, the patient "must be present and the telecommunication technology must allow the consulting practitioner to control an interactive medical examination of the patient." The justification for not including "store and forward" technologies is that it "would not allow a medical examination of the patient but would allow only a review of a prior examination, test, or diagnostic procedure, which would be outside the scope of this proposed rule." *Id.* at 33,884. Thus, an interactive patient encounter must meet the criteria for reimbursement consideration under the proposed regulations. The final rule makes it clear that HCFA has not changed its position on allowing reimbursement for "store-and-forward" technology as described in its earlier proposed rule, 63 Fed. R. 33882 (June 22,

present on both ends of the consultation. The regulations will make teleconsultation reimbursement difficult. HCFA has determined that Medicare will not pay for a consultation involving a pre-recorded exam, and that the consultation must include a clinical assessment directed by the physician-consultant and involve feedback from the consultant to the referring physician. This real-time exchange of information also requires the patient's presence.<sup>358</sup> In addition, telemedicine advocates face a number of problems concerning regulation. HCFA limits reimbursable services to live interactive video, ruling out most store-forward services.<sup>359</sup> The final rule states that "review of dermatology photos would not be considered a consultation. We believe that this would be a new service for which payment could not currently be made under Medicare."<sup>360</sup> Moreover, the final rule restricts who will be considered eligible to practice under the program; it also forbids certified nurse anesthetists, and anesthesiologist assistants to provide referrals under the program.<sup>361</sup>

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1998), when the patient is not present in real-time. In addition, although registered nurses and certain other medical professionals would have been permitted to act as presenters during a teleconsultation under the proposed rule, the final rule prohibits this practice.

358. See 63 FR 588863-58912 (Nov. 2, 1998). If all of this is accomplished, payment for the teleconsultation can also be made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, nurse midwives, clinical social workers, and clinical psychologists. Services covered would include office or other outpatient consultations, initial inpatient consultations, follow-up inpatient consultations, and confirmatory consultations. The services furnished by physicians would be paid at 80 percent of the lower of either the actual charge or the fee schedule amount for the consulting physician. The consulting physician would have the obligation to file the claim to the Medicare carrier and would receive the payment. The consulting physician would be required to forward 25 percent of the Medicare payment to the referring provider and would keep the remaining 75 percent. Interestingly, the agency said it would not regard the consulting practitioner as actually making a payment to the presenting physician. This is a "conduit" to pass a portion of the Medicare payment on to the referring physician. *Id. Telemedicine: HCFA Outlines Proposed Payment for Telemedicine in Rural Areas*, 7 BHLR 1027 (June 25, 1998). The final rule, however, does provide certain circumstances where the patient may be presented for the telemedical consultation without any presenting practitioner. The rule states: "We clarify, that for circumstances where the condition of the patient may not medically require the participation of a presenting practitioner, we would not require the participation of a presenting practitioner as a condition of payment for the teleconsultation." However, because this could become a large number of eligible consultations, HCFA also state that it would regularly monitor the provision of these services.

359. In fact, as remarked by the American Telemedicine Association, "for advocates in the telemedicine world, the final regulations contain no new developments from the draft proposed rule. HCFA ignored the pleadings contained in many comments, including ATA's, and have restricted reimbursable services to include live interactive video. This rules out telemedicine practiced through store-forward services, except for the existing single-purpose services that are currently funded under Medicare . . ." <<http://www.atmeda.org/news/finalized.html>>.

360. F.R. Nov. 2, 1998, Vol. 63, number 211, pp. 58879, 58886.

361. *Id.* The rule states: "After further review of this proposal, we have determined that allowing clinical psychologists, clinical social workers, certified nurse anesthetists, and anes-

In addition to providing reimbursement for telemedical consultations, the Secretary must also provide for a single, four-year demonstration project to use eligible health care provider telemedicine networks to apply high-capacity computing and advanced networks to improve primary care, and prevent health care complications, to Medicare beneficiaries with diabetes mellitus who are residents of medically underserved rural areas or medically underserved inner-city areas.<sup>362</sup>

To understand telemedicine's cost efficiencies, studies need to produce clearly defined outcome results. These studies should take into account not just issues of getting medicine to patients in rural areas, but health care to the patient population of the future.<sup>363</sup> In January 1999, Medicare began covering teleconsults in professional shortage areas.<sup>364</sup> In contrast to Medicare, HCFA permits Medicaid state agencies to

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thesiologist assistants to provide a teleconsultation is inconsistent with the Medicare benefit." Although fraud and abuse have not been addressed specifically in this paper, the potential is clearly possible and, in fact, already noticed by HCFA. The fact that HCFA will probably heavily regulate this area is indicated by a recent opinion of the Office of the Inspector General. Interestingly, the Office of the Inspector General posted Advisory Opinion No. 98-18 on Dec. 3, 1998 intending to provide guidance on the application of federal fraud and abuse laws to certain proposed arrangements. No.98-18 addresses the lease of equipment specifically for telemedicine consultations. Although the specific facts of the opinion were found not to be in violation of the laws prohibiting remuneration or inducements of referrals, the opinion does state that such violations are based on the intent of the parties. The opinion analyzes a relationship between an optometrist and an ophthalmologist, both licensed in the same state. However, neither the referring nor the consulting practitioners charge the patient nor any insurer for the telemedicine consultation. The optometrist is prohibited from advertising or marketing her access to telemedicine consultations.<<http://www.arentfox.com/telem/telem.new.html>>.

362. P.L. 105-33. *Summary of Health Related Provisions of P.L. 105-33 Balanced Budget Act*, HEALTH LEGISLATION & REGULATION, No. 43, VOL. 23, (Oct. 29, 1997). Recently, HCFA has sought proposals for project treating Medicare patients with diabetes, 63 FR 13260. Up to \$30 million in payments will be made to the project over the four years in the demonstration.

363. As early as the IOM Study, it has been recognized that telemedicine is not just a potential panacea in rural areas, but will be critical in urban areas as well. Home care is an area that is growing faster than any other industry in the United States. It is now viewed "as a clinical and management tool that physicians can use daily to meet the specialized needs of a diverse group of home care patients. . . it has been at the forefront of a paradigm shift in medical care delivery from hospital care." *Physician's Outraged by E & M Guidelines*, AMA's *Participation in Development Process*, WESTLAW Database, BNA-HCD (June 16, 1998).

364. In an interesting article on telemedicine, Professor Peter Yellowless describes "How Not to Develop Telemedicine Systems." His key messages include do not do the following: make decision centrally, set up a central bureaucracy, decide on applications and telemedicine sites on a geographic needs basis, install the technology with "bells, whistles and flashing lights," insist delivery of telemedicine services without appropriate training or support or over-evaluate the telemedicine system. Peter Yellowless, *How Not to Develop Telemedicine Systems*, TELEMEDICINE TODAY, pp. 6-7, 17 (May/June 1997).

establish state-coverage policies for telemedicine.<sup>365</sup> To date, approximately 10 states permit reimbursement for telemedicine.<sup>366</sup> The states are a fertile area for study, comparison, and outcome data research. HCFA should be looking to the states' experience to learn what telemedicine services should be employed to improve quality and access while reducing costs.<sup>367</sup> For example, telemedicine has gained increasing popularity in the provision of mental-health and substance-abuse services for Medicaid beneficiaries. The Montana Medicaid program has been providing telemedicine services to patients who are more than 100 miles away from the nearest mental health or substance abuse practitioner.<sup>368</sup> There have been a number of outcome studies that clearly demonstrate certain telemedical services do, in fact, provide increased access and assist the patient in need. Until very recently, however, public and private reimbursement for telemedicine services has been a mirror image of the federal government's fragmented and scattered view of telemedicine reimbursement policies.<sup>369</sup>

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365. HCFA has recently informed managed health care plans and Federally qualified health-maintenance organizations with Tax Equity and Fiscal Responsibility Act of 1982 ("TEFRA") risk-based contracts, that they do not need a waiver to offer telemedicine services. These plans, however, would not receive additional reimbursement for covering telemedicine services. This use of telemedicine networks in the Medicare managed care program could be a means of increasing access to quality health care for rural and under-served Medicare beneficiaries, reducing distance and isolation in patient/physician relationships, and, developing a baseline of information for on-going evaluation of utilization and outcomes. <<http://www.ntia.doc.gov/reports/telemed/payment.htm>>.

366. HCFA, Office of Research and Demonstrations and Medicaid Bureau 9/1996. These states are Arkansas, Georgia, North Dakota, New Mexico, Montana, South Dakota, Utah, Virginia and West Virginia.

367. Many groups are taking the lead in provoking HCFA to explore more demonstration projects, such as the ATA's Tele-Homecare Task Force, which aims to develop projects and reimbursement for tele-homecare services, assess tele-homecare technologies and to develop a national data base and registry on tele-homecare. *Id.* <<http://www.atmeda.org/members/homecare.html>>. On Oct. 23, 1998, the American Telemedicine Association advocates for Medicare funding of tele-homecare requested that HCFA approve the use of remote visits by means of telemedicine for inclusion under the Medicare's Interim Payment Guidelines for homecare. ATA suggested that the clinical guidelines for homecare might be used to govern HCFA's regulation of homecare agencies that use Medicare funding for telehomecare. <<http://www.arentfox.com/telemed/telmed.new.html>>.

368. Nancy Ellery, Administrator of the Health Policy and Services Administration of Montana has stated that telemedicine has saved the state substantial transportation and other costs, while also expanding access for rural Montana residents. <<http://www.ntia.doc.gov/reports/telemed/payment.htm>>.

369. For instance, HCFA continues to support a teleconsultation demonstration project based in Georgia, North Carolina, West Virginia and Iowa in which the Medicare program will reimburse 53 hospitals for teleconsultation services through the hospital's outpatient departments. Initiated in 1996, this project will continue for two years.

### B. State Approaches To Reimbursement

If telemedicine is going to work, if it is going to be studied and resources provided, it will be far more advantageous to provide those resources in a steady “stream” of reliable funds, than, as in the past, on the drips and drabs of funding or grant moneys.<sup>370</sup> The States recognized that self-reliance is marked by the development of their own reimbursement mechanisms. Although many projects began, a number of projects failed, not for lack of interest or success, but simply as a result of the spigot running dry. States have taken various approaches to telemedicine and to their territorial state health issues. In contrast to HCFA’s limited reimbursement of telemedicine services, in which the state has great control over the reimbursement of medical services, such as with Medicare, other types of telemedicine consultations may be reimbursed.<sup>371</sup> A number of states have provided for reimbursement for telemedicine under their Medicaid plans or have legislated telemedical services be treated in the same manner as face-to-face delivery services. California has been an active laboratory, and certainly has been the vanguard in all areas relating to telemedicine—especially on the issue of reimbursement.<sup>372</sup> On September 24, 1996 California passed S.B. 1665, which now requires all payers in California—as a matter of law—to have integrated telemedicine into their reimbursement policies. It also required that by July 1, 1997 Medi-Cal eliminate its requirement for a face-to-face consultation. Until this law was enacted there were no provisions for telemedicine reimbursement in California.<sup>373</sup> To date, at least twelve

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370. Although HCFA is working toward a national coverage policy for Medicare, as set forth above, it is a slow process. HCFA does, however, allow state Medicaid agencies to establish their own coverage policies for telemedicine. “The lack of clear and consistent policy makes it difficult to cover the costs of telemedicine systems with reliable sources of revenue.” Orbach, *supra* note 128, at 59.

371. For instance, Medicaid agreed to pay for telemedicine services in Montana, because it will save money. Without telemedicine, Medicaid has to pay travel expenses for those who are referred by their private physicians to specialists. *Id.* 12 J.L. & HEALTH 173.

372. California is a Model state and also an example of how the states and federal government could work together. California sets an example of what an individual state did to encourage telemedicine, not only within its own boundaries, but also across state lines. “Establishing the legitimacy of telemedicine through the provision of state funded reimbursement is a critical first step . . .” Orbach, *supra* note 128, at 53.

373. Kaiser Permanente, Allina Health Systems, and some other large health care plans had looked into the use of telemedicine technologies in their health care systems. By enacting the telemedicine law, California afforded its citizens guidelines and parameters to follow for telemedical applications. California also removed the shackles prohibiting telemedical practice. The Act prohibits health-maintenance organizations, non-profit hospital service plans, the Medi-Cal program and disability insurers from demanding face-to-face contact as a condition precedent for reimbursement of medical services. In fact, the Act took a strong stance not just in the legislation, but in the timing of the law (unlike HHS) and all were required to address telemedicine into their reimbursement policies by January 1997. The state Medi-Cal program



states<sup>374</sup> have some form of Medicaid coverage for telemedicine services and some states have limited reimbursement for home health and/or mental health services,<sup>375</sup> which will be reimbursed under Medicaid.<sup>376</sup> Four states, including California, have enacted non-discrimination insurance provisions, thus precluding exclusion of coverage because it is tele-based and encouraging private insurers to begin indemnifying telemedicine consultations.<sup>377</sup> In addition, Hawaii and Vermont have similar provisions pending.<sup>378</sup> Other states are following the lead and taking aggressive action.<sup>379</sup>

### C. Private Funding of Telemedicine

Although originally few in number, a growing number of private organizations have issued studies on the cost-effectiveness of telemedicine.<sup>380</sup> While conclusions indicate that telemedicine can save

was given until July 1997 to develop a plan to address telemedicine applications. *See generally* Hezel, TELEMEDICINE, *supra* note 195 at 52–53.

374. Arkansas, California, Georgia, Iowa, Illinois, Kansas, Minnesota, Montana, North Dakota, South Dakota, Virginia and West Virginia. Nebraska and Texas are reported as developing plans to cover telemedicine. This account changes rapidly as more and more states begin to look into the cost-effectiveness of telemedicine in the health plans.

375. Minnesota and Kansas.

376. *See* <<http://www.hcfa.gov/Medicaid/telemed.htm>>. “The Health care Financing Administration has not formally defined telemedicine for the Medicaid program, and Federal Medicaid law does not recognize telemedicine as a distinct service. Nevertheless, Medicaid reimbursement for services furnished through telemedicine applications is available, at the State’s option, as a cost-effective alternative to the more traditional ways of providing medical care.”

377. California, Montana, Oklahoma and Texas; (Cal. Health & Safety Code Sec. 1374.13(c)(Healthcare service plans issued, amended, or renewed in California after Jan. 1, 1997 may not require face-to-face contact between a healthcare provider and the patient “for services appropriately provided through telemedicine.”)

378. Hawaii (H.B. 2852), (S.B. 2855) Vermont (H.J.R. 210).

379. Ariz. Rev. Stat. Ann. § 36-2921 (authorizing the appropriation of up to \$250,000 annually for fiscal years 1995–1996, 1996–1997 and 1997–1998 for telemedicine pilot programs designed to provide medical services to underserved areas.) *See also* 1997 Ariz. Sess. Laws 1, H.B. 2001 (Appropriates \$1,240,900 for a telemedicine network); 1997 Ark Acts 604 (appropriates \$500,000+ to the Computer Service Department to develop a statewide distance learning network); 1997 Ariz. Acts. 559 (Appropriates \$4 million for grants to public and non-profit entities for development of the distance learning and telemedicine network); Hawaii (pending) S.B.2258(Appropriates \$500,000 to plan and develop telemedicine project); Kentucky (pending) H.B. 321 (\$1,000,000 for telemedicine equipment and systems); 1997 NM H.B.2 (appropriates funds to the University of New Mexico for telemedicine projects); 1997 Tex. Gen. Laws § 1452 (\$500,000 for telemedicine systems); 1996 VA H.J.R. 53 (Appropriates \$600,000 over a period of two years for telemedicine programs). Arizona, Georgia, Iowa, Louisiana, Oklahoma, Virginia and West Virginia have all taken steps to assure some reimbursement mechanisms are put into place.

380. The October 1998 edition of *Telemedicine Today* reviewed the cost-effectiveness research to date. The article presented an overview of peer-reviewed economic analyses of a variety of telemedical applications and found that four applications, teleradiology, telepsy-

costs, no one study is definitive, and a common framework from which to draw comparisons does not exist.<sup>381</sup> The Texas Telemedicine demonstration project was probably the first to deal with the issue of costs. A study of the Texas data conducted by Arthur D. Little documented a savings of approximately 14% over conventional practice, with a pay-back projected in 2.6 years.<sup>382</sup> The study, privately-funded, linked major public and private providers in Austin, Texas with a 23-bed hospital, a renal dialysis center, a community mental health center, and a prison infirmary in a town of 4,000 people 65 miles away. No providers were reimbursed, no state or federal funds were obtained. Foundation moneys were used, together with contributions from telecommunications industry and health care sources.<sup>383</sup>

In reviewing a number of the projects, both federally and privately funded, a number of observations can be made. Telemedicine is a viable option for systems with limited resources. However, when the health care provider is responsible for the greater part of the total costs of illness . . . the economic benefit of telemedicine becomes immediately apparent. Additionally, telemedicine systems are cost-effective in non-clinical services, such as continuing medical education. Moreover, the use of telemedicine and medical centers "can deliver quick and efficient patient services without the overhead costs of bringing and keeping patients on site."<sup>384</sup> Most importantly, initial studies report that patient satisfaction with telemedicine is "quite high."<sup>385</sup>

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chiatry, tele-home care and tele-prison care, represent the "poster children" of telemedicine cost-effectiveness. Ace Allen, *supra* note 353, at 10.

381. Interesting, the issue of cost savings is not being studied as much as predicting the market for telemedicine. Although there is no common answer or definitive study, there are four groups that are studying this issue, all predicting growth of different magnitudes, e.g. Frost and Sullivan predict a growth rate of about 28 percent over the next six years yielding a total annual market of \$1.6 billion by 2004 (market growth for PACS and radiological systems). See <<http://www.frost.com>>; <<http://www.telemag.com>>; <<http://www.buscom.com>>; <<http://www.fed-back.com>> (Feedback Research Services predicting growth in the US for telepathology, teleradiology, and videoconferencing today under \$100 million but projecting a worldwide growth rate of 15%).

382. This means that the return on the money invested in the project would be recouped in 2.6 years.

383. Britton Berek and Marilyn Canina, *Telemedicine on the Move: Health care Heads Down the Information Superhighway*, Hospital Technology Series, VOL. 13, NO. (1997) at 7. This project provided a template for conducting a cost analysis of telemedicine in a rural setting and at the end of the first year, they telemedicine system had 1999 patient care reports, including six lives saved.

384. *Id.*

385. *Id.*

HCFA's regulations provide recognition that telemedicine is both a new delivery system and "significant opportunity"<sup>386</sup> for the further enhancement of telemedicine coverage. But the regulations are too restrictive, especially for a "pilot program." The proposed regulations require the teleconsult be "interactive," that the "provider" be actually present on each end of the consultation, that beneficiary eligibility depends upon the place of residence or location of service, that the site of the teleconsult must "effectively transport the patient to the consultation," and that the payment process is cumbersome, providing for only the consulting practitioner to submit the claim and receive the payment, and then remitting the fee to the presenting practitioner.<sup>387</sup>

The issue of telemedicine and regulation of health care costs, in many ways, mirrors the same issues relating to quality and access. There is a role for the federal, state and private sector in which each plays a part in moving telemedicine toward a health-delivery system that can provide improvements to quality and access to care simultaneously saving costs. Such a solution calls for a "balanced federalism" in health reform.<sup>388</sup> In this context, the federal government regulates the broad outline, or national standards, after consultation with the states and the input of the private sector. The states, however, implement these standards, and have the regulatory imprimatur to improve and expand. The entrepreneurial spirit of the states, coupled with unshackling the reins of prohibitive reimbursement schemes, should spur the private marketplace to do what it does best—"follow the money." In following the money, however, states must not trade savings for quality. It is fair to expect that telemedical technologies will assist the health care industry to better deliver health care at costs that approach those of the traditional practices.<sup>389</sup> So far, however, there is scant proof that those in rural areas will get care at less cost than traditional methods.<sup>390</sup> No doubt, as the

386. Stephen J. Schanz, *Proposed HCFA Regulations Offer Telemedicine Opportunities*, TELEMEDICINE TODAY (August 1998) at 13.

387. It is hardly unusual for HCFA to be so cautious, but in this sense, the cautiousness will probably turn more and more serious telepractitioners into finding better routes of reimbursement for the time being. Although the proposed rules would appear reasonable on their face, expanding the availability of health care services to needed places, the HCFA reimbursement process is hardly the answer to telemedicine's presume "barrier." HCFA is now reviewing the comments submitted to the proposed regulation. *Id.* at 13.

388. The Reforming States Group, *Balanced Federalism and Health System Reform*, HEALTH AFFAIRS, May, 1998–June, 1998.

389. *Id.* Hezel Associates, Telemedicine, *supra* note 195, at 8.

390. The government's approach to telemedical services is half-pregnant by nature. HHS will reimburse to services in areas of need, but *only* for the medical service, not for the systems needed to support the telemedical service. Assuming that telemedicine will proceed with or without the government's support, the government may need to provide additional support to those who need the telemedical service most—the patients that are living in rural

money flows to support new technologies, this will change.<sup>391</sup> Many of telemedicine's economic benefits may be difficult to assess through the traditional economic measures in use today.<sup>392</sup> For example, if a rural patient cannot get any care at all, is this a fair method to approach telemedicine's cost-effectiveness? Reimbursement mechanisms for telemedicine consults need to be aligned with goals for health care reform.<sup>393</sup>

A number of options exist with respect to reimbursement initiatives. The federal government could facilitate education by disseminating information regarding initiatives, including states' initiatives in telemedicine, centering its study around the issues of cost, quality and access. Such an would be especially appropriate insofar as many states have provided special appropriations for telemedicine studies.<sup>394</sup> Gathering information is a function the federal government performs well since it has the infrastructure and assistance and professional expertise.<sup>395</sup>

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and inner-city areas "where market forces are unlikely to provide the services needed" in the first instance. Gitlin, *supra* note 291, at 171. It is therefore more critical that when the government conducts its cost-effectiveness study it weighs the fact that it is not providing funds for the communication set-up, thus, the government's study may falsely accuse the demonstration project not worthy of its standards of cost-effectiveness if only costs are used as the denominator. *Id.*

391. D. Puskin, *Financial Issues: Reimbursement*; TELEMEDICINE JOURNAL, (1995) Vol. 1, No. 6, at 357–63.

392. The Telemedicine Report to Congress noted that on the private sector side, very little information exists about private payer-coverage of telemedicine. <<http://www.ntia.doc.gov/reports/telemed/payment.htm>>. There is information to date that suggests that few private payers cover telemedicine consultation services, although most of these payers cover radiology and similar imaging services. J. Grigsby, M. Kaehny, and E. Sandberg, *Effects and Effectiveness of Telemedicine*, HEALTH CARE FINANCING REVIEW (1995).

393. There is, however, hope that many of the reimbursement issues will be resolved in the next few years. "As the world turns to digital technologies, prices for equipment and infrastructure will continue to drop. At today's prices, the same system installed in the Texas Telemedicine Project in 1992 would now cost about half as much and yield equal or greater performance." Berék and Canna, *supra* note 383, at 29.

394. *Telemedicine: IOM Panel Recommends Framework for Gauging Value of Clinical Uses*, BNA HCD Oct. 10, 1996, WL BNA-HCD.

395. In fact, there is telemedicine activity in virtually every state, including state-supported initiatives, university initiatives and private endeavors. The federal government has set up a four-year demonstration program to address telemedicine and the needs of rural, underserved areas. California is a laboratory where the experiment is already well underway. With eight major or networks addressing telemedicine endeavors, and 49 counties designated as federally medically underserved, California should provide a wealth of information. Additionally, California is planning to address telemedicine in the state's prisons. The University of California Davis Medical Center is specifically directing efforts to meet the needs of primary care clinics. See Hezel, TELEMEDICINE, *supra* note 195, at 53–54. In fact, universal health care is a reality "in one part of the United States: prison." *Id.* Telemedicine is being tested in efforts to cut costs of treating prisoners. See Kate Murphy, *Telemedicine Getting a Test in Efforts to Cut Costs of Treating Prisoners*, THE N.Y. TIMES, June 8, 1998, at D5.

Since many of our federal health care dollars are spent on presently employed and former federal employees, the federal government should encourage health plans to propose policies on telemedicine and provide coverage, if appropriate. The federal government should also: (1) have the medical communities in the federal government work with the professional medical associations to address the Official Medical Fee Schedule to facilitate reimbursement for telemedical services;<sup>396</sup> (2) immediately address any barriers to the Telecommunications Reform Act of 1996 and facilitate removal of those barriers; (3) employ grants for scientific research; (4) provide financial support, either directly or through incentives, for telemedical public health initiatives;<sup>397</sup> and, (5) bolster the educational use of telemedicine and telehealth by providing incentives/reimbursement for preventive medicine. Study after study indicates there is a forceful role for the federal government to play in the area of preventive medicine.<sup>398</sup> In the area of education, significant expense could be avoided by educating physicians and patients alike.

States have an important role to play too. States have incredible leverage to move forward and accomplish more, tailor the reimbursement schemes to the needs of what is in the best interests of their patient constituency. States should consider California and Oklahoma's approaches to telemedicine.<sup>399</sup> Additionally, states could (1) examine the practices of California,<sup>400</sup> Georgia, Kansas,<sup>401</sup> Texas and Louisiana, (2) provide

396. See *Summary of Health Related Provisions of 104-33, Balanced Budget Act*, HEALTH LEG. & REG. No. 43, Vol. 23 (Oct. 29, 1997) at 52.

397. The National Telecommunications and Information Administration awarded a grant of approximately \$600,000 to the University of Medicine and Dentistry of New Jersey (UMDNJ) Health Network. With the grant moneys, the UMDNJ plans to link two underserved low-income neighborhoods through kiosks to primary-care sites in Camden and Newark. The UMDNJ plans to place resources of UMDNJ into the underserved clinics, deliver preventative health education and provide telemedicine services. The kiosks will be placed in public housing and will allow patients to converse with clinicians through a two-way video kiosk.

398. The federal government is financing support for diabetes mellitus, and, hopefully, this will create a precedent that investments in education may avoid more serious problems in the future.

399. Allen suggests that the states have the power, within their own borders, to support their own telemedical programs. He submits that the "real culprit," is "a failure to recognize that the hardest work of a telemedicine director, "is the sheer intellectual challenge of figuring out what nurses and physicians and patients really need . . ." and figuring out "how technology can address the need. . . ." Ace Allen, *Telemedicine's Prime Directive*, TELEMEDICINE TODAY, June 1998 at 1.

400. CALIFORNIA TELEHEALTH/TELEMEDICINE PROJECT (1997).

401. Kansas University Medical Center has been addressing telemedicine services for a number of years. The clinical services reach patients at more than 20 sites throughout the state. Teleconsultations enable specialists to treat patients within the state, saving traveling time of the specialist (or the patient). See TELEMEDICINE, video (on file with author). For

funding for physicians in underserved areas, whether it be rural or inner city, (3) reimburse and/or provide tax incentives for education, (4) provide funds to train health care professionals and (5) examine the patient's needs in the state and begin to address where there is a telemedical solution to address some of those needs.<sup>402</sup>

Telemedicine needs stable sources of revenue. Congress, and the states should establish what sources are necessary for their respective patients, designate task forces to study what telemedicine services should be reimbursed and specify the types of services, amounts, mechanisms for financing services and a clear basis for reimbursement. Moreover, Congress should demand, as a condition precedent for federal funding, outcome studies detailing telemedicine's successes. Such outcome studies, whether directed by the government, or by the private sector,<sup>403</sup> will provide useful benchmarking data of the benefits telemedicine can bring.<sup>404</sup> The funding from private sources came, in the past, from the telephone companies, from private foundations, and, most recently, from selected providers. The private sector today is very much involved in telemedicine and has determined where it ought to invest, but it is the responsibility of regulators to assure that all laws and regulations are followed to protect the best interests of the patients and to enact laws that will facilitate telemedicine rather than stunt its growth.

## VI. TELEMEDICAL POLITICAL PROPOSALS

The reality of telemedicine's current legal framework and the promises telemedicine brings to address the issues of quality, access and care is bridged by numerous proposals at the federal, state and private levels.

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instance, the Hays Medical Center uses telecommunications to provide access to home health care for homebound patients in the state.

402. Georgia is another leader in setting a comprehensive state-wide system for telemedicine, and one of the first states to pass legislation providing a financial support for the state's telecommunications projects. In addition, Georgia facilities have received moneys from private foundations to address ways in which telemedicine could assist patient pressure ulcers.

403. Already, the managed-care institutions are looking into various telemedicine applications. If telemedicine brings reduction of costs to the services, then it is very likely telemedicine will be attractive to managed care institutions.

404. See David Blumenthal, *The Future of Quality Measurement and Management in a Transforming Health care System*, JAMA, VOL. 278, No. 19 (Nov. 19, 1997) at 1622, 1997 WL 15878212; E. Andrew Balas, Farah Jaffrey et al., *Electronic Communication with Patients: Evaluation of Distance Medicine Technology*, JAMA VOL. 278, No. 2, (July 9, 1997) at 152, 1997 WL 11228030; Donald F. Phillips, *Physicians Put Promise of Telemedicine to the Test: Reports from Rural Practitioners, Anesthesiologists*, MEDICAL NEWS & PERSPECTIVES, JAMA, vol. 276, no. 4 (July 24, 1996) at 267.

The sheer number of proposals—each one addressing a one or more of the barriers to telemedicine implementation—reinforces the difficulty in managing telemedicine as a proposal or a legislative solution. Again, telemedicine exemplifies the issues and barriers that already hinder delivery of health care.

In the last three Congressional sessions, there have been over sixty pieces of federal legislation relating to telemedicine. During the 103<sup>rd</sup> Congress, at least twenty-two different legislative bills were introduced.<sup>405</sup> During the 104<sup>th</sup> Congress,<sup>406</sup> another twenty-two pieces of proposed telemedicine legislation were introduced, and the 105<sup>th</sup> Congress also introduced twenty-two pieces.<sup>407</sup> Of these federal proposals,

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405. See S. 1088 Rural Telemedicine Development Act of 1993, H.R. 3249 Rural Telemedicine Development Act of 1993; H.R. 3070 Rural Telemedicine Development Act of 1993; H.R. 4725 Presidential Commission on Telemedicine Act; H.R. 3009 To amend Title XVII of the Public Health Service Act to authorize the Secretary of Health and Human Services to make grants to establish and develop telemedicine projects for rural areas; H.R. 2639 Telecommunications Infrastructure and Facilities Assistance Act of 1993; H.R. 2639 Telecommunications Infrastructure and Facilities Assistance Act of 1993; S. 1883 National Telecommunications and Information Administration Authorization Act of 1994; S. 2111 Telecommunications Services Enhancement Act of 1994; S. 1865 Community Health Improvement Act of 1994; H.R. 3573 Community Health Improvement Act of 1993; HS. 2351 Health Security Act; S. 2374 To improve the United States private health care delivery system and Federal health care programs, to control health care costs, to guarantee access health insurance coverage; S. 2374; S. 2357 Health Security Act (Introduced in the Senate); S. 2357 Health Security Act (Placed in the Senate); S. 2296 Health Security Act (Placed in the Senate); H.R. 3955 Health Reform Consensus Act of 1994; S. 2396 Affordable Health care Now Act of 1994.

406. See S.7, Family Insurance Protection Act, S. 168 Affordable Health care for All Americans Act, S. 933 Healthy Mothers, Healthy Children Act of 1995; S. 963 Rural Health Improvement Act of 1995, S. 80, Rural Health Care Protection and Improvement Act of 1995; S. 1044 Health Centers Consolidation Act of 1995; S. 1268, Rural Health Development Act; S. 1357 Balanced Budget Act of 1995; S. 1534 Clinical Research Enhancement Act of 1996; S. 1541 Agricultural Reform and Improvement Act of 1996; S. 2171 Comprehensive Telehealth Act of 1996; H.F. 426 the National Commission on Telemedicine Act; H.R. 851, Rural Telemedicine Act of 1995; H.R. 2175 Rural Health Consolidated Grant Act of 1995; H.R. 2411 Rural Health Development Act; H.R. 2854, Federal Agriculture Improvement and Reform Act of 1996; H.R. 3981, Health Centers Consolidation Act of 1996; H.R. 3425 Newborns' and Mothers' Health Protection Act of 1996, H.R. 3587, Clinical Research Enhancement Act of 1996, H.R. 3603, A bill to make appropriations for Agriculture; Rural Development and other agencies for fiscal year ending September 30, 1997; H.R. 3610, Department of Defense Appropriations Act for FY 1997.

407. See H.R. 337, Managed Care Consumer Protection Act of 1997; H.R. 966, Improved Access for Telehealth Act of 1997; H.R. 1054, Internet Tax Freedom Act, 1997; H.R. 1101, Medicare Telemedicine and Medical Informatics Demonstration Act of 1997; H.R. 1189, Rural Health Improvement Act of 1997; H.R. 1415, Patient Access to Responsible Care Act of 1997; H.R. 1670, Airline Passenger Safety Act of 1997; H.R. 1715, National Institute of Biomedical Imaging Establishment Act; H.R. 2015, Balanced Budget Act of 1997; H.R. 2112, Telephone Slamming Prevention and Internet Connection Act; H.R. 2160, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1998; H.R. 2338, To amend title 38, United States Code, to require that health care pro-

few became law and many are still bills pending legislative action. At last count there were 15 federal agencies directly addressing telemedicine projects.<sup>403</sup> Countless agencies can affect telemedicine applications, federal projects, and funding.<sup>409</sup> On the state level, at least 20 states have taken legislative action, either through laws directly addressing telemedicine, or laws that impact telemedicine. In addition, there are state commissions, compacts, intergovernmental agencies, various licensing boards, state committees and professional associations addressing issues of "distance" medicine.<sup>410</sup> One federal bill, the Telehealth Act of 1996, has lingered in Congress for over two years, with little sign of movement. In addition to requiring HCFA to reimburse for telemedicine activities,<sup>411</sup> it would have required a status report on the efforts to ease licensing burdens on practitioners, and provided seed money to local communities to support telemedicine programs. This ill-fated bill, however, did not address privacy and confidentiality.<sup>412</sup>

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professionals of the Department of Veterans Affairs be assigned to facilities of the Department only in States in which they are licensed to practice, and to require that the Secretary of Veterans Affairs follow state requirements concerning the filing of death certificates; H.R. 2905, Comprehensive Managed Health Care Reform Act of 1997; H.R. 3001, Clinical Research Enhancement Act of 1997; H.R. 3009; Health Care Consumer Protection Act of 1997; S. 385, The Comprehensive Telehealth Act of 1997; S. 386; Medicare Modernization and Patient Protection Act of 1997; S. 644; Patient Access to Responsible Care Act of 1997; S. 848; Rural Telemedicine Demonstration Act of 1997; S. 990 National Institute of Biomedical Imaging Establishment Act; S. 1402 The Alaskan Community Health Aide Program Extension Act of 1997; S. 1421 Clinical Research Enhancement Act of 1997; S. 2603 Promoting Health in Rural Areas Act of 1998; *see also* S. Res. 86, resolution expressing the sense of the Senate with respect to telephone-access charges for use of the Internet and the growth of advanced interactive communications networks like the Internet.

408. Among these agencies are: the Department of Health and Human Services, the Veterans' Administration, the Federal Communications Commission, the Department of Agriculture's Rural Service, the National Telecommunication and Information Administration, Department of Defense, Department of Justice, the National Library of Medicine, the Health Care Financing Administration (within HHS), the Food and Drug Administration, National Aeronautics and Space Administration.

409. It has been reported that HCFA has spent \$10.7 million on telemedicine-related projects for a demonstration in Georgia, Iowa, North Carolina, and West Virginia. *See Federal Developments*, TELEMEDICINE, 5 HCPR 38 d25 (Sept. 29, 1997).

410. Until 1998, there had been no single federal agency in charge of the issues, and there is still no strategic plan to address the identified barriers. In 1998, the Department of Health and Human Services' Health Resources and Services Administration (HRSA) created a new Office for the Advancement of Telehealth, the purpose of which is to assist the agency's efforts with respect to telemedicine coordination efforts. This office, within the Department of HHS, does not have the power to direct other governmental agencies in their telemedicine endeavors, but it is a first step in approaching the issues relating to the overall problems. Dr. Dena Puskin, formerly the Acting Director of the Office of Rural Health Policy (ORHP) will head this new office, the goal of which will be to "bring all Americans to the table when it comes to health resources." TELEMEDLAW, Vol. 3, No. 3, Summer 1998, p. 3.

411. A suggestion which, in part, has already been accomplished.

412. S. 385.



The Institute of Medicine (IOM) has supported the exploration of telemedicine, but has strongly recommended that before Congress or the States adopt this new technology, a business plan should be implemented. The IOM seeks to address the clinical process of caregiving, the patient's status or health outcome, access to care, the costs to the patients, payers, providers and society, and the satisfaction of the clinicians and patients with the technology.<sup>413</sup> The JWGT has submitted a report that raised a number of barriers to the expansion of telemedicine, including reimbursement, lack of an explicit and fair policy for paying for telemedicine services, assessment of barriers to support telemedicine in managed-care systems, national licensing system, removal of barriers relating to liability and patient confidentiality and a telemedical code of ethics. Other potential barriers include hospital-admitting privileges, liability, privacy and system design issues, a clear definition of telemedicine and administration programs.<sup>414</sup> The states have clearly preceded the federal government in reforming telemedicine regulation, but it is clear that there are many remaining barriers to be removed. Federal and the state governments, working together toward this end, could strike a regulatory balance that would avoid the pitfalls of past health care reforms.

## VII. A CALL TO ACTION

Analysis of telemedicine's future resembles a glance into a crystal ball. There is a flurry of activity, but no clear design or direction. Telemedicine portends a long life with lots of promise but also a rocky journey with many snags along the way. With telemedicine's ability to track diabetes patients at home, to monitor physicians' health scaling the highest mountain top in the world, to provide emergency treatment to soldiers wearing smart shirts, to assist early detection and treatment of an isolated patient's rare cancer, and to enable a father to find a physician to treat the spinal cord injury of his paralyzed son, telemedicine is struggling to grow against the weight of legal and governmental restraints.

Although telemedicine is not the solution to the national health care quandary, it promises a series of breakthroughs to problems that beset the delivery of services to our patients. A unified approach might ad-

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413. "This evaluation will help decision makers determine which uses of the technology to encourage and which to discourage." TELEHEALTH & TELEMEDICINE, *supra*, note 8.

414. See *Reimbursement for Telemedicine Is a Major Obstacle to Expansion*, HEALTH CARE POLICY REPORT, 4 HCPR 11d 58 (Mar. 11, 1996). See also NTIA's World Wide Web site: <<http://www.ntia.doc.gov>>.

dress a number of legal and financial hurdles. However, neither our legal, financial nor political system welcomes a one-shot solution. Rather, the idiosyncratic and diverse systems compete, often producing a far better product. Telemedicine is unique because despite numerous stakeholders and operation on multi-functional levels, it lacks uniform leadership.

With respect to quality, my assumption is that quality is not an end, but a process of improvement. As such, our unique federal-state system has traditionally left to the various states the determination of appropriate criteria to regulate the practice of medicine in the best interests of the patient. Credentialing is governed by state laws that regulate hospital licensure. Likewise, the task of punishing those who breach the state's standards and the duty of care owed to their patient has been addressed by the states. Even as states move toward a national standard of care, it is state law that governs in any civil malpractice action.

There are numerous reasons that militate for the states retaining their police powers, especially with respect to telemedical advances. One overarching reason, however, argues against federal preemption. As we strive to minimize defects in this health-delivery quality process, the more innovation, guarded experimentation, and flexibility will produce a better delivery system, admittedly not all occurring in one miraculous cure, but rather in an incremental fashion over a period of time. States should adopt critical laws that drive politicians, institutions, and caregivers to act in the best interest of patients. To ensure quality of care is not compromised, states, rather than the federal government should enact laws to protect their constituents.<sup>415</sup> In this regard, three proposals are suggested. First, a registration program, directed by the state medical licensing board, should require that physicians practicing telemedicine across state lines be registered by the state's licensing board. California's approach is an appropriate model. Second, the Medical Board should coordinate telemedicine licensure and credentialing with other states. Third, either the appropriate state agency or medical licensing board should review telemedicine programs and technologies, providing policies and guidelines for credentialing off-site telemedicine practitioners. Specifically, policies should set forth when, and under what circumstances, a hospital must credential a remote physician. Moreover, JCAHO and NCQA should develop guidelines for credentialing at health care centers where the remote physician's only practice is via telemedicine. By continuing to use the state-regulating bodies as gatekeepers of

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415. The federal government's role could be the critical one of establishing and supporting national standards that would apply to all federal reimbursement schemes. The states, of course, would be free to improve upon these standards.

registration, licensing and credentialing, the states' medical boards retain the power to issue regulations, to screen physicians, and to ensure standards are equal or better to that within the state. Additionally, the states retain the flexibility to make improvements as technology and other laws in this area change. The foregoing keeps focus on the patient consumer and provides latitude for the state-licensing board to both regulate, enforce and suggest appropriate legislative changes.

The second line of recommendations addresses accelerating and regulating access to telemedical practice. It is ironic that telemedicine is a key proposal to solve access problems, especially for those in medically underserved areas, and yet, access to the underserved is more of a problem than ever before. Both the federal and state regulators have key roles to play. The federal government, through Congress' broad grant of authority in the Telecommunications Act of 1996, should more aggressively propose solutions to the underserved. Instead of focusing on the many difficulties involved with arranging access to rural areas, the FCC should work closely with HHS to design cost-effective incentive programs to enhance service in urban and rural areas. Additionally, the states have an obligation to implement Section 254(h) of the Reform Act. States should be held accountable for the provision of services that deliver remote care at rates that are reasonably comparable to rates charged for similar services in urban areas in that State. Second, although the FDA has been aggressive in addressing telemedicine, it should propose regulations defining a "teledevice." Additionally, the FDA should address what recommendations might be necessary to manage the international implications of telemedical practice.

Last, privacy and confidentiality are critical issues, not unique to telemedicine, but important in the telemedical context. A number of parallel solutions should be pursued. First, initial procedural measures can be put in place immediately. Such measures should include educating physicians and patients, training telemedical staff, identifying sensitive data, providing contractual protection and setting up periodic monitoring of the security policies. Second, there are a number of possible technical safeguards, including firewalls, encryption, authentication, and verification. The most significant changes will take place through imposition of stringent privacy and confidentiality standards for telemedicine practitioners. Each practitioner has not only a legal obligation but also an ethical obligation to assure confidentiality. In this area, a federal law establishing uniform national standards would ensure privacy and confidentiality of medical records. There is, however, no overarching federal law establishing uniform national standards. Nonetheless, a number of bills are currently pending. State laws, as they exist today, are

inconsistent. In the absence of federal legislation, a uniform medical-information protection statute should be drafted, and each state should then adopt and improve upon its model language. Although implementation in this area may be difficult, a state-by-state approach may lead to the same end. In addition to protective language, this bill should impose severe penalties for any breaches of privacy. Moreover, aggrieved patients should have, either under federal or state law, a private right of action for improper disclosure of their medical records.

Telemedicine promises ultimately to save costs, thus satisfying a third major problem in our health care delivery process. In the interim, like any start-up or pilot project, it may take money and research to find the best approaches for telemedicine. All parties have a role in this regard, and all have vested interests. The role of federal and state governments should support those projects that bring the care to their patients in the most cost-effective manner. Much could be done to improve the federal government's approach to telemedicine. Organization of the issues has already begun. Sadly, though, no funds have been directed to the programs that most greatly benefit patients. Although the federal government has appointed a task force, no visible federal leadership, no clear federal or fiscal policy, and certainly no strategic outline have developed. Reimbursement policies set by HCFA, however, pave the way for the private marketplace. Although there is now a demonstration project studying telemedicine's virtues, the reimbursement policy proposed seems far too restrictive. Since HCFA already allows state Medicaid agencies to establish their own coverage policies, Medicaid spending in telemedicine should be tracked by the federal government. In this regard, California could be a model example for the federal government to follow. Instead of limiting reimbursement to the narrow area carved out in the pilot program, Congress should not only permit but *require* private health insurance and managed-care plans to integrate telemedicine into their existing reimbursement policies, treating telemedicine as traditional face-to-face care.

## CONCLUSION

Telemedicine is not the magic pill that will cure our ailing health care system, but it is a potentially miraculous treatment that promises improvements to our delivery systems, bettering quality, access and eventually even costs. Telemedicine will not thrive on a one-shot approach; it requires a regimen of treatments. Its future solution to our health care system's problems of access, quality and costs is best insured

by a collaboration of efforts—by the federal, state and private sectors, by bureaucrat, physician and technician. This collaborative effort should have one driving force and end: acting in the best interest of the patient. By moving toward this goal, all players can compete and even without a strategic plan, guarantee improvements and better access and treatments to patients.