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# Legal and Political Issues Facing Telemedicine

Kathleen M. Vyborny\*

## INTRODUCTION

The practice of telemedicine—medical diagnosis and treatment via telecommunications—is becoming more prevalent in the medical industry.<sup>1</sup> Telemedical services can be as basic as interpreting a medical image<sup>2</sup> or as futuristic as robot-controlled surgery.<sup>3</sup> This method of practicing medicine is not new.<sup>4</sup> One commentator has described it as being at the stage of “giddy adolescence.”<sup>5</sup>

The increased focus on telemedicine has prompted attention to legal issues that are unique to the practice, as well as familiar issues that are altered or complicated by new telemedical facts. Perhaps the most distinguishing telemedical fact is the ability of

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1. About 2000 nonmilitary telemedical consultations were performed in the United States in 1993, while the armed forces have established satellite connections for medical education, diagnosis, triage, and treatment to more than 70 remote locations throughout the world. Troy A. Eid, *Roadblocks on the Information Superhighway: Removing the Legal & Policy Barriers to Telemedicine*, in NATIONAL INFORMATION INFRASTRUCTURE TESTBED, VISION BECOMES REALITY 46 (Jan. 1995). See also TELEMEDICINE: PAST, PRESENT, FUTURE (bibliography, 1634 citations) (Kristine M. Scannel, et al. compilers, Bethesda, Md., Nat'l Library of Medicine, Jan. 1966-Mar. 1995) (available from U.S. Gov't Printing Office, Washington, D.C.) [hereinafter TELEMEDICINE BIBLIOGRAPHY].

2. Teleradiology may be the grandfather of telemedical applications, beginning some twenty years ago. It developed as an alternative to recruiting medical specialists for isolated communities. Joseph N. Gitlin, *Introduction to UNDERSTANDING TELERADIOLOGY* (Soc'y for Computer Applications in Radiology, Harrisburg, Pa.), 1994, at 3.

3. The term “telesurgery” has been used to describe invasive activities such as remote-controlled robot surgery. See, e.g., *Remote Surgery: Operating on Patients From Afar*, SCI. NEWS, Oct. 22, 1994, at 266.

4. See TELEMEDICINE BIBLIOGRAPHY, *supra* note 1.

5. *Technology Can Increase Access to Care, But Political, Practical Issues Remain*, BNA HEALTH CARE DAILY, May 25, 1995, at 234 [hereinafter *Technology*] (quoting Eric Tangelos, Associate Professor of Medicine at the Mayo Clinic).

telecommunications to separate doctor and patient by miles, and thereby move the medical relationship from one spanning the room to one crossing state lines.

### *The Emergence of Telemedicine*

Until recently, telemedicine has been used primarily in special situations where distance from routine channels of medical delivery is unavoidable. Telemedicine has provided medical service to patients during space exploration as well as patients in ocean-going vessels, deep-sea mining ships, and oceanographic laboratories.<sup>6</sup> Telemedicine has benefited isolated, underserved populations that do not routinely attract medical service providers, such as rural inhabitants, Native Americans, and prison inmates.<sup>7</sup> The military has been another frequent user, and telemedicine has been a part of large-scale coordination efforts required for international disaster relief.<sup>8</sup>

Rapid advances in technology, especially during recent years,<sup>9</sup> have focused increased attention on telemedicine.<sup>10</sup> New systems, equipment, and other aids are being developed for telemedical practice; computer-based electronic communication along the "information superhighway," which is integral to telemedicine, has mushroomed on the Internet.<sup>11</sup> Thus, health

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6. See TELEMEDICINE BIBLIOGRAPHY, *supra* note 1.

7. *Id.*; see also Robert M. Allman et al., *The Teleradiology Attraction*, in UNDERSTANDING TELERADIOLOGY, *supra* note 2, at 7. For example, Teleradiology Associates, headquartered in Durham, N.C., "is linked to 45 hospitals in 20 states and reads up to 20,000 studies per year. The company provides radiologic services primarily to radiologists and hospitals in rural settings . . ." Lori D'Agincourt, *Best of Teleradiology: How It's Being Done*, DIAGNOSTIC IMAGING, Apr. 1994, at 42. Also, many of the telemedical projects described in the literature included in TELEMEDICINE BIBLIOGRAPHY, *supra* note 1, deal with rural applications. The federal government has contributed significant funds to the development of telemedical pilot programs in rural areas of the United States.

8. See TELEMEDICINE BIBLIOGRAPHY, *supra* note 1.

9. Over 60% of the journal articles listed in TELEMEDICINE BIBLIOGRAPHY, *supra* note 1, were written since early 1993. Many of these recent papers deal with the subjects of telecommunications systems, networks, and equipment. Also, more than one-half of the articles addressing legal and privacy topics were written from 1993 through 1995.

10. *Id.* Certain telemedical applications depend on "high-tech" equipment. See, e.g., UNDERSTANDING TELERADIOLOGY, *supra* note 2. However, new technology is not a prerequisite for telemedical practice. One commentator reports that between 80% and 85% of telemedicine procedures can be accomplished using existing telephone systems. Paul G. Neumann, *Telemedicine—The Diagnostic Tool of the Future*, HEALTH CARE L. NEWSL., Aug. 1995, at 7.

11. See Douglas D. Bradham et al., *The Information Superhighway and Telemedicine: Applications, Status and Issues*, 30 WAKE FOREST L. REV. 145 (1995).

care providers can practice telemedicine on a wider basis simply because more tools are available.

This wider availability achieves another major goal of telemedicine: increased access to medical care.<sup>12</sup> Telemedicine has the potential to serve other isolated patients, such as inner city residents and homebound patients.<sup>13</sup> On the practitioner side, telemedicine can "link an isolated physician with specialty consultants [and] decrease feelings of medical isolation."<sup>14</sup> Decreasing such isolation might help induce practitioners to relocate to underserved areas.<sup>15</sup>

Finally, the drive in recent years to contain health care expenditures<sup>16</sup> has also heightened interest in telemedicine because the practice is perceived as a cost-efficient method to deliver services.<sup>17</sup> Treating patients in their communities, rather than physically transporting them to the nearest qualified facility, will likely save money.<sup>18</sup> Hours of "windshield time" by circuit-riding physicians could also be eliminated.<sup>19</sup>

Telemedicine may also lead to reduced health care expenditures by allowing patients to be treated earlier when an illness is less serious, rather than waiting until a condition has reached a more advanced, critical stage. In addition, telemedical triage could prevent patients from using emergency rooms for minor

12. The American Medical Association observes that improved access to health care is the "major rationale" for federal funding. T. REGINALD HARRIS & GEORGE T. LUKEMEYER, AMERICAN MEDICAL ASS'N, *EVOLVING IMPACT OF TELEMEDICINE: JOINT REPORT OF COUNCIL ON MEDICAL SERVICE AND COUNCIL ON MEDICAL EDUCATION* 380 (June, 1994).

13. See *TELEMEDICINE BIBLIOGRAPHY*, *supra* note 1.

14. HARRIS & LUKEMEYER, *supra* note 12, at 380.

15. In addition to professional isolation, other significant barriers to recruiting or retaining physicians in these areas are income and lifestyle factors. *Id.*

16. President Clinton identified cost concerns as a principal impetus of his proposed Health Security Act. H.R. 3600, 103d Cong., 2d Sess. § 2(1) (1993) ("The Congress finds . . . [that] under the current health care system in the United States, continued escalation of health care costs threatens the economy of the United States, undermines the international competitiveness of the Nation, and strains Federal, State and local budgets.").

17. Many reference sources cited or consulted in preparing this article identify the potential for cost savings. A recent Arthur D. Little study estimated that telemedicine might reduce America's health care expenses by some \$30 billion annually. *Health Care*, in NATIONAL INFORMATION INFRASTRUCTURE TESTBED, THE UNFINISHED BUSINESS OF THE NIIT 19 (1996).

18. See *Technology*, *supra* note 5 (comments of Dena S. Puskin, Deputy Director of the Office of Rural Health Policy).

19. Leslie A. Sandberg, *Reflections on Building a Transitional Telemedicine Demonstration Network*, in *VISION BECOMES REALITY*, *supra* note 1, at 11.

ailments.<sup>20</sup> And, although treating patients rather than ignoring their health care needs will likely boost costs, enhanced health can create a more productive work force. Thus, a more robust economy is arguably "purchased" with these additional health care dollars.

Telemedicine's potential for cost savings is still being examined. For example, Medicare does not generally reimburse the cost of telephone calls used to diagnose or treat health conditions. However, the Health Care Financing Administration (HCFA) recently decided to reimburse these costs in certain telemedicine pilot programs funded by the Department of Health and Human Services,<sup>21</sup> hoping to determine whether telemedical services are cost effective.<sup>22</sup>

However, any cost analysis of telemedicine will be misleading if it focuses only on short-term costs, such as the potentially high cost of purchasing new equipment, and ignores the more intangible long-term benefits. Consider, for example, a nontelemedical device, the stent. While this device quadruples the cost of a regular angioplasty,<sup>23</sup> it can eliminate the need for further surgery often required after a regular angioplasty. Yet, because Medicare does not reimburse for the stent, hospitals are, in effect, encouraged to perform repeated angioplasties on a single patient at a possibly higher long-term cost to the Medicare program. Similarly, telemedicine has the potential to provide health care more efficiently, but only after a large capital outlay for the telemedical infrastructure. Furthermore, telemedicine has the potential to deliver other intangible benefits such as "improved patient care, improved service to referring physicians and a more rapid response to clinical needs,"<sup>24</sup> as well as "greater choice, convenience and control [by patients] over their lives."<sup>25</sup> These are important factors in assessing health care outcomes, and, while difficult to value in dollars and cents, must be included in any assessment of telemedicine's cost effectiveness.

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20. Bill Richards, *Telephone Triage Cuts Costly ER Visits*, WALL ST. J., Oct. 24, 1995, at B1.

21. See discussion *infra* note 28.

22. Neumann, *supra* note 10, at 8.

23. Ron Winslow, *Going for the Flow: Simple Device to Prop Clogged Arteries Open Changes Coronary Care; Johnson & Johnson's 'Stent' Is a Hit, but the Cost is Worrying Hospitals; Wearing a Sleeve on the Heart*, WALL ST. J., Oct. 23, 1995, at A1.

24. Alan H. Rowberg, *General Considerations*, in UNDERSTANDING TELERADIOLOGY, *supra* note 2, at 16.

25. Sandberg, *supra* note 19, at 11.

*Telemedical Issues*

While policymakers debate the potential costs and benefits of telemedicine, actual telemedical consultations are underway and demonstration projects are being conducted nationwide<sup>26</sup> both by private groups<sup>27</sup> and with the aid of government money.<sup>28</sup> This burgeoning use has raised concerns about sources for continued funding.<sup>29</sup> It has also prompted calls to remove barriers erected by a host of laws that never envisioned the telemedical

26. On September 20, 1994, the National Information Infrastructure Testbed (NIIT) conducted a demonstration project before members of Congress and the Clinton Administration, which it touted as the "first-ever cross-country medical information system integrating high-speed networks with satellite service to rural areas." Letter from Troy A. Eid, Executive Director, NIIT, accompanying NIIT document (Feb. 10, 1995) (on file with the *Annals of Health Law*). The demonstration "enabled primary care physicians and specialists located in geographically dispersed sites throughout the United States to engage in real-time collaboration over high speed communications networks, integrating medical, clinical and imaging information to support treatment planning." *Technical Backgrounder for NIIT Healthcare Demonstration*, in *VISION BECOMES REALITY*, *supra* note 1, at 65 [hereinafter *Technical Backgrounder*]. The NIIT is a consortium of more than 50 companies, academic institutions, and government agencies that are working together to accelerate the development of a national information infrastructure. The work of NIIT is not limited to health care issues. For information about other telemedical demonstration projects, see *TELEMEDICINE BIBLIOGRAPHY*, *supra* note 1.

27. The NIIT demonstration project was presented by a consortium of private industry and academia, as well as government and national laboratories. *NIIT Healthcare Demonstration: Network Components*, in *VISION BECOMES REALITY*, *supra* note 1, at 31. Privately funded projects tend to emphasize state-of-the-art equipment. Neumann, *supra* note 10, at 8. Such equipment was highlighted in the NIIT project.

28. In late 1992, Congress enacted a law designed to improve health care through telecommunications in rural areas. 7 U.S.C. § 950aaa-5 (1994). It addresses consultations between health care providers, transmitting and analyzing x-rays and other images, and innovative health care education programs. 7 U.S.C. § 950aaa-5(b)(6)(I) (1994). As of November, 1994, the Department of Health and Human Services (HHS) awarded \$4.5 million in grants to ten states for various rural telemedicine pilot projects and has promised some \$7.4 million in additional grants under the Rural Telemedicine Grant Program for fiscal year 1995. Unlike privately funded projects, federal government grants tend to encourage the use of low-cost technologies such as existing telephone lines, telephones, and fax machines. Neumann, *supra* note 10, at 8. See also the category "Grant Programs, Awards & Funding," in *TELEMEDICINE BIBLIOGRAPHY*, *supra* note 1.

29. One commentator has identified federal funding of telemedical practice as an "immediate concern" in the development of telemedical programs, technology, and equipment. Neumann, *supra* note 10, at 9. He notes that without the HHS pilot programs, the Health Care Financing Administration (HCFA) believes that it would be "unable to assess the effect of Medicare reimbursement for telemedicine consultations" and thus be "unwilling to relax the current restrictions" on these reimbursements. *Id.* Without government endorsement of these practices through its reimbursement program, third-party payers may be less likely to support such applications. This, in turn, could dampen the telecommunications industry's enthusiasm for new research and development. *Id.*

practice,<sup>30</sup> and to formulate new policy and new federal laws to address issues unique to this form of technological medical practice. There have been at least two recent attempts at federal legislation impacting telemedicine, one involving physician licensure and the other addressing confidentiality of medical records.

Perhaps the most significant barrier to a nationwide telemedical practice is the traditional system of state-by-state physician licensing. That is, a physician in State A may not be able to legally provide his services via telecommunications to a patient located in State B, unless he is licensed in both states. This prohibition stops teledoctors and telemedical applications at state borders. Representative Ronald Wyden (D-Or.) attempted unsuccessfully<sup>31</sup> to amend an early United States House of Representatives version of a bill that became the Telecommunications Act of 1996.<sup>32</sup> This amendment would have preempted state licensure laws, "free[ing] telemedicine from the regulatory morass which threatens to keep this technology from the American people."<sup>33</sup>

Another potential evil of telemedicine is the misuse of telecommunications, prompting concerns about privacy protection, including confidentiality of medical records transmitted via electronic networks. This problem is not unique to telemedicine since much patient data is now stored and transmitted electronically. However, two new federal laws—the Medical Records Confidentiality Act of 1995<sup>34</sup> and the Health Information Modernization and Security Act<sup>35</sup>—were proposed in 1995 to address these issues and will impact telemedicine if adopted.

Other oft-cited topics ripe for attention in the telemedical context are credentialing the remote physician, payment and reimbursement for telemedical consultations,<sup>36</sup> and standards of

30. Eid, *supra* note 1, at 46. Representative Pat Schroeder addressed the September 20, 1994, NIIT health care demonstration. She urged Congress, the Clinton Administration, and the states to remove legal barriers that impede widespread telemedical practice in the United States. *Id.*

31. 141 CONG. REC. E1392 (daily ed. June 30, 1995) (comments of Representative Ronald Wyden) [hereinafter Wyden Comments]. He withdrew the amendment at the behest of his colleagues, pending further study. *Id.*

32. Pub. L. No. 104-104, 110 Stat. 56 (1996).

33. Wyden Comments, *supra* note 31, at E1392.

34. S. 1360, 104th Cong., 1st Sess. (1995). This legislation proposed to preempt state law.

35. H.R. 1766, 104th Cong., 1st Sess. (1995). A companion Senate bill was also proposed. See S. 872, 104th Cong., 1st Sess. (1995).

36. Eid, *supra* note 1, at 49-51.

care and concomitant liability for telemedical procedures.<sup>37</sup> Additional practice-related issues include the availability of professional liability insurance for out-of-state services,<sup>38</sup> the unauthorized practice of medicine in a telemedical context, state taxation of out-of-state businesses, civil procedural rules in multistate disputes, informed consent for telemedical applications, and the power of the Food and Drug Administration (FDA) to regulate medical “devices” used to facilitate the practice of telemedicine.

Most of these practice issues are now governed at the state level. Thus, state law and its underlying policy goals are obvious targets of federal rule makers, particularly because the interstate potential of telemedicine allows the federal government to wield more power. However, states, by extending their historical primacy in medical practice regulation to address these issues, may also enter the fray both individually and collectively (using multistate approaches).

For example, the federal legislative efforts aimed at physician licensure and confidentiality, discussed above, may be met by individual state efforts. Twenty-eight states are reportedly involved in telemedicine in some respect, and eighteen have undertaken a “significant role.”<sup>39</sup> Also, in October, 1995, the Federation of State Medical Boards proposed “A Model Act to Regulate the Practice of Telemedicine or Medicine By Other Means Across State Lines.”<sup>40</sup> It is intended as uniform state leg-

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37. R. James Brenner, *Teleradiology Poses Host of Thorny Legal Issues*, DIAGNOSTIC IMAGING, Apr. 1994, at 37.

38. AMERICAN COLLEGE OF RADIOLOGY, ACR STANDARD FOR TELERADIOLOGY § V (Res. 21 1994).

39. *Telemedicine: Privacy, Confidentiality Important, But Can Be Overemphasized, Panel Agrees*, 3 BNA'S HEALTH CARE POL'Y REP. 1052 (1995) (comments of Tim Henderson, Director of Primary Care at The George Washington University's Inter-governmental Health Policy Project). For example, Kansas is reportedly interpreting its laws to require Kansas licensure for out-of-state teledoctors who provide primary diagnosis and treatment to in-state patients. *Eid, supra* note 1, at 50.

40. FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC., A MODEL ACT TO REGULATE THE PRACTICE OF TELEMEDICINE OR MEDICINE BY OTHER MEANS ACROSS STATE LINES: EXECUTIVE SUMMARY (1995) [hereinafter EXECUTIVE SUMMARY]; Telephone Interview with Theresa L. Huskey, Administrative Assistant for Public Relations/Education, Federation of State Medical Boards of the United States (Oct. 25, 1995).



isolation.<sup>41</sup> This multigovernmental approach will likely prompt federal-state tension.<sup>42</sup>

Although several commentators have listed legal issues potentially impacted by telemedical practice,<sup>43</sup> certain other practice issues have not been addressed, nor has there been discussion of federal principles that may hamper state regulatory responses to this industry when medical practice crosses state borders.<sup>44</sup> This article will examine these topics, including how the "New Federalism"<sup>45</sup> may impact the development of new telemedical policy. Before this discussion, however, this article begins by reviewing definitional aspects of telemedicine that will provide an organizational framework for the various medical practice issues.

## I. DEFINITIONAL ASPECTS OF TELEMEDICINE

Not unlike that infamous comment about obscenity, telemedical practice may be tough to define, but easy to identify. Consider this hypothetical:<sup>46</sup>

A vacationer is injured in a car accident while driving through a California desert. Over a computerized telecommunications network, a team of physicians including a rural doctor, specialists at the University of Southern California Medical Center, and the patient's personal physician at Johns Hopkins Univer-

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41. AN ACT TO REGULATE THE PRACTICE OF MEDICINE ACROSS STATE LINES (Federation of State Medical Boards of the United States, Inc. 1995) [hereinafter FSMB's ACT]. The Act addresses only one of the myriad of telemedical issues—licensure.

42. States may be aided in enforcing their licensing laws for this purpose, because at least one industry group recommends licensure in every state in which its specialists provide services. For example, the American College of Radiology recommends licensure for teleradiologists who provide the "official, authenticated interpretation of images" transmitted by teleradiology in both the transmitting and receiving states. ACR STANDARD FOR TELERADIOLOGY, *supra* note 38.

43. See, e.g., Eid, *supra* note 1, and Brenner, *supra* note 37.

44. The Center for the New West, an NIIT consultant, and the University of Southern California School of Medicine (also an NIIT member) proposed a national conference to be held in April of 1995, for the purpose of bringing together legal and medical experts to develop policy recommendations for telemedical practice. Eid, *supra* note 1, at 51. Personnel at NIIT report that the conference was canceled because it did not generate hoped-for interest.

45. "New Federalism" has been explained with terms such as "popular sovereignty," "civil competence," and "subsidiarity," and seeks to devolve federal government functions in favor of local control. See, e.g., Andy Bane, *The New Federalism: A Growing Grassroots Movement*, POINTS WEST CHRONICLE (Center for the New West, Wash., D.C.), Autumn 1994, at 4. See also discussion *infra* at Section III (A) (2).

46. The following summary is paraphrased from the NIIT health care demonstration held on September 20, 1994. See *Technical Backgrounder*, *supra* note 26, at 65-68.

sity Medical Center in Baltimore, share her prior medical records and currently generated medical images, and engage in real-time consultation to make a diagnosis and decide on treatment.

This is an obvious example of telemedicine and is the basis for working definitions of “telemedicine.” Since the practice is interdisciplinary—involving information technology and health care—these definitions come from disparate sources, each of which can highlight legal issues or unique facts that may be important when developing new policies or new laws for this emerging method of practicing medicine.

This section of the article will examine several such definitions.

### *A. Dictionary Definition*

“Tele-” means operating at a distance,<sup>47</sup> and “telemedicine” can thus be broadly defined as the practice of medicine over distances. In the time of Hippocrates,<sup>48</sup> remote medical practice was impossible—unless an ancient healer was willing to diagnose illness or prescribe treatment via foot messenger.<sup>49</sup> Even today, some 2400 years later, the typical patient meets the treating physician to be interviewed and palpated for at least part of the relationship. Telemedicine promises to radically alter that interaction by swapping the hands-on, face-to-face relationship for one separated by potentially vast spacial barriers between participants. Distance is the single most important factor in telemedical legal issues.

### *B. Industry Definitions*

#### *1. Information Industry Definition*

Because of its generality, defining telemedicine as practicing medicine over distances is not particularly descriptive. For example, telemedicine does not include nonelectronic communications between physician and patient over distances using correspondence via mail. Such a broad definition misses the

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47. WEBSTER’S DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 1873 (Encyclopedia ed. 1977).

48. Hippocrates lived from approximately 460 to 377 b.c. *Id.* at 862.

49. Reference to a foot messenger illustrates the *conduit* function of telemedicine. Presumably, the foot messenger is medically unskilled and merely relays information from one place to another, not unlike the technician-aided apparatus that actually transmits voice, video, and data over distances.

mark because the "defining aspect" of telemedicine is the transfer of information using electronic signals.<sup>50</sup> However, a definition incorporating the concept of electronic transfers is still very broad because it can encompass both informal diagnosis and treatment prescription for simple ailments over the telephone as well as the earlier example of high-tech telemedical application, which used supercomputers, workstations, satellite links, terrestrial networks, and expert software.<sup>51</sup>

The information industry incorporates the concept of electronic data transfer in its definition of telemedicine. It broadly defines telemedicine as the application of information technology to health care.<sup>52</sup> Information technology has two major components—systems to process information (computers) and systems to transmit that information (telecommunications). Thus, telemedicine uses computers and telecommunications to electronically transfer medical information over distances.<sup>53</sup>

Telemedicine has components in addition to direct physician-patient interactions. For example, the National Library of Medicine divides telemedicine into three areas: aids to decision making, remote sensing, and collaborative arrangements for the real-time management of patients at a distance.<sup>54</sup> The first category is the oldest in concept and includes remote expert systems used in patient diagnosis or on-line databases used in medical practice.<sup>55</sup> Remote sensing concerns transmittal of patient information and records between sites, as well as more general (nonpatient) uses such as medical education.<sup>56</sup> The latter is similarly mature: articles touting television for medical education go back some twenty-five years.<sup>57</sup> The last category, collaborative arrangements, describes real-time patient diagnosis and treatment.<sup>58</sup>

The information industry makes a similar distinction between real-time diagnosis and treatment and other aspects of telemedicine. Some authors define telemedicine as the real-

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50. See Wyden Comments, *supra* note 31.

51. *Technical Backgrounder*, *supra* note 26, at 67-68.

52. Eid, *supra* note 1, at 51.

53. Melvyn Greberman, et al., *Glossary*, in UNDERSTANDING TELERADIOLOGY, *supra* note 2, at 25.

54. *Series Notes*, in TELEMEDICINE BIBLIOGRAPHY, *supra* note 1.

55. *Id.*

56. *Id.*

57. See the category "Telemedicine in Education," in TELEMEDICINE BIBLIOGRAPHY, *supra* note 1.

58. *Id.*

time or near real-time transfer of medical information between places<sup>59</sup> for purposes of patient diagnosis and treatment. This definition provides a close substitute for the hands-on, face-to-face, real-time interaction of the traditional medical practice.

One information industry definition of telemedicine discloses another potentially significant factor affecting telemedical legal issues. Telemedicine requires a conduit between practitioner and patient to span the spacial barrier between them. That conduit—computers and telecommunications hardware and software—reduces information about a patient to bits and bytes,<sup>60</sup> which are transmitted over the spacial barrier and “re-constructed” for viewing and interpretation at the receiving end. Consultation about that information is also “translated” back and forth over that barrier. Thus, in addition to a distance barrier, telemedicine employs a nonhuman conduit.

For example, with traditional radiology, medically trained technicians might include certified technologists and physicists who operate, supervise, and evaluate radiological systems and aid in quality control. However, teleradiology can also require participation from computer technicians and telecommunications experts who possess nonmedical expertise.<sup>61</sup> Thus, telemedicine may employ technicians and other personnel possessing either lesser medical credentials than traditional practitioners or no medical expertise<sup>62</sup> to aid in transmitting information for medical treatment and diagnosis.

Also, the use of two or more sites—the patient’s location and the remote physician site—as well as transmitting stations along the way<sup>63</sup> suggests the need for these additional personnel.

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59. Tanya Freeman & Barbara Southern, *Telemedicine and CHINS: Interviews With Two Experts*, J. AM. HEALTH INFO. MGMT. ASS’N, Aug. 1994, at 40.

60. The smallest unit of computer data is a “bit.” “Bit” is a contraction for *binary digit*. A byte is a “word” consisting of eight bits, which is the unit of data with which most computers work. PETER NORTON, *INSIDE THE PC* 318-19 (1995).

61. ACR STANDARD FOR TELERADIOLOGY, *supra* note 38, at § III(B) and (C).

62. For example, in the NIIT demonstration project described above, the several physicians were aided by technical (nonmedical) support furnished by AT&T, Hewlett-Packard Company, Hughes Aircraft Company, NASA’s Jet Propulsion Laboratory, Lawrence Livermore National Laboratory, Network Systems Corporation, Pacific Bell, Polaroid Corporation, SynOptics Communications (now Bay Networks), USC/LAC Medical Center, and WilTel. *Participants’ Backgrounder for NIIT Healthcare Demonstration*, in *VISION BECOMES REALITY*, *supra* note 1, at 55 [hereinafter *Participants’ Backgrounder*]. In teleradiology, engineers and communications or image systems specialists are recommended to operate and evaluate teleradiology systems. ACR STANDARD FOR TELERADIOLOGY, *supra* note 38, at § III(D).

63. See *Technical Backgrounder*, *supra* note 26, at 65, 67.

Although the traditional physician visit *could* involve the physician and patient alone, telemedicine usually *requires* both machines and possibly human conduits to facilitate the encounter.

## 2. Medical Industry Definition

While the information industry focuses on the kinds of technology available to telemedicine, from a practitioner's perspective, telemedicine *merely allows the practitioner to practice medicine in the normal manner*. Thus, telemedical procedures provide a working environment for the health care practitioner similar in many respects to the traditional one.<sup>64</sup> From this perspective, telemedicine is neither a new diagnostic tool<sup>65</sup> nor a new treatment modality.<sup>66</sup> Although telemedicine uses technology to facilitate diagnosis or treatment,<sup>67</sup> it is designed to transmit to a remote location the same kind of information that is normally available "in person." As such, a physician deliberates in substantially the same manner as if the patient were present in the doctor's offices, and the *substance* of the interaction is largely unaffected.<sup>68</sup>

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64. See generally ACR STANDARD FOR TELERADIOLOGY, *supra* note 38.

65. For example, computerized tomography (CT) is an x-ray technique that creates medical images from an original source: the patient. *Application Backgrounder for NIIT Healthcare Demonstration*, in VISION BECOMES REALITY, *supra* note 1, at 61-64 [hereinafter *Application Backgrounder*]. Telemedical procedures merely transmit the original CT image over spacial barriers. Rowberg, *General Considerations*, *supra* note 24, at 15. Although that image may be manipulated or enhanced during the telemedical consultation, the raw data are first collected and then digitized for transmission over the telemedical link. Alan H. Rowberg et al., *Technical Factors in Teleradiology*, in UNDERSTANDING TELERADIOLOGY, *supra* note 2, at 11-14. Thus, the remote teleradiologist views substantially the same image as seen on site.

66. X-rays can be used passively, to generate information for diagnostic purposes. X-rays can also be used actively, to therapeutically destroy damaged tissue. *Application Backgrounder*, *supra* note 65, at 63. Telemedicine is passive and involves the transmission of information. It can transmit x-ray images used for diagnostic purposes but cannot now be used for therapeutic services. Thus, telemedicine does not provide treatments that are not now available in the traditional practice.

67. The NIIT demonstration project established a prototype national medical information network utilizing existing communications and computing technologies, including satellite and high-speed digital switching technology communications systems as well as computer hardware and software for the simultaneous transmission of video, voice, and data. *Technical Backgrounder*, *supra* note 26, at 65-68. Although this demonstration included the use of very sophisticated technology, *see id.*, actual telemedicine applications often include less ambitious methods such as the unidirectional transmission of images without real-time voice consultation using a dial-up modem over ordinary telephone lines. Rowberg, *General Considerations*, *supra* note 24, at 16-17.

68. Consider the Pandora's box if the various components of telemedical technology are considered to be new medical *devices*. As such, they could be subject to

A medical industry definition of telemedicine suggests other factors, in addition to those disclosed by an information industry definition. First, because telemedicine affects the medical process but does nothing particularly new *medically*, it provides a substitute for that process. Telemedicine does not supplant the actors, physician and patient, but substitutes technology, intermediaries, and distance for the more traditional face-to-face interaction. To avoid falling short of the required standard of care, however, telemedicine must provide a substitute of sufficient quality for the traditional medical process it seeks to replace.<sup>69</sup>

Second, telemedicine promises to provide medical expertise for unserved and underserved areas. Although it could be used for consultations between peers, telemedicine's highest utility achieves links between rural areas and urban ones, primary care physicians with specialists, and nonphysician practitioners with physicians, generally connecting participants with unequal knowledge and expertise to further a team approach to comprehensive patient care.<sup>70</sup> Thus, it facilitates synergy in medical practice.

Finally, telemedicine is also a consultative endeavor. A referring physician can choose a teledoctor for specific services in a manner similar to that of a health care practitioner seeking a consulting physician or a second opinion.

### C. Summary

The preceding discussion has examined definitions of telemedicine from various sources. These definitions indicate that telemedicine uses a *conduit* to transmit patient information over *distances* to permit the physician to practice medicine from a remote location. In the example cited at the beginning of this section, the computer screen in the remote radiologist's office can receive a limb x-ray from the accident victim, allowing the radiologist to diagnose the injury to the leg. Based on this diagnosis, the remote radiologist and local practitioner can decide

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regulation by the Food and Drug Administration. See discussion *infra* section II(D)(1).

69. *Introduction to ACR STANDARD FOR TELERADIOLOGY*, *supra* note 38.

70. Sandberg, *supra* note 19, at 11-12. See also, Freeman & Southern, *supra* note 59, at 40. A team approach to medical care is not particularly new. For example, a doctor and nurse constitute a common and traditional kind of medical team. Rather, telemedicine extends the team over greater distances and has the potential to include as team members participants who were previously unavailable.

on the proper course of treatment. Additional examples of telemedical applications abound.

Computers are well suited for the imaging needs of the radiologist. In fact, they can "become" the radiologist's eyes by using a computer system to interpret images such as mammograms.<sup>71</sup> The machine's ability to access or store vast amounts of information and its precise "hand" make computers attractive to other specialties as well. Computers can become active participants in surgery. They can plan craniofacial surgery. Robotic devices can actually assist in laparoscopic surgery and can sometimes assume solo surgical duties such as gallbladder operations. When local practitioners do not possess expertise in tumor typing, telepathologists can view cross-sections of tissue samples and access computer network databases to facilitate diagnosis, and can then transmit their findings to the attending physician. Telepsychiatrists can test adult psychiatric patients remotely or conduct their sessions interactively through a television. A fetal heart rate can be monitored by a remote pediatric cardiologist via a facsimile machine to assist a midwife attending a rural delivery. And message systems rather than humans can inform patients of their laboratory test results by telephone.

Since the physician is still practicing medicine in all these examples,<sup>72</sup> albeit from a different "piece of geography," telemedicine provides a *substitute* for the traditional health care encounter. It uses *consultation* between remote and attending health care providers in a *synergistic* approach to health care. All of the factors encompassed by both information industry and medical industry definitions of telemedicine correlate to various practice issues pertinent to telemedicine. These practice issues will be examined in the next section of this article.

## II. PRACTICE ISSUES IN TELEMEDICINE

As noted in the preceding discussion, telemedicine provides a substitute for aspects of traditional medical practice by utilizing conduits to transmit information over distances between consulting physicians who provide a synergistic approach to diagnosis and treatment. These factors raise new legal issues and recast familiar issues with new facts.

71. Carl J. Vyborny & Maryellen L. Giger, *Computer Vision and Artificial Intelligence in Mammography*, 3 AM. J. ROENTGENOLOGY 699 (1994).

72. These examples have been taken from various articles appearing in TELEMEDICINE BIBLIOGRAPHY, *supra* note 1.

### A. Overview

More than one technique can be used to categorize medical practice issues in a telemedical context. Also, attempts to distinguish interrelated practice issues—such as licensure (required to practice) and unauthorized practice (when a license is lacking)—may oversimplify any arrangement or make it artificial. This portion of the article assigns various practice issues to the categories developed from telemedical definitions in the previous section as a way to approach these topics.

The following table indicates the location of the discussion on each of these practice issues appearing in this article.

TELEMEDICAL FACTOR	PRACTICE ISSUE	REFERENCED AT
Distance	Licensure	§ II(B)(1)
	Unauthorized Practice	§ II(B)(1)
	Credentiailling	§ II(B)
	Privacy Protection	§ II(B)
	State Taxation	§ II(B)(2)
	Malpractice Insurance	§ II(B)
	Civil Procedural Rules	§ II(B)(3)
Substitute	Informed Consent	§ II(C)(1)
	Standard of Care	§ II(C), notes 145, 154
Conduit	Unauthorized Practice	§ II(D)
	Products Liability	Note 161
	Medical “Devices”	§ II(D)
Consultation and Synergy	Payment for Services	§ Introduction (A)
	Malpractice	Note 76
	Vicarious Liability	Note 76
	Joint and Several Liability	Note 76
	Corporate Liability	Note 76

Several of the issues listed above, such as licensure, privacy protection, and standard of care, have already been addressed by other commentators,<sup>73</sup> and this paper will not attempt to duplicate their work. However, certain aspects of these issues have not yet been examined in the telemedical context, and the following discussion will address some of these unexplored areas. Other issues addressed in this article have been relatively unexplored from the standpoint of telemedicine. These issues include state taxation of telemedical practitioners, civil procedural rules, informed consent, unauthorized practice of telemedicine by nonmedical personnel, and FDA regulation of

73. See, e.g., Eid, *supra* note 1; Brenner, *supra* note 37.



devices used to practice telemedicine. The discussion begins with various "distance-related" issues including licensure, which is arguably the most significant factor that impacts the future growth of telemedicine.

### B. Distance

Distance is the single most important factor in telemedical issues. It affects many practice issues; licensure may be the most significant. Without authority to practice medicine in another state, practitioners could be stopped at their home state borders because unlicensed practitioners can go to jail.<sup>74</sup> In this regard, varying state definitions about what constitutes the practice of medicine complicate the issue. In any event, the risk of unauthorized practice sharply inhibits a broad use of telemedicine.<sup>75</sup>

Credentialling is an issue closely related to licensure. Because of the potential for vicarious liability<sup>76</sup> and corporate liability,<sup>77</sup> hospitals and other health care institutions must assure the competence of physicians and others who treat their patients. Thus, they are well advised to credential nonstaff telemedical physicians who consult with hospital practitioners.<sup>78</sup>

Privacy protection has been called "the best-known and potentially greatest challenge to interstate telemedicine."<sup>79</sup> It arises as a "distance" issue because of the need to transmit

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74. See, e.g., 225 ILCS 60/59 (1993).

75. Many of the current telemedical consultations are conducted within states, no doubt due to the constraints imposed on state-by-state licensure. See the category "Telemedical Applications, Named Projects," in *TELEMEDICINE BIBLIOGRAPHY*, *supra* note 1.

76. See *Richmond County Hosp. Auth. v. Brown*, 361 S.E.2d 164 (Ga. 1987). Medical practice is generally a consultative endeavor, utilizing many persons, institutions, and entities with differing roles, skills, and professional levels. Such parties may be jointly and severally liable under existing law, or one party may be vicariously liable for the errors of others, such as in an employment or apparent agency context. Legal relationships involving the remote teledoctor are likely to raise similar principles. See, e.g., George E. Stevens, *Malpractice Liability of a Referring Physician*, 32 *MED. TRIAL TECH. Q.* 121 (1986). Liability of telecommunication network service providers might also arise, raising issues of regulated and nonregulated common carriers and their immunities from lawsuits. See also Eid, *supra* note 1, at 49-50.

77. See *Darling v. Charleston Community Memorial Hosp.*, 211 N.E.2d 253 (Ill. 1965), *cert. denied*, 383 U.S. 946 (1966).

78. The American College of Radiology, which has established standards for its doctors in relation to licensure, also recommends credentialling teledoctors under the receiving (remote) hospital's medical staff bylaws. *ACR STANDARD FOR TELERADIOLOGY*, *supra* note 38, at § V.

79. Eid, *supra* note 1, at 47. Elements of this issue include transmission, storage, and retrieval of patient information across state lines and involve user verification, authentication, security, and data integrity. *Id.* See also *ACR STANDARD FOR TELER-*

records, potentially over vast distances. Concerns develop where transmission lines are not secure. However, some experts believe that perceived problems are overemphasized, because privacy protection of medical records is hardly assured now.<sup>80</sup>

The state taxation of out-of-state businesses and the state regulation of and coverage provided by malpractice insurance companies are also "distance" issues.<sup>81</sup> Finally, a whole host of civil procedural rules and doctrines that determine *where* someone may be sued and which rules (state or federal) will apply to resolve the dispute round out the issues that arise from the telemedical fact that distance exists between the principal actors.<sup>82</sup>

## 1. Licensure

### a. Physician Licensure

A person who practices medicine without a license to do so violates state medical practice or licensing statutes, which control entry into the medical profession<sup>83</sup> and provide disciplinary sanctions.<sup>84</sup> The license comes from the state, exercising its police power to protect the health and safety of its citizens.<sup>85</sup> De-

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ADIOLOGY, *supra* note 38, at § IV(5); Molla S. Donaldson, *Health Data: Disclosure, Protection, and Privacy*, J. AM. HEALTH INFO. MGMT. ASS'N, July 1994, at 22-27.

80. Some experts believe that efforts to assure a perfect system of medical record confidentiality in electronic transmission could create obstacles to developing telemedical systems. Acknowledging that present systems do not assure full protection of the privacy of all patients, former United States Surgeon General C. Everett Koop has suggested: "Let's not try to create a standard that doesn't exist now." *Telemedicine: Privacy, Confidentiality Important*, *supra* note 39, at 1051.

81. Insurance policies often assume single-state practice. Professional bodies recommend that teledoctors review their professional liability coverage to determine if it applies to telemedical services. ACR STANDARD FOR TELERADIOLOGY, *supra* note 38 at § V.

82. The distance factor may not change the basic physician-patient relationship. A physician-patient relationship may be said to arise where a doctor performs one or more of the following functions: examines, diagnoses, or treats a patient. Although knowledge or consent may be involved, it is not strictly necessary since an unconscious patient or otherwise incompetent person is no less a patient of the treating doctor than one who has formally consented. See *Golden v. Kishwaukee Community Health Servs. Ctr., Inc.*, 645 N.E.2d 319 (Ill. App. Ct. 1994) (upholding part of the jury's verdict in an alleged malpractice and vicarious liability case and remanding some of the issues of liability back to the circuit court for adjudication). Accordingly, the distance separating the patient from the remote teledoctor should not particularly impact whether a doctor-patient relationship with the teledoctor exists.

83. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 523 (1934).

84. See, e.g., Medical Practice Act of 1987, 225 ILCS 60/1-63 (1993).

85. For example, the State of Illinois allows allopathic, chiropractic, and osteopathic physicians to practice. 225 ILCS 60/11 (1993). This would exclude homeopaths

spite this state-centered control of medical practice, disease is not limited by state borders; medical "centers of excellence," such as the Mayo Clinic, serve multistate regions rather than single state territories;<sup>86</sup> and telemedicine can traverse state boundaries in an instant. Some commentators argue that these facts make state-by-state licensure obsolete.

To avoid requiring teledoctors to be licensed in each state where they treat patients,<sup>87</sup> some commentators recommend adopting a national licensing statute for telemedicine akin to the system used in the United States military.<sup>88</sup> Essentially, a physician is qualified to practice medicine for the armed forces, regardless of location, so long as the physician is legally licensed to practice in any state.<sup>89</sup> One rationale for a national licensing system is based upon the fact that components of the physician licensure examination are standard throughout the nation.<sup>90</sup> In addition, there is greater uniformity among state licensure requirements, and, thus, it may be "illogical to have a system of individual state licensure in the first place."<sup>91</sup> This approach to telemedical licensing is embodied in Representative Wyden's failed amendment to the recently enacted telecommunications bill.<sup>92</sup> It would have allowed physicians licensed in one state to

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(doctors who perform treatment based "on the theory that large doses of a certain drug given to a healthy person will produce certain conditions which, when occurring spontaneously as symptoms of a disease, are relieved by the same drug in small doses"). In re Guess, 393 S.E.2d 833, 834 (N.C. 1990) (citing STEDMAN'S MEDICAL DICTIONARY 654 (24th ed. 1982)). It also would exclude reflexologists (doctors who perform treatment "based on the theory that the human body has designed nerve zones" ending in the feet; they believe that ailments can be cured by rubbing the applicable reflex area. *Evans v. Hoyme*, 105 N.W.2d 71 (S.D. 1960)).

86. See Wyden Comments, *supra* note 31, at E1392-93.

87. For a general discussion of various state medical licensure statutes and regulations in a telemedical context, see Howard J. Young & Robert J. Waters, *Licensure Barriers to the Interstate Use of Telemedicine*, TELEMEDICINE: NEWSLETTER (Arent, Fox, Kintner, Plotkin & Kahn, Washington, D.C.), Issue 1, 1995, at 1 (on file with the *Annals of Health Law*) (available at <http://www.arentfox.com/telemed.5.html>) [hereinafter Arent, Fox Newsletter].

88. Eid, *supra* note 1, at 50.

89. 10 U.S.C. §§ 1094(a)(1), (d)(1)(A) (1994). Foreign national physicians who render services to the armed forces need only be licensed in their native country. 10 U.S.C. §§ 1094(a)(1), (d)(1)(B) (1994).

90. Eid, *supra* note 1, at 50. These include the examination of the National Board of Medical Examiners or the Federal Licensure Exam. See Arent, Fox Newsletter, *supra* note 87.

91. *Id.* (quoting testimony of Professor Jay H. Sanders, Medical College of Georgia, before the Subcommittee on Oversight & Operations, House Committee on Veterans Affairs (July 20, 1994)).

92. See Wyden Comments, *supra* note 31.

conduct telemedical consultations with licensed health care practitioners in any other state.

In arguing for his amendment, Representative Wyden rejected as too restrictive for broad telemedical applications the limited exceptions to state-specific licensure currently afforded, which allow physicians to occasionally practice in other states. For example, some states recognize "consultative" exceptions, which permit an out-of-state practitioner to consult there.<sup>93</sup> However, this exception is usually limited in duration and often requires the presence of a licensed practitioner in that state.<sup>94</sup> Furthermore, some states are prohibiting the use of this exception for telemedical applications.<sup>95</sup> Other exceptions, such as licensure of out-of-state physicians either by reciprocity or by endorsement, are equally restrictive. Licensure by reciprocity is "rarely" used,<sup>96</sup> and licensure by endorsement requires "applications, personal interviews, fees, pictures, school and hospital records and even letters from locally licensed physicians . . . to each state where a license is required."<sup>97</sup>

In addition to these, some states also permit "emergency" exceptions, which allow a physician who holds an active license in another state to become involved in preparing a patient for interstate transit.<sup>98</sup> Emergency exceptions also permit doctors to render gratuitous services in emergencies under "Good Samaritan" laws.<sup>99</sup> However, these exemptions suffer the same shortcomings as those noted above because they do not accommodate routine telemedical applications by out-of-state practitioners on an ongoing basis.

In contrast to the "military licensure" approach adopted by Representative Wyden's unsuccessful federal legislation, the Federation of State Medical Boards (FSMB) is working on a uniform state law that provides for a "special" state-issued li-

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93. *Id.* See, e.g., TEX. REV. CIV. STAT. ANN. art. 4495(b), § 3.06(b)(11) (West Supp. 1996).

94. Wyden Comments, *supra* note 31, at E1392.

95. *Id.*

96. *Id.* Indiana allows reciprocity for physician licensure by waiving examination requirements provided the applicant has performed successfully on an examination taken in another state. IND. CODE ANN. § 25-22.5-5-2(a)(2)(A) (West 1993). However, this option is available only where the other state's examination is "equivalent in every respect" to the Indiana examination. *Id.*

97. *Id.* See, e.g., TEX. REV. CIV. STAT. ANN. art. 4495(b), § 3.0305(a) (West Supp. 1996).

98. See, e.g., 225 ILCS 60/3 (1993).

99. See, e.g., *id.* at 60/4 (1993).

cense for telemedical practitioners.<sup>100</sup> Unlike Representative Wyden's proposal, which would have *exempted* out-of-state practitioners from also being licensed in the remote state where the patient is located, the FSMB proposal would require licensure in the remote state. The FSMB proposal is an "abbreviated" license,<sup>101</sup> called a "license limited to the practice of medicine across state lines."<sup>102</sup> It would authorize a physician physically located outside a state to render medical care by "transmission of individual patient data by electronic or other means from within" that state,<sup>103</sup> but does not contemplate licensure in emergencies or where services are provided in informal, irregular, or uncompensated instances.<sup>104</sup> The law of the patient's state would apply to most aspects of the telemedical interaction, including such matters as what constitutes the practice of medicine, discipline of the remote physician, and patient confidentiality.<sup>105</sup> These provisions are intended to protect the patient.<sup>106</sup>

There are legitimate concerns about allowing licensed physicians to enter other states via telecommunications. However, nonmedical technicians or persons possessing lesser medical credentials may become more involved in telemedical application too. Whether new kinds of ancillary personnel must also be licensed, and who will license them and where they will be licensed are issues related to physician licensure.

### *b. Other Medical Licensure*

Activities undertaken by nonphysician telemedical assistants may fall under the usually broad language that describes the "practice of telemedicine" and, thus, raise licensure issues. Generally speaking, each state is free to define for itself, through its legislature and courts, what constitutes the practice of medicine. Many activities can fall within the nonphysician medical licensure category.

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100. EXECUTIVE SUMMARY, *supra* note 40, at 3.

101. *Id.*

102. FSMB's ACT, *supra* note 41, at 2, "Issuance of License."

103. *Id.* at 1, "Definition." If that out-of-state physician traveled to the patient's state to render care, he would be subject to the normal licensing rules. EXECUTIVE SUMMARY, *supra* note 40, at 3.

104. FSMB's ACT, *supra* note 41, at 1, "License Requirement."

105. EXECUTIVE SUMMARY, *supra* note 40, at 4-5.

106. *Id.* at 3.

For example, acupuncture may fall within the medical practice license in some jurisdictions, but not others, as might tattooing or ear piercing.<sup>107</sup> Midwifery is another example where states treat medical licensure differently. Some states license midwife practitioners and exclude their services from the statutory definition of medical practice,<sup>108</sup> while others do not.<sup>109</sup> In Florida, naturopaths are licensed to use a variety of techniques including dietetics, external applications, suggestotherapy, hygiene, first aid, and sanitation<sup>110</sup> while “purifying, cleansing, and normalizing human tissues for the preservation or restoration of health.”<sup>111</sup> Services such as nutrition counseling, massage, and hypnosis, which arguably fall within these statutory examples, are often provided by persons without any kind of medical-related license.

Some states, such as Illinois, license “physician assistants”<sup>112</sup> who are permitted to provide, under the supervision of a physician, various types of care that fall within the definition of that state’s medical practice statute.<sup>113</sup> However, a physician’s presence may not be strictly required as long as there is “communication available for consultation by radio, telephone or telecommunications”<sup>114</sup> between the physician and the assistant. This statutorily authorized mode of communication implicitly regards Illinois physician assistants as telemedical practitioners. Furthermore, Illinois physician assistants are expressly author-

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107. An Indiana statute defines the practice of medicine in that State as:

(1) Holding oneself out to the public as being engaged in (A) the diagnosis, treatment, correction, or prevention of any disease, ailment, defect, injury, infirmity, deformity, pain, or other condition of human beings; (B) the suggestion, recommendation, or prescription or administration of any form of treatment, without limitation; (C) the performing of any kind of surgical operation upon a human being, *including tattooing, . . . or the penetration of the skin or body orifice by any means*, for the intended palliation, relief, or cure; or (D) the prevention of any physical, mental, or functional ailment or defect of any person . . . .

IND. CODE ANN. § 25-22.5-1-1.1 (West 1993) (emphasis added).

108. Colorado is one state that does this. See COLO. REV. STAT. ANN. § 12-36-106(f) (West 1990).

109. Illinois does not license midwives. Presumably, their services fall within the Medical Practice Act. A case under an old Illinois Medical Practice Act, which expressly prohibited the unlicensed practice of midwifery, made a distinction between assisting at birth and physically removing or extracting a baby from the mother’s womb. See *People v. Jihan*, 537 N.E.2d 751 (Ill. 1989).

110. FLA. STAT. ANN. § 462.01(1) (West 1991).

111. *Id.*

112. See, e.g., 225 ILCS 95/1 (1993).

113. *Id.* at 95/4(3) (1993).

114. *Id.*

ized to provide health care to underserved populations in jails and prisons<sup>115</sup>—populations traditionally targeted for telemedical services.

Just as physicians may be stopped at state borders by the state-by-state system of medical licensure, nonphysician medical practitioners may be similarly curtailed. Additionally, the status of such personnel may be more uncertain because some states do not recognize their expertise, or require that their services be rendered solely by doctors. Hence the use of nonphysician practitioners raises additional issues for telemedicine.

Beyond the use of physician assistants and other medically trained personnel who are *not* doctors, telemedicine has the potential to utilize personnel completely outside traditional areas of medical practice. For example, telesurgery may one day be routinely possible and scalpelless surgery using a “gamma knife,” which focuses radiation to excise brain tissue,<sup>116</sup> might be guided from across state lines rather than from across an operating room. Depending on the degree to which such surgical functions become more precisely controlled by machines than human hands, nonphysician human technicians or even computer software may ultimately perform these functions. Consider, then, the telecommunications software expert as an integral part of the telesurgical team. Such a possibility raises the prospect that software designers and other telecommunications experts may need to be licensed in a manner similar to that of the physician assistant. After all, one government agency—the FDA—regulates software utilized in medical procedures. It may not be a far jump to license its creator as well.

This potential for substituting technicians or nonhuman intelligence for physicians raises potentially new issues about nonphysicians *or machines* engaging in the authorized practice of medicine, as that practice is traditionally understood today.<sup>117</sup> Whether this will change the nature or scope of medical-related

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115. *Id.* at 95/8 (1993).

116. Stephen D. Moore, *Elekta Studies New Gamma-Knife Uses by Launching Clinical-Trial Program*, WALL ST. J., Dec. 22, 1995, at A4.

117. The medical industry definition of telemedicine, developed in an earlier section of this article, suggests that telemedicine is not a new kind of medical practice as much as it is a new way to perform traditional activities. Accordingly, whether current telemedical practice now falls within statutory definitions of practicing medicine should be easily resolved on the basis of the underlying services provided, for example, radiology.

licensure is presently unclear. However, it will likely complicate the topic.

## 2. State Taxation

Where states have enacted an income tax, that tax is usually levied on income allocable to that state.<sup>118</sup> The state taxes the income of its residents.<sup>119</sup> Income derived by nonresidents from activities performed wholly or mostly within a state may be taxable in that state.<sup>120</sup> Other taxes may be levied on telemedical practices; for example, many states have sales or use taxes, which affect in-state transactions by out-of-state residents. Multistate distances involved in telemedical practice raise the potential of telepractitioners paying taxes in other states. Thus, the remote teledoctor sitting in one state may owe income tax to another.

There must be a definite link between a state and the person, property, or transaction that the state seeks to tax.<sup>121</sup> Yet, physical presence is not strictly required, particularly because “it is an inescapable fact of modern commercial life that a substantial amount of business is transacted solely by wire communications across state lines.”<sup>122</sup> Accordingly, state taxes are usually not restricted to taxpayers with physical assets in the taxing state.

A remote state may tax a nonresident who does not live there, maintains no offices there, and has no employees there.<sup>123</sup> Soliciting business in a state through telecommunications<sup>124</sup> or using software in the state may be sufficient to subject a transaction to tax under a statute’s literal language.<sup>125</sup> And transactions handled through intermediaries located in the state who actually effect the transaction using parties *outside* the state may be taxable.<sup>126</sup> Provided that the connections to the taxing state are

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118. See, e.g., 35 ILCS 5/202 (1993).

119. See, e.g., *id.* at 5/301(a) (1993).

120. See, e.g., *id.* at (a)(3)(C)(ii) (1993).

121. *Quill Corp. v. North Dakota*, 504 U.S. 298, 306 (1992) (citing *Miller Bros. Co. v. Maryland*, 347 U.S. 340, 344-45 (1954)).

122. *Id.* at 308 (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 476 (1985)).

123. *Id.*

124. See, e.g., 35 ILCS 110/2 (1993) and the definition of “[s]erviceman maintaining a place of business in this State.” On the other hand, mere solicitation of business may not be enough for this purpose. *Quill*, 504 U.S. at 316 n.9 (citing 15 U.S.C. § 381).

125. See, e.g., 35 ILCS 110/3 (1993).

126. For example, the Illinois Retailers’ Occupation Tax makes specific reference to Illinois florists who receive purchase orders, but who use florists in another state to



more than incidental,<sup>127</sup> a person such as a teledoctor may be taxed in another state for doing business there. In this connection, state taxing bodies may entertain creative arguments that favor taxing remote teledoctors, such as the argument that patients are "electronically transported"<sup>128</sup> to the teledoctor's office through telecommunications, or vice versa.<sup>129</sup>

Novel tax law interpretations, such as this developed for cyberspace, as well as routine interpretations of existing tax law provisions could prompt state revenue officers to levy taxes on nonresident teledoctors for procedures performed on in-state residents. In fact, one state has already tried, but recently failed, because the nonresident was impermissibly taxed twice on the same income.<sup>130</sup> If states can successfully maneuver through the complex issue of multistate taxation,<sup>131</sup> telemedical transactions may fall prey to tax laws outside the practitioner's home state. This could increase and complicate the cost of doing telemedical business.

### 3. Civil Procedure Rules

Where all of the relevant actors and actions that give rise to a legal claim are located in the same state, the parties will appear before a court in that state, which will apply that state's substantive and procedural laws. That is, it is a wholly internal matter

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fill those orders. 35 ILCS 120/1 (1993). Such transactions are taxable under this statute.

127. *Quill*, 504 U.S. at 306.

128. *Eid*, *supra* note 1, at 50.

129. *But see* Wyden Comments, *supra* note 31, at E1392 (quoting an American Telemedicine Association report stating that the concept of teletransportation of a patient to the physician's home state is a legal fiction, which likely would not be respected by "a majority of state courts").

130. *State Court Rules Unconstitutional Minnesota Tax on Out-of-State Providers*, 3 BNA'S HEALTH LAW REPORTER 1370-71 (1994) (discussing *Baertsch v. Minnesota Dep't of Revenue*, No. C7-93-2680 (D. Minn. Sept. 14, 1994)).

131. In addition to the workings of individual state tax levies, both the Commerce Clause, U.S. CONST. art. I, § 8, cl. 3, and concepts of procedural due process may limit the reach of state taxing authorities. For example, the Illinois Service Occupation Tax Act provides that its tax may not be imposed "upon the privilege of engaging in any business in Interstate Commerce or otherwise, which . . . may not, under the Constitution and Statutes of the United States, be made the subject of taxation by this State." 35 ILCS 145/3(d) (1993). The effect of state regulation on the national economy is examined when interstate commerce is involved. *See Quill*, 504 U.S. at 312. This contrasts with due process considerations, which tend to look at fairness and one individual's connection with a state. *Id.* at 315. Whereas factual connections between a transaction and a state may permit a tax under the due process test, the tax may nevertheless fail because of the commercial burden it imposes. *Id.* at 306. A more detailed examination of this topic is beyond the scope of this article.

for that state. However, where actors are located and actions performed in more than one state, laws may conflict, and the court must decide which state may assert jurisdiction and which state's laws will apply. In a medical context, for example, if State A caps noneconomic damages but State B does not, an injured patient may prefer State B's law to apply while the physician (and the insurer) would naturally favor the other state. A threshold question is whether one state can assert jurisdiction over another state's physician. Where citizens of more than one state become embroiled in a dispute, special rules determine whether and how each interested state may become involved or otherwise exert extraterritorial power to adjudicate the matter. Because of this multistate involvement, multiple forums—including federal courts—may become available, and telemedical practitioners will have to be prepared to be summoned to a remote state to resolve disputes.<sup>132</sup>

Principles of civil procedure govern all these matters. The concept of multistate torts is not unique to medical transactions, and there is a well-developed body of law to address matters such as which state is the proper forum, which court has jurisdiction over the parties, and which state's substantive laws will apply. The American Law Institute (ALI) has proposed one uniform approach to multiparty, multiforum "mass tort" lawsuits,<sup>133</sup> the "Complex Litigation Project."<sup>134</sup> The first tentative

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132. A plaintiff may be permitted to summon a nonresident defendant to the plaintiff's state either because the defendant has transacted business in that state, has committed a tortious act there, uses real estate in the state, or has performed a contract or promise connected to that state. *See, e.g.*, 735 ILCS 5/2-209(a)(1)-(3), (7) (1993). In such instances, the plaintiff is taking advantage of a rule that says the remote defendant has submitted to the jurisdiction of the plaintiff's local courts. This concept is appropriately titled "long-arm" jurisdiction because one state moves beyond its borders to reach another state's citizen. The United States Supreme Court validated this procedure in *International Shoe Co. v. Washington*, 326 U.S. 310, 319 (1945). In that case, the Court held that it was fair to permit a state to exercise jurisdiction over a nonresident where that person

exercises the privilege of conducting activities within a state, [because the person] enjoys the benefits and protection of the laws of that state. The exercise of that privilege may give rise to obligations, and, so far as those obligations arise out of or are connected with the activities within the state, a procedure which requires [the defendant] to respond to a suit brought to enforce them can, in most instances, hardly be said to be undue.

*Id.* at 319. States have often resorted to legal fiction to find "consent" by a nonresident to service and suit in a state. *Id.* at 318. Consider "teletransportation" of a teledoctor to the patient's home state as a new legal fiction for this purpose.

133. This proposal applies to federal court adjudication of mass torts. There are two kinds of mass torts. One is called the single-disaster case and affects multiple victims from one accident, such as an airplane crash. The other, called the multi-

draft was produced over five years ago; a proposed final draft is now available.<sup>135</sup> The project's authors believe that a single federal rule will eliminate the ability to forum shop among courts and eliminate conflicting results attributable to applying different choice of law rules from each affected jurisdiction.<sup>136</sup> Opponents to the ALI proposal describe such federal rule making as an attack on state sovereignty that will frustrate the individual states' legitimate interests and policies applicable to their citizens.<sup>137</sup>

In lieu of a single federal rule or a state-by-state application of internal civil procedural rules, participants in medical transactions might borrow a technique often seen in commercial property transactions. There, the parties *voluntarily* designate an exclusive forum and stipulate a choice of law for the adjudication of any dispute. Such a designation may be made by private contract, with or without statutory authority. For example, the Uniform Commercial Code contains a "territorial application" provision, which gives parties the power to choose applicable law in commercial transactions. The statutory condition to this voluntary choice of law option is a "reasonable relation" of the transaction to more than one state.<sup>138</sup>

This kind of voluntary approach is not now routinely employed in medical practice disputes with patients, but it could be. A physician-patient relationship is basically contractual. Although the parties rarely sign a written agreement to this effect, the contract is often considered to be implied.<sup>139</sup> Not unlike the commercial contract situation, then, physician and patient may simply contract for the same purpose.<sup>140</sup> In addi-

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exposure case, involves a large number of plaintiffs injured in separate accidents from the same source, such as asbestos. Robert A. Sedler, *The Complex Litigation Project's Proposal for Federally-Mandated Choice of Law in Mass Tort Cases: Another Assault on State Sovereignty*, 54 LA. L. REV. 1085, 1085 n.1 (1994). Although the scope of the single-accident, single-victim case of telemedical malpractice is hardly comparable to that of a mass tort, the program's principle of simplifying the rules may be applicable.

134. *See id.*

135. *Id.* at 1086.

136. *Id.*

137. *See id.*

138. *See, e.g.*, 810 ILCS 5/1-105 (1993).

139. *See, e.g.*, *Hiser v. Randolph*, 617 P.2d 774 (Ariz. Ct. App. 1980); *Childs v. Weis*, 440 S.W.2d 104 (Tex. Ct. App. 1969).

140. However, a court might not enforce a choice of law provision selecting the laws of a state without contacts to the transaction or its parties. *See* RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 187 (1989).

tion, private third-party payers account for a significant share of health care expenditures. If such a contractual provision was not addressed at the doctor-patient level, procedures for conflict resolution might be inserted in agreements with managed care entities or as part of insurance contracts.

However created, any such provision in a private contract could be attacked on the ground that it is a "contract of adhesion." That is, courts can find a contract unconscionable and therefore unenforceable where one party has no choice but to "take it or leave it." Because there is unequal bargaining power, one party cannot negotiate meaningful changes.<sup>141</sup> This dynamic is no doubt present in scenarios involving a patient versus an insurance company or the patient versus a managed care entity. Where the patient's capacity to understand the consequences of a contract provision such as this is questionable, care would have to be taken to assure that it is truly a voluntary designation.<sup>142</sup> And state policy could consider such designations to be against public policy for this reason.<sup>143</sup>

Civil procedural rules promise to make adjudication of telemedical disputes more procedurally complex than those arising solely from intrastate transactions. It remains to be seen whether participants in such transactions can streamline the process, either by borrowing from proposals in other multiparty, multiforum lawsuits, or by introducing voluntary choices now often employed in commercial contract situations.

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141. See, e.g., *Preston v. Kruezer*, 641 F. Supp. 1163 (N.D. Ill. 1986).

142. Note that the legal capacity to consent to medical procedures may be different than legal capacity to contract. For example, incompetent mentally ill persons may have the legal capacity to make some medical decisions for themselves, even if they are institutionalized and stripped of legal capacity to contract. "It is plain that these two capacities [legal and mental competence] are not the same." *United States v. Charters*, 829 F.2d 479, 495 (4th Cir. 1987). It is unclear which standard would be used to evaluate a patient's competence to agree to procedures for conflict resolution, because they are intertwined with medical concerns.

143. Contract provisions that convey benefits to one party can be void. For example, in Illinois, a landlord's purported exculpation from liability to his tenant for his own negligence is "void as against public policy and wholly unenforceable." 765 ILCS 705/1 (1993). In a medical context, physicians may be permitted to incorporate, for example, to limit their liability for commercial transactions. However, a corporate shield does not change the basic physician-patient relationship. See, e.g., 805 ILCS 15/14 (1993) ("This Act [Medical Corporation Act] does not alter *any law* applicable to the relationship between a physician furnishing medical service and a person receiving such service, including liability arising out of such service."). *Testin v. Dreyer Medical Clinic*, 605 N.E.2d 1070 (Ill. Ct. App.), *appeal allowed*, 612 N.E.2d 524 (Ill. 1992) (physician-patient privilege).

### C. Substitute

The definitional section of this article identified telemedicine's function as a substitute for certain aspects of conventional medical practice. Because telemedicine substitutes for aspects of traditional practice, it raises issues of informed consent: the telemedical patient receives care in a nontraditional manner, which may pose certain unique risks. The standard of care can also be an issue in the substitution category because a telemedical method of diagnosis and treatment is being substituted for a more traditional method, which has highly evolved malpractice standards.<sup>144</sup>

#### 1. Informed Consent

A basic tenet of the doctor-patient relationship is informed consent. Essentially, informed consent obligates a physician to provide information that will allow the patient to evaluate the options for medical treatment. The disclosure includes "just what would be done and . . . its consequences."<sup>145</sup> The emerging view<sup>146</sup> is that informed consent is a patient-oriented standard requiring disclosure of risks "material" to a "reasonably prudent" patient about a treatment or procedure.<sup>147</sup> Experimental procedures raise additional duties, and may impose a greater burden on the physician, such as requiring disclosure of its experimental nature<sup>148</sup> and any uncertainty as to risks.<sup>149</sup> Experi-

144. The adequacy of the telemedical medium for clinical purposes is a concern for the standard of care issue. In a radiological context, the standard requires images of sufficient quality to allow appropriate interpretations and transmission to users in an appropriate time frame. Brenner, *supra* note 37, at 39. See also ACR STANDARD FOR TELERADIOLOGY, *supra* note 38 at §§ VII, VIII. Commentators also believe that the potentially nationwide reach of telemedicine will eviscerate what remains of the "locality rule," which compares a practitioner's performance with that of practitioners in the local medical community. Eid, *supra* note 1, at 50. For a general discussion of the development of this rule and replacement by a rule of nationwide scope, see Shilkret v. Annapolis Emergency Hosp. Ass'n, 349 A.2d 245 (Md. 1975).

145. Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 67 n.8 (1976).

146. One commentator reports that "most newly examined cases call it the majority rule in American jurisprudence." WILLIAM J. CURRAN ET AL., FORENSIC SCIENCE AND PUBLIC POLICY 305 (4th ed. 1990). However, current state law appears to be evenly split between those jurisdictions that apply a patient-oriented standard and those that apply a professional or community standard. This latter standard requires a doctor to tailor his disclosures to those generally being made in the medical community. Judith F. Daar, *Informed Consent: Defining Limits Through Therapeutic Parameters*, 16 WHITTIER L. REV. 187, 188 n.3 (1995).

147. See Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972).

148. See, e.g., Ahern v. Veterans Admin., 537 F.2d 1098, 1102 (10th Cir. 1976).

mental procedures are distinguished from established procedures because there are *known* risks for the latter, but risks for the former may simply be unknown and thus not susceptible to disclosure.<sup>150</sup>

At present, many telemedical applications are conducted on a demonstration basis.<sup>151</sup> This “testing” suggests some level of uncertainty in telemedical procedures.<sup>152</sup> Whether this uncertainty places the practice into the “experimentation” category for informed consent purposes is unclear. Factors that may be important in analyzing this issue include how data gleaned from a telemedical procedure compare with the quality of data obtained from the same procedure conducted in traditional fashion; whether skill, experience, and knowledge accessed during a telemedical consultation is inferior, similar, or better than an on-site consultation; and how the telecommunications process may skew (or enhance) results.<sup>153</sup>

Telemedicine itself may not be the proper focus for special disclosure. That is, since telemedicine is intended to permit a remote physician to practice medicine in the same manner as an on-site physician, telemedicine is not an “experiment.”<sup>154</sup> Telemedical applications may have experimental aspects, however, based on the above and other criteria. In addition, the importance of these factors may vary depending on medical specialty. For example, general practice medicine may in most instances be considered to have less opportunity for experimentation than specialties that rely in large part on high-

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149. See, e.g., *Estrada v. Jaques*, 321 S.E.2d 240 (N.C. Ct. App. 1984).

150. *Id.*

151. *Eid*, *supra* note 1, at 49-50.

152. Industry experts suggest that the reliability of telemedical procedures may still be an open issue. For example:

As of this writing [1994], the most important factor related to clinical acceptance of teleradiology is its utility in facilitating the primary diagnosis of conventional radiographic examinations performed at distant sites. Many well-designed comparative studies of screen and film interpretations have shown the accuracy of screen readings is *significantly lower* than film viewing . . . . These studies have indicated the need for improved contrast and spatial resolution of the images . . . . The data also have emphasized the need for more intensive user training . . . .

Gitlin, *supra* note 2, at 4 (emphasis added).

153. The potential for telemedical procedures to be inferior to those procedures conducted in a traditional fashion also impacts standard of care considerations. The relevant inquiry here is whether the procedure is so flawed that it does not satisfy the prevailing standard, which is a minimum requirement to avoid legal liability.

154. *But see* Freeman & Southern, *supra* note 59, at 40. Telemedicine may be considered experimental by certain industry experts.

technology equipment and novel processes. Techniques that produce remote radiological images with less than full resolution of the original may fall within this category.<sup>155</sup>

Another factor in determining the applicable scope of patient disclosure is whether there are any viable diagnosis and treatment options at the time. In this connection, medical innovation is permitted, and often encouraged, to avoid serious consequences to the patient's health. Thus, risky procedures employed in the hope of saving a life when death is imminent may be entitled to more latitude.<sup>156</sup> However, this is a *malpractice* concept, and informed consent is a separate obligation.<sup>157</sup> Accordingly, invoking the potential life-saving effects of telemedicine may not be sufficient to avoid the issue of human experimentation, and the uncertainties about telemedical procedures may become part of the informed consent discussion.<sup>158</sup>

#### D. Conduit

The definitions of "telemedicine" developed earlier reveal that telemedical procedures provide a conduit for information and can employ various components in the transmission of voice, video, and data. The conduit function of telemedical devices and personnel raises the specter of unauthorized practice, an issue that was discussed earlier in connection with the "distance" issue of licensure.<sup>159</sup> The remaining significant "conduit"

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155. Rowberg, *General Considerations*, *supra* note 24, at 15.

156. See, e.g., *Brook v. St. John's Hickey Memorial Hosp.*, 380 N.E.2d 72 (Ind. 1978).

157. Informed consent is informational in nature and goes to whether the patient has approved the bodily invasions which are part of medical care. See, e.g., *Kozup v. Georgetown Univ.*, 851 F.2d 437 (D.C. Cir. 1988). Informed consent is deemed given in an emergency situation. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 778 (D.C. Cir. 1972); *Kozup*, 851 F.2d at 439.

158. There are resources that may aid in this determination. For example, the Basic Policy for Protection of Human Research Subjects adopted by the Department of Health and Human Services deals with medical research and contains a litany of topics that must be included when obtaining informed consent for research involving human beings as subjects. 45 C.F.R. § 46.116 (1994). "Research" is broadly defined as "a systematic investigation designed to develop or contribute to generalized knowledge." 45 C.F.R. § 46.102(d) (1994). Telemedical demonstration projects seek to contribute to the knowledge of various aspects of telemedical procedures, and thus may be analogous to "research" for informed consent purposes. If so, the requirements for informed consent in the regulation may provide a helpful checklist for telemedicine. Note, however, that this research policy specifically exempts the provision of emergency medical care. 45 C.F.R. § 46.116(f) (1994).

159. See *supra* section II(B)(1).

issues involve the application of products liability principles<sup>160</sup> to the use of telemedical devices and the possible regulation as “devices” under the Federal Food, Drug and Cosmetic Act (FDCA).<sup>161</sup>

The FDCA regulates medical “devices” used in interstate commerce to protect public health;<sup>162</sup> it preempts all similar state laws.<sup>163</sup> The FDCA defines “device” as

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, or prevention of disease, in man or other animals.<sup>164</sup>

Thus, articles that aid the diagnostic process are considered “devices” for purposes of this law.<sup>165</sup> The fact that an article is not the *sole* basis for diagnosis or treatment does not mean that it can avoid scrutiny as a regulated “device.”<sup>166</sup> Indeed, even though an article is not designed solely for medical use and may have common nonmedical uses, this does not prevent its classification as a “device” under the FDCA.<sup>167</sup>

Telemedicine employs an array of familiar products such as supercomputers, workstations, satellite links, terrestrial networks, and expert software. Further, new technologies may be developed specifically for telemedical applications.<sup>168</sup> All these

160. Whenever products are involved, the specter of product liability is raised. Congress has considered a bill to create a single national law covering injuries from defective products. Richard B. Schmitt, *Senate Panel Clears Measure for Liability*, WALL ST. J., Apr. 7, 1995, at A3.

161. 21 U.S.C. §§ 301-95 (1994).

162. *Id.* See *Barnes v. United States*, 142 F.2d 648 (9th Cir. 1944); *C.C. Co. v. United States*, 147 F.2d 820 (5th Cir. 1944) (citing *United States v. Antikamnia Co.*, 231 U.S. 654 (1914)).

163. No state is currently allowed to establish or continue in effect any regulation for medical devices that has the effect or force of law that is different from, or in addition to, regulations under the FDCA. 21 U.S.C. § 360k(a)(1) (1994).

164. 21 U.S.C. § 321(h) (1994).

165. See *United States v. 25 Cases, More or Less, of an Article of Device*, 942 F.2d 1179 (7th Cir. 1991) (latex bag filled with a silicone lubricant that was intended to improve a woman's ability to feel breast abnormalities).

166. See *United States v. An Article of Device*, 731 F.2d 1253 (7th Cir. 1984).

167. See, e.g., *United States v. 23, More or Less, Articles*, 192 F.2d 308 (2d Cir. 1951) (phonograph record intended for use in alleviating insomnia); *Rutherford v. United States*, 542 F.2d 1137 (10th Cir. 1976) (laetrile used in cancer therapy, derived from a common food product).

168. See, e.g., Edward Chow, *System Design, Integration & Performance, in VISION BECOMES REALITY*, *supra* note 1, at 21-22.



products may be used in nonmedical contexts, but when used in telemedicine, they are intended to aid diagnosis and treatment.

The "intended use" of an article is defined under the FDCA as the objective intent of the persons legally responsible for labeling the article,<sup>169</sup> and can be shown by the product's *actual* use.<sup>170</sup> Thus, the actual use of common computer hardware and telecommunications components and software, as well as the use of any articles specially designed to aid telemedical practice, raises issues about the applicability of the FDCA.<sup>171</sup>

The Food and Drug Administration is generally accorded wide latitude in determining which articles constitute devices regulated under the FDCA.<sup>172</sup> And although the FDA encourages development of "investigational devices" for the purpose of the discovery and development of new tools for medical purposes,<sup>173</sup> an aggressive interpretation of the FDCA may place some telemedical apparatus within the jurisdiction of this federal agency.

### E. Summary

Many medical practice issues are potentially affected by telemedical procedures. Whether those issues will be addressed at the state or federal level (or at all) will depend on many factors, including the historical role of state and federal government in such matters and the resurgence of the local control philosophy under the "New Federalism" banner, as well as federal principles that become operative as soon as telemedical practice crosses state lines. The final section of this article will address these topics.

## III. FEDERAL-STATE DYNAMICS IN TELEMEDICINE

As demonstrated above, telemedicine raises new practice issues. One such issue is a doctor's "virtual presence" in a state

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169. 21 C.F.R. § 801.4 (1994).

170. *United States v. 22 Rectangular or Cylindrical Finished Devices, More or Less*, 714 F. Supp. 1159, 1165 (D. Utah 1989) (citing H.R. REP. NO. 853, 94th Cong., 2d Sess. 14 (1976)).

171. For example, the FDA recently ordered a recall of a blood management software program. G. Pascal Zachary, *FDA Orders Recall of Informedics, Inc. Software for Blood*, WALL ST. J., Apr. 12, 1995, at B3.

172. See 25 Cases, *More or Less*, 942 F.2d at 1182. See also *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784 (1969) ("[r]emedial legislation such as the Food, Drug and Cosmetic Act is to be given liberal construction consistent with the Act's overriding purpose to protect the public health").

173. 21 C.F.R. § 812.1(a) (1994).

for medical licensure or state taxation. Telemedicine also creates a different factual environment in which to analyze old issues; fee payments to doctors using telephone consultations rather than office visits fall into this category. Both public and private insurance or health care programs will grapple with this issue of reimbursements for telemedical consultations as well as other issues. Private industry may borrow government policy on these topics, or government may follow private industry to address these matters. Where telemedicine raises issues susceptible to governmental policy or regulation, state, federal, or both governments may become involved.

As discussed earlier, states have traditionally governed the practice of medicine within their borders. Through licensure, states say *who* may practice. By comparing a physician's conduct with applicable standard of care, states determine *how* medicine may be practiced. If medicine is not practiced correctly, state judiciaries decide who is at fault and what damages are to be paid by applying medical malpractice, vicarious, corporate, and other liability principles. There are several reasons for state primacy in this area. They include the Tenth Amendment to the Constitution; the reinvigorated "New Federalism;" the traditional lack of federal response; the overwhelming state response to the need for health care, including the relatively free hand afforded states in crafting medical legislation; the state's proximity to its citizens and its ability to legislate more quickly; the tools available to craft state policy into regulatory schemes with extraterritorial effect; and the intimate nature of health care.

On the other hand, the federal government is a principal payor for health care services through such programs as Medicare, Medicaid, and federal employee benefit programs. For example, Medicare now serves about 36 million people—one-seventh of the country's population—and funds more than one-sixth of all health care spending.<sup>174</sup> This power of the checkbook gives the federal government considerable de facto power over health care matters.

The federal government also has jurisdiction over *interstate* commerce under Article 1 of the Constitution. Once telemedicine "teletransports" practitioners and patients across state

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174. *Prospective Payment Assessment Comm'n, Medicare and the American Health Care System, Report to Congress, Medicare & Medicaid Guide (CCH) No. 751, pt. 2, at 15 (June 11, 1993).*

borders, interstate commerce principles and the Privileges and Immunities Clause of the Constitution give the federal government broad powers to regulate medical practices. These powers include federal preemption of state law, and they limit the manner in which states can address “common callings,” such as medicine and medical commerce, which pass through their borders. This is true not only because residents of one state are being provided services from outside the state, but because telecommunications—an industry primarily regulated by the federal government—is the mechanism for those interactions.

Both state and federal governments now have power to legislate in areas that are or will become significant to routine telemedical practice. If individual states legislate in these areas, they risk creating schemes potentially dissimilar to those adopted by their neighbors. To avoid this result, states might “sign on” to uniform state legislation or employ other techniques to achieve a more consistent multistate approach. Because telemedical applications can occur between or among any two or more states in the nation, any approach comprising fewer than all fifty states can limit telemedicine’s nationwide potential.

Rather than challenge federal jurisdiction on topics impacting telemedicine, states could try to maintain control over (or the federal government could defer to state primacy over) areas relegated to traditional (nontelemedical) health care practice. States might also attempt to govern *intrastate* telemedical practice on the theory that telemedicine arguably falls within the ambit of the Tenth Amendment and outside federal interstate commerce rules. However, because telemedicine allows a physician to practice medicine with the use of telecommunications in the same manner as practiced in person, this kind of approach may make an inappropriate distinction between telemedical and traditional health care.

Telemedicine *is* medicine, and, thus, any approach to telemedical issues can intrude into traditional medical practice as well. Consider two cases of a broken leg, one diagnosed by an out-of-state teleradiologist and the other by an on-site radiologist. They may result in identical diagnosis and treatment. If a federal scheme limited to telemedical practice governs the teleradiologist’s actions while state law governs the on-site physician, aberrations in health care delivery and inconsistent legal consequences could result. Attempts to “unbundle” telemedical *in-*

*trastate* activities from *interstate* ones<sup>175</sup> may be both difficult and problematic. These realities may not only encourage a uniform, federal approach for telemedicine, but also prompt federal incursions—either intentional or de facto—into traditional health care regulation. In any event, any federal action in telemedicine promises to create federal-state tension by infringing on the traditional role of state governments in medical practice areas.

Because of its state and federal aspects, telemedicine is ripe for attention from both quarters. The final section of the article will discuss principles that have contributed to the states' historical primacy in health care matters and federal principles that will apply when telemedicine crosses state borders. These federal principles may hamper individual state response to telemedical matters and may undermine historical state primacy in medical-related topics.

### A. State Issues

#### 1. The Tenth Amendment

The primary reason for federal deference to the states on medical practice topics may simply be the lack of federal jurisdiction over intrastate medical care. That is, although Article I of the United States Constitution expressly grants Congress power over interstate commerce, the Tenth Amendment reserves to the states the powers not delegated to Congress.<sup>176</sup> Matters relegated to the states comprise

[a]n immense mass of legislation which embraces every thing within the territory of a State, not surrendered to a general government: all of which can be most advantageously exercised by the States themselves. Inspection law, quarantine laws, *health laws of every description*, as well as laws for regulating the internal commerce of a State . . . are components of this mass.<sup>177</sup>

Arguably, then, the federal government may have no power to govern medical practice matters until they spill over state borders.<sup>178</sup> Telecommunications create this interstate potential

175. The concept of "unbundling" arises in the dual system of state and federal telecommunications laws. See *infra* section III(B)(2)(a).

176. U.S. CONST. amend. X.

177. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824) (emphasis added). See also *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525 (1949).

178. See, e.g., David B. Rivkin, Jr., *Rule of Health Care Reform v. the Founders*, WALL ST. J., Sept. 29, 1993, at A19; *Dent v. West Virginia*, 129 U.S. 114 (1889).

and invite federal involvement in this historically insular category of state regulation.

## 2. The "New Federalism"

The Tenth Amendment provides a centuries-old precedent for state primacy in statewide medical practice issues. That is, unlike coining money, declaring war, or punishing piracy on the high seas,<sup>179</sup> practicing medicine is not mentioned in the Constitution. Purists argue that the founders' original intent was to allow the states to govern these matters under the Constitution's Tenth Amendment. These present-day purists have been termed "new federalists," and their cause termed "New Federalism"<sup>180</sup> or the "Tenth Amendment Movement."<sup>181</sup> They seek to stop, then reverse, the federal government's power grab and return power to state and local governments.<sup>182</sup>

Under the banner of New Federalism, eleven states have recently enacted "state sovereignty" resolutions,<sup>183</sup> and a Conference of States had been called for the Fall of 1995<sup>184</sup> for the purpose of "conven[ing] states in an historic way and sending forth their collective action,"<sup>185</sup> as well as to discuss methods to "restore the balance of power between the state and federal governments."<sup>186</sup> However, infighting among factions and the slow pace of authorizations to attend the conference threatened both the timing and any tangible results from the conference.<sup>187</sup>

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179. U.S. CONST. art. I, § 8.

180. See also Bane, *supra* note 45.

181. John J. Fialka, *Far-Right Movement Is Trying to Torpedo Plans for Conference on Returning Power to the States*, WALL ST. J., Apr. 4, 1995, at A22.

182. See, e.g., Richard C. Reuben, *The New Federalism*, A.B.A. J., Apr. 1995, at 76.

183. Fialka, *supra* note 181. Colorado, Hawaii, Illinois, and Missouri are included. Reuben, *supra* note 182, at 77.

184. Fialka, *supra* note 181.

185. Press Release, *Fall Meeting Set to Plan Conference of the States* (The Council of State Governments, Lexington, Ky.), Apr. 26, 1995 (comments of Utah Governor Mike Leavitt) (on file with the *Annals of Health Law*).

186. *Id.* (comments of Alabama State Representative Mike Box).

187. *Id.* As of May 18, 1995, 29 states had taken some action concerning the Conference of States. Fourteen states had passed resolutions in both chambers of their state legislatures to attend the conference, six states had passed a resolution in at least one chamber, seven states had introduced a resolution in at least one chamber, and introduction was pending in two states. Organizers had agreed to wait to convene the conference until at least 26 states had passed resolutions of participation. Report by The Council of State Governments, Lexington, Ky. (May 18, 1995) (on file with *Annals of Health Law*).

In addition to the Conference of States, an “unprecedented” joint meeting among executive committees from five national state government groups was held in October of 1995.<sup>188</sup> The agenda for this “States’ Federalism Summit” included giving states power to require Congress to reconsider laws that the states believe the public no longer supports, letting states propose constitutional amendments without the need for a constitutional convention, and more effectively curbing federal regulations or unfunded federal mandates.<sup>189</sup> Governors and legislators from forty-three states attended the summit.<sup>190</sup> However, federal concern, as well as uncertainty *within states* about their abilities to assume control of matters traditionally handled by the federal government,<sup>191</sup> may stymie any wholesale transfer of power. To prepare for possible federal devolution in a health care context, conferences such as one on “fiscal federalism” to discuss “effective and innovative state actions in health care and welfare” in response to the changing fiscal and regulatory environment are being convened<sup>192</sup> and scholars are publishing commentaries that debate health care and federalism.<sup>193</sup>

Despite the uncertainties about such state-based efforts, the federal government may take note of this movement, possibly by softening any federal response that may be attempted for regulating telemedicine. This softening may come from the recently enacted federal law that curtails unfunded mandates to the states,<sup>194</sup> or in the form of federal guidelines that give states wide latitude to legislate a particular topic, as opposed to detailed federal regulations that seek to micromanage an issue.<sup>195</sup>

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188. Albert R. Karr, *State Officials Ready to Take Control of More Programs, But Many See Risks*, WALL ST. J., Oct. 23, 1995, at C14.

189. *Id.*

190. News Release, *New Report Assesses Status of American Federalism* (The Council of State Governments, Lexington, Ky.), Apr. 1996 (on file with the *Annals of Health Law*) [hereinafter *States’ Federalism Summit Statement*].

191. *Id.*

192. A conference entitled “Managing the New Fiscal Federalism: State Strategies in Health and Welfare” was cosponsored in May of 1996 by The Council of State Governments, which is based in Lexington, Ky.

193. See, e.g., Commentary, *On the Future of State Health Care Reform*, 28 CONN. L. REV. 113 (1995).

194. For example, new federal telemedical regulation may fall within constraints established under the new mandates law. See, e.g., Robin Toner, *G.O.P. Blitz of First 100 Days Now Brings Pivotal Second 100*, N.Y. TIMES, Apr. 9, 1995, § 1, at 1.

195. Reuben, *supra* note 182, at 77.

Tangential to states' action in this area are recent United States Supreme Court decisions reaffirming state sovereignty.<sup>196</sup> For example, Justice O'Connor recently wrote:

The states retain substantial sovereign authority under our Constitution. "The powers delegated by the proposed clause to the federal government are few and defined. Those which are to remain in the State governments are numerous and indefinite . . . . The powers reserved to the several States will extend to all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State."<sup>197</sup>

This judicial response strongly suggests the possibility that the courts are becoming predisposed to warding off federal encroachment on state sovereignty, and may look critically at any federal response to telemedicine. On the other hand, many aspects of telecommunications fall squarely within federal power;<sup>198</sup> providing medical services using telecommunications systems is arguably the "transportation of a commodity through the channels of commerce,"<sup>199</sup> one of the three broad categories recently recognized by the Supreme Court as those falling within Congress's commerce power.<sup>200</sup>

### 3. The Traditional Lack of Federal Response

In addition to Tenth Amendment principles, reinvigorated by New Federalism, a third reason for states' traditional primacy in medical practice issues is the simple fact that the federal government has not legislated in many areas impacting health care. Although the past thirty years have seen an explosion of federal health-related legislation, much of it addresses the economics of health care, such as Medicare<sup>201</sup> and Medicaid,<sup>202</sup> which pay for care, while other laws, such as the Employee Retirement Income Security Act (ERISA),<sup>203</sup> govern employee benefit plans—including health care benefits—for private industry. A

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196. For a general discussion of recent Supreme Court cases on this topic, see Richard C. Reuben, *Court Bolsters 10th Amendment*, A.B.A. J., Apr. 1995, at 79.

197. *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) (quoting THE FEDERALIST NO. 45, at 292-93 (C. Rossiter ed. 1961)).

198. See *infra* section III(B)(2)(a).

199. *United States v. Lopez*, 115 S. Ct. 1624, 1630 (1995).

200. *Id.*

201. 42 U.S.C. §§ 1395-1395ccc (1994).

202. 42 U.S.C. §§ 1396-1396v (1994).

203. 29 U.S.C. § 1003 (1994).

large portion of President Clinton's now-defunct Health Security Act dealt with financing mechanisms for the promised comprehensive health care benefits. More recently, federal tort reform legislation has been proposed, seeking to cap noneconomic damages in medical malpractice cases.<sup>204</sup>

Of course, categorizing this group of laws simply as "economic" belies the overwhelming impact that economic factors have on medical practice, regardless of how or where practiced. Combined federal expenditures account for billions of dollars spent on behalf of millions of people. It is true that the federal government does not supervise the "practice" of medicine,<sup>205</sup> does not license Medicare and Medicaid practitioners,<sup>206</sup> does not adjudicate disputes between doctors and patients about allegedly improper medical care, and does not determine what damages are paid when there are errors. However, the power of the checkbook allows the federal government to say who may provide medical care to program beneficiaries, through its sanctioning and enforcement powers.<sup>207</sup> This power also allows the federal government to determine when services are improper or not medically necessary by refusing to pay for them,<sup>208</sup> and to "assess damages" when it stops practitioners from dunning a beneficiary when the government refuses to pay.<sup>209</sup> Thus, the federal government may have great de facto power over these "traditional" state issues for a large portion of physician-patient interactions. There is no reason to believe that including telemedical procedures in federal medical care reimbursement programs will have any less effect.

Federal economic power may also indirectly influence practice patterns for patients who are not covered by government reimbursement programs. Physicians may choose to follow

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204. *Medical Malpractice Awards Limited in House-Approved Product Liability Bill*, 4 BNA'S HEALTH L. REP. (BNA) 419 (1995); but see *Senators Offer 'Moderate' Liability Bill, Say President Would Veto House Measure*, 4 BNA'S HEALTH L. REP. (BNA) 445 (1995).

205. For example, the Medicare statute expressly prohibits such activities: "Nothing in this subchapter [XVIII] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine . . . ." 42 U.S.C. § 1395 (1994).

206. Participating physicians must be state licensed. See 42 U.S.C. § 1395x(r) (1994).

207. See, e.g., 42 U.S.C. § 1320a-7 (1994) (exclusion) and 42 U.S.C. § 1320a-7a (1994) (civil monetary penalties).

208. See 42 U.S.C. §§ 1395g, 1395y (1994).

209. See 42 U.S.C. § 1395u (1994) (carrier contracts), 42 U.S.C. § 1395pp (1994) (limitation on liability of beneficiary where claim disallowed).



mandates or guidelines for federal programs when treating private patients. Thus, the de facto power of the federal government in medical practice matters may be much greater than otherwise surmised from payment practices alone. This indirect effect may apply to telemedical procedures as well.

In addition to enacting economic legislation in health care, the federal government also controls the tools that medical professionals use. The federal Food, Drug and Cosmetic Act, which includes the Medical Device Amendments and Safe Medical Devices Act,<sup>210</sup> regulates drugs and medical devices. Although federal food and drug laws have yet to directly regulate medical *procedures* (for example, how a surgeon performs a balloon angioplasty), federal regulations affecting the availability of tools necessarily constrain what physicians can do in treating their patients. And these laws are interpreted broadly, in a manner which can cover telecommunications systems and equipment utilized in furnishing medical care.

Although there are federal programs that provide *payment* for medical care dispensed to certain segments of the population and that regulate *tools* used by medical professionals, the federal government does not purport to substitute governmental wisdom for a physician's judgment or a state's power to control the actual practice of medicine. Federal payment schedules or reimbursement procedures may create de facto constraints on medical judgment, but "medical necessity" is generally determined by prevailing medical practice.<sup>211</sup> Even President Clinton's unsuccessful attempt to usher in national health care reform largely steered clear of these matters. His reform act may have been ambitious about controlling the practice of medicine, for example, through the creation of a "National Health Board" to establish national medical necessity criteria,<sup>212</sup> but his draft law deferred to states in several areas including, significantly, state licensure.<sup>213</sup> Thus, despite some significant

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210. 21 U.S.C. § 301 (1994).

211. See, e.g., *Montoya v. Johnston*, 654 F. Supp. 511, 513 (W.D. Tex. 1987). Peer review organizations, which determine whether medical services and items are reasonable and medically necessary for purposes of reimbursement under Medicare, generally comprise local practitioners within a geographic area. See 42 U.S.C. § 1320c-2 (1994). They use national or regional norms as they deem appropriate. 42 C.F.R. § 466.100 (Oct.1, 1994).

212. Health Security Act, *supra* note 16, at § 1154.

213. *Id.* at § 1112(c). The Health Security Act defines "health professional services" as those provided by a person "legally authorized to provide such services in the State in which the services are provided." *Id.*

federal legislation, many aspects of medical practice are still under individual state control.

#### 4. The Overwhelming State Response

The Tenth Amendment arguably relegates health law regulation to the states, and the lack of federal legislation on certain topics has left the states fairly free to craft their own laws. Under their police powers, states have broad power to protect their citizens against perils to health and safety.<sup>214</sup> In fact, principles of equal protection<sup>215</sup> require only that the relationship between a state regulation and its goal is rational. There is no requirement that the regulation be logical<sup>216</sup> or be wise social policy.<sup>217</sup> In this connection, the Supreme Court wrote:

It is enough that there is an evil at hand for correction, and that it *might* be thought that the particular legislative measure was a rational way to correct it . . . . Evils in the same field may be of different dimensions and proportions, requiring different remedies. *Or so the legislature may think.* Or the reform may take one step at a time, addressing itself to the phase of the problem which *seems* most acute to the *legislative mind*. The legislature may select one phase of the one field and apply a remedy there, *neglecting the others*.<sup>218</sup>

And a needless, wasteful result, without more, does not invalidate such a law.<sup>219</sup> So long as the rational relationship between the regulation and its goal is "at least debatable,"<sup>220</sup> it is likely to be upheld.

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214. See *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525 (1949).

215. The Fifth Amendment assures the right to be free "from invidious discrimination in statutory classifications and other governmental activity." *Harris v. McRae*, 448 U.S. 297, 322 (1980). A statutory classification is presumptively constitutional unless it impinges on a constitutional right or liberty, or the classification is suspect. *Id.* The Supreme Court has not recognized the opportunity to practice medicine as a constitutional right or liberty, see, e.g., *Shaw v. Hospital Auth. of Cobb County*, 614 F.2d 946 (5th Cir. 1980) (constitutionally permissible to exclude podiatrists), and health care providers are not generally considered a protected class. See *Meier v. Anderson*, 692 F. Supp. 546 (Pa. 1988), *aff'd*, 869 F.2d 590 (3d Cir. 1989). The inquiry does not stop there, however. For if no suspect class is implicated, the classification must be examined to determine that it "rationally furthers some legitimate, articulated state purpose . . . ." *Maier v. Roe*, 432 U.S. 464, 470 (1977) (quoting *San Antonio Sch. Dist. v. Rodriguez*, 411 U.S. 1, 17 (1973)).

216. *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 487-88 (1955).

217. *Harris*, 448 U.S. at 326.

218. *Williamson*, 348 U.S. at 488-89 (emphasis added).

219. *Id.* at 487. The Court defers to legislatures to "balance the advantages and disadvantages" of this kind of regulation. *Id.*

220. *Metropolitan Life Ins. Co. v. Ward*, 470 U.S. 869, 893 (1985) (quoting *Western & S. Life Ins. Co. v. State Bd. of Equalization*, 451 U.S. 648, 674 (1981)).

Given this latitude, state legislatures have the authority to be as insular, as creative, or as cooperative as they reasonably desire. They have accepted the challenge to craft health care legislation. For example, California has thirteen volumes of "health and safety" statutes. This does not include the pages of administrative regulations or other laws tangential to the health care topics. Multiplying this by fifty states yields massive legal requirements. The fact that states have played a major role in creating health care laws is the fourth reason for state primacy in medical practice issues.

### 5. States: Lowest Common Denominator and Faster to Act

States have been regarded as a unit of government closer to the people (the so-called "lowest common denominator") and better able to address social needs such as health care. This is the fifth reason for traditional state primacy in medical practice matters. The Supreme Court recognized this some sixty years ago. In 1932, Justice Brandeis wrote: "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."<sup>221</sup> The Court reaffirmed this principle in a recent opinion, writing:

[State power] assures a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry.<sup>222</sup>

This judicial sentiment was recently summarized by a member of a state government's executive branch. In commenting upon his newly created Advisory Council on Self-Determination and Federalism, Virginia Governor George Allen noted: "People understand [that] if decisions are made by people closer to them, [the decisions] will be more reflective of their views."<sup>223</sup>

One example of such a "novel" experiment is Oregon's health care law for Medicaid patients.<sup>224</sup> It is an explicit rationing

221. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

222. *Gregory v. Ashcroft*, 501 U.S. at 458 (citations omitted).

223. States' Federalism Summit Statement, *supra* note 190.

224. OR. REV. STAT. ANN. §§ 414.025, 414.036, 414.042, 414.065, 414.705 to 414.750 (Butterworth Supp. 1994).

plan,<sup>225</sup> which forces recipients to forego medically necessary care for certain kinds of ailments in exchange for providing greater access to the program. For example, conditions such as viral hepatitis, breast reconstruction after mastectomy, nutritional counseling for obesity, and medical therapy for “end-stage HIV disease” will not be covered for fiscal years 1993 through 1995.<sup>226</sup> This experiment hopes to provide a basic package of health care for 120,000 new participants in the plan.<sup>227</sup>

This lowest common denominator approach, perhaps always considered the most direct and efficient, is also consistent with the philosophy of the new Republican majority in Congress that promises to restore local control in many matters. For example, welfare reform legislation proposed by Republican sponsors proposes to provide block grants to the states,<sup>228</sup> enabling them to tailor benefits to the needs of their citizens. However, if the ability to tailor entitlements to the needs of individual states’ citizens is not a part of this new state authority, a “lethal combination” may result if sufficient federal funds are not transferred to states to pay for the mandated services.<sup>229</sup>

Now that power may actually shift to the states, however, experience and expertise may vary among state officials. State governing bodies may consist of part-time “citizen” legislators who also have regular jobs. Term limits may require a new crop of freshmen lawmakers every few years. And local officials may be more susceptible to lobbying and political influence.<sup>230</sup> These factors may impede some states from acting in the telemedical field.

As a fifth reason for state primacy in health-related areas, states may be able to move faster than the federal government in crafting laws, and might address telemedical issues more

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225. “Implicit” rationing occurs in this country through barriers to access, such as the high cost of health care and the inability to obtain insurance. Uwe E. Reinhardt, *Reforming the Health Care System: The Universal Dilemma*, 19 AM. J. L. & MED. 21, 31 (1993).

226. W. John Thomas, *The Oregon Medicaid Proposal: Ethical Paralysis, Tragic Democracy, and the Fate of a Utilitarian Health Care Program*, 72 OR. L. REV. 47, 104-105 (1993).

227. *Id.* at 103.

228. In comments about the legislation, then Senate Finance Committee Chairman Bob Packwood observed: “Clearly the states are going to have more flexibility.” Janet Hook, *Sweeping Reform Seems Inevitable*, CHI. SUN-TIMES, Mar. 25, 1995, at 12.

229. Karr, *supra* note 188.

230. Sam Howe Verhovek, *Can States Handle the New Authority From Congress? GOP Plans to Shift Power From D.C., But Many Ask if Legislatures Up to Task*, S.F. EXAMINER, Sept. 24, 1995, at A6.

quickly. For example, national health care reform and tort reform have both languished in Congress, while states keep churning out local laws. As noted earlier, Oregon has adopted a rationing law for its Medicaid population. Also, Illinois recently enacted comprehensive tort reform,<sup>231</sup> and Mississippi adopted a law<sup>232</sup> modeled after the American Medical Association's 1996 proposed patient protection legislation.<sup>233</sup> However, the states' legislative reach is limited by their borders, unless they can get together with other states on a unified approach.

## 6. States' Extraterritorial Reach

States are not without the power to make agreements with extraterritorial effect. They have the ability to facilitate cross-border interaction without federal action through reciprocal agreements with one or more states. For example, some medical license applicants may transfer examination results from State A to fulfill State B's examination requirement.<sup>234</sup>

States may also adopt "uniform" state legislation. Past proposals include a Uniform State Medical Information Code, using the Uniform Commercial Code as a model, to address privacy protection;<sup>235</sup> a Model Health Care Act; and a Uniform Rights of the Terminally Ill Act. These proposed uniform laws have recently been replaced by a proposed Uniform Health Care Decision Act.<sup>236</sup> Also, the newly proposed Model Act to Regulate the Practice of Telemedicine or Medicine by Other Means Across State Lines, discussed earlier,<sup>237</sup> could be adopted as uniform legislation by several states.

Interstate compacts might also be used. For example, the Interstate Compact on Mental Health has been adopted by some forty-five states. The Compact acknowledges that furnishing care and treatment to the mentally ill "bears no primary rela-

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231. Pub. Act No. 89-7, 1995 Ill. Legis. Serv. P.A. 89-7 (West) (to be codified in scattered chapters of ILCS).

232. Miss. CODE ANN. §§ 83-41-203, 83-41-209, 83-41-211, 83-41-213 (1973).

233. On file with the *Annals of Health Law*.

234. See, e.g., IND. CODE ANN. § 25-22.5-5-2(a)(2)(A) (West 1993 & Supp. I 1995). However, since reciprocity exceptions to state-by-state medical license requirements as currently enacted may vary widely, they may be more of an impediment than a help to facilitating medical practice across state borders.

235. Eid, *supra* note 1, at 49.

236. Charles P. Sabatino, *The New Uniform Health Care Decisions Act: Paving a Health Care Decisions Superhighway?*, 53 MD. L. REV. 1238 (1994).

237. See FSMB's ACT, *supra* note 41.

tionship to the residence or citizenship of the patient.”<sup>238</sup> The same might be said for maladies that lend themselves to telemedical intervention. After all “[b]ones break and heal in Washington the same as in Florida, in Minnesota the same as in Texas.”<sup>239</sup>

On the topic of professional qualifications, there is the Interstate Agreement on Qualification of Education Personnel. About thirty-five states have adopted complementary legislation. Its purpose is to “facilitate and strengthen cooperation in interstate certification and other elements of educational personnel qualification.”<sup>240</sup> State legislators might similarly consider an interstate compact for qualifying telemedical personnel.

The states are not without guidance in multistate legislation. For example, The Council of State Governments (CSG)<sup>241</sup>—the body calling for the Conference of States, described earlier—promotes “the sovereignty of the states and their role in the American federal system.”<sup>242</sup> The Council facilitates cooperation among states through formal proposals such as compacts and uniform and reciprocal statutes, and also encourages informal cooperation among federal, state, and local governments.<sup>243</sup> One of the CSG’s current priorities is “State Health Capacity and Related Issues.”<sup>244</sup> Among other issues, CSG intends to focus attention on building individual state capacity to deal with their own health reform issues.<sup>245</sup> The efforts of bodies such as CSG demonstrate the strong drive among states to keep jurisdiction over health care policy matters.

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238. See, e.g., N.Y. MENTAL HYG. LAW § 67.07(a) (McKinney 1988). The compact is intended “to provide a legal basis for the institutionalization or other appropriate care” for these patients. This compact establishes the responsibilities of the party states in achieving those goals to assist interstate patients. *Id.*

239. *Hall v. Hillbun*, 466 So. 2d 856, 870 (Miss. 1985).

240. See, e.g., CAL. EDUC. CODE § 12500, art. V(2) (West 1994).

241. The Council of State Governments is a nonpartisan organization founded some 60 years ago on the premise that “states are the best source of insight and information.” The Council of State Governments, Organization Background 1 (Wash., D.C., 1995) (on file with the *Annals of Health Law*).

242. The Council of State Governments, Mission Statement 1 (Wash., D.C., 1995) (on file with the *Annals of Health Law*).

243. See, e.g., THE UNIFORM LAW FOR MEMBERSHIP IN THE COUNCIL OF STATE GOVERNMENTS § 6 (The Council of State Governments, Wash., D.C., 1995) (on file with the *Annals of Health Law*).

244. The Council of State Governments, CSG Priorities (Wash., D.C., 1995) (on file with the *Annals of Health Law*).

245. *Id.*

Although states have no power to legislate outside their borders, they can agree with other states on a uniform approach, which will facilitate interstate relationships. Such state flexibility is the sixth reason for continuing state involvement in medical subject matter.

## 7. The Intimate Nature of Health Care

The simple fact that medical practice is conventionally conducted *within* a state, often inches apart from patients, is the seventh and perhaps most obvious reason for state control of that activity. Doctors typically sell their services within a small community, which they can easily traverse, and they dispense medical care using a hands-on, face-to-face approach. This “up-close” interaction has spawned local rules. Even the “locality” rule, which permits a physician’s performance to be measured against the standard practice of his local colleagues, still prevails in some jurisdictions.<sup>246</sup>

However, local rules are increasingly being replaced by national ones. The “nationalization” of medical education and training, similar admission standards and curricula across the country, common components of internship and residency programs, access to developing professional and scientific knowledge through written literature, computer databases and continuing education seminars, and national uniform standards for certified specialists<sup>247</sup> have all contributed to the trend towards “national” medical standards.<sup>248</sup> However, traditional approaches such as the locality rule demonstrate the inherently local nature of the traditional medical practice and its inclusion within the *internal* commerce of a state.

Despite evolving national standards, vast geographic variances in health care still prevail in this country, which strongly suggests that medical *practice* remains distinctly local. A health care atlas, just published by The Center for Evaluative Clinical Sciences of Dartmouth Medical School,<sup>249</sup> found “remarkable” variations in certain common medical treatments among the

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246. For a general discussion of the locality rule, see *Shilkret v. Annapolis Emergency Hosp. Ass’n*, 349 A.2d 245, 248-52 (Md. 1975).

247. See *Hall v. Hillbun*, 466 So. 2d 856, 870 (Miss. 1985).

248. See *Shilkret*, 349 A.2d at 250, 252.

249. THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES (1996), available in <http://www.dartmouth.edu/atlus/> (on file with the *Annals of Health Law*).

country's 3436 "geographic hospital service areas."<sup>250</sup> The variations include a fourfold difference in per capita rates of coronary bypass surgery among Medicare enrollees in 1992-93, an eight-fold variation in rates of radical prostatectomy (operation used to treat early prostate cancer), and an over thirty-three-fold variation in use of breast-sparing surgery in the treatment of breast cancer.<sup>251</sup> Thus, the intimate nature of health care has persisted, no doubt in part because until recently medicine could not easily be practiced across state borders.

## 8. Summary

States have a complex array of health law regulations and policies pertaining to the practice of medicine within their borders. They have exercised primary jurisdiction over these matters for various reasons. However, telemedicine affects interstate commerce and, along with it, the specter of federal influence and involvement. If it decides to act, the federal government may simply impose its will. Where it does not, federal principles may still hamper states in their own regulatory efforts. The final portion of this article will examine these federal concepts.

### *B. Federal Issues*

#### 1. Two Constitutional Provisions Affecting Telemedical Legislation

Because telemedicine has the potential to be thrust into interstate commerce, federal constitutional provisions, principally the Commerce Clause<sup>252</sup> and the Privileges and Immunities Clause,<sup>253</sup> can now apply in areas where states have previously exercised broad jurisdiction. These provisions grant Congress the power simply to force state rule makers aside, to second-guess state rule makers when state laws have impermissible effects on commerce, or to require state rule makers to put their citizens on an equal footing with citizens of other states.

The Commerce Clause has two purposes. Originally, this provision was intended to prevent discrimination by states who sought to favor their local products and businesses.<sup>254</sup> It re-

250. *Id.* at Introduction, available in <http://www.dartmouth.edu/~atlas/intro.html>, at 2, 4. These geographic areas do not necessarily conform to state lines. *Id.* at 2.

251. *Id.* at 4.

252. U.S. CONST. art. I, § 8, cl. 3.

253. U.S. CONST. art. IV, § 2, cl. 1.

254. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 512-13 (1935).



stricts state regulatory schemes to achieve this equality. The other purpose, which the Supreme Court has noted is of increasing importance, seeks uniform regulation for commercial activity conducted on an interstate basis.<sup>255</sup> This goal is usually accomplished by direct federal regulation.

The Privileges and Immunities Clause is intended to “place the citizens of each State upon the same footing with citizens of other States, so far as the advantages resulting from citizenship are concerned.”<sup>256</sup> It primarily seeks to fuse the nation into a collective by providing citizens of State A who venture into State B the same privileges as those afforded to citizens of State B.<sup>257</sup> Thus, as with one aspect of the Commerce Clause, this clause operates by restricting state regulatory schemes.

## 2. How the Clauses Work: Direct Action and Legislative Restrictions

### *a. Direct Action*

The federal government holds a decided advantage in areas where it chooses to legislate. “As long as it is acting within the powers granted it under the Constitution, Congress may impose its will on the States.”<sup>258</sup> This will is imposed directly on citizens, not on the states. Thus, “Congress may not simply ‘commandeer[r] the legislative processes of the States by directly compelling them to enact and enforce a federal regulatory program.’”<sup>259</sup> That is, the federal government cannot put a new statute on a state’s books, or compel state legislators to enact a law. However, Congress may *encourage* states to regulate their own citizens in a particular way, or use incentives to influence state policy choices.<sup>260</sup>

Medicare is an example of federal legislation directly affecting individual citizens. It provides federal dollars to pay for senior citizen health care.<sup>261</sup> Legislation proposals such as Representative Wyden’s federal preemption of state medical licensure and

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255. *Id.*

256. *Paul v. Virginia*, 75 U.S. (8 Wall.) 168, 180 (1869).

257. *Toomer v. Witsell*, 334 U.S. 385, 395 (1948).

258. *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991).

259. *New York v. United States*, 505 U.S. 144, 161 (1992), (quoting *Hodel v. Virginia Surface Mining & Reclamation Ass’n, Inc.*, 452 U.S. 264, 288 (1981), and holding that Congress could not require states to implement the Low Level Radioactive Waste Policy Amendments Act of 1985).

260. *Id.* at 166.

261. 42 U.S.C. §§ 426, 1395j (1994).

Representative Gary Condit's federal preemption of state laws governing confidentiality and access to medical records, both discussed earlier, are other examples of direct federal action. Most recently, congressional Republicans proposed to exempt health care provider service networks from state regulation that governs other managed care entities,<sup>262</sup> such as those run by insurance companies. All these purport to create a direct relationship between state citizens and the federal government.

Medicaid, on the other hand, is an example of a federal incentive. The program induces states, through the promise of federal dollars, to provide a comprehensive health care program for their poor citizens.<sup>263</sup> Medicaid does not order states to provide these services, but when states sign on to the program, they agree to play by federal rules. States retain some control, however. For example, a state can request a waiver from the program's requirements and create its own rules, such as Oregon did when it substituted its novel Medicaid rationing program. And state law generally governs the concept of medical necessity and thus determines which services will be paid for under a state Medicaid program.<sup>264</sup>

Telemedicine may encourage direct congressional legislation if only because it is intertwined with telecommunications. The area of telecommunications is governed under a dual system of state and federal regulation.<sup>265</sup> The federal statute<sup>266</sup> was created, in part, to protect safety of life and property through the

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262. Laurie McGinley & Christopher Georges, *Unequal Treatment: Medicare Bill Passed by House Would End Egalitarian Approach, The Wealthy Stand to Gain, The Poor May Be Hurt; Tradeoffs for the Middle Class; Is Health Care a Basic Right?*, WALL ST. J., Oct. 20, 1995, at A1, A8.

263. 42 U.S.C. § 1396 (1994).

264. The Supreme Court has noted that "[a]lthough serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage, it is hardly inconsistent with the objectives of the Act for a State to refuse to fund *unnecessary*—though perhaps desirable—medical services." *Beal v. Doe*, 432 U.S. 438, 444-45 (1977). Medicaid requires states to provide "necessary medical services." 42 U.S.C. § 1396 (1994). The phrase "medically necessary services" was described in a letter Medicaid used to explain why services are ineligible for reimbursement: "In making such a decision whether to provide payment for a particular service, a basic consideration is whether the service *has come to be generally accepted by the professional medical community* as an effective [and proven treatment] for which it is being used." *Montoya v. Johnston*, 654 F. Supp. 511, 513 (W.D. Tex. 1987) (quoting *Rush v. Parham*, 625 F.2d 1150, 1156 n.11 (5th Cir. 1980), and holding that a liver transplant for a six-year-old child was medically necessary under Medicaid) (emphasis added).

265. *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 360 (1986).

266. 47 U.S.C. §§ 151-612 (1994).

use of wire and radio communication.<sup>267</sup> Federal law preempts state law when a matter has both intrastate and interstate components,<sup>268</sup> particularly where "the interstate aspects of the matter cannot be 'unbundled' from regulation of the intrastate aspects."<sup>269</sup> On the other hand, court decisions have held that the federal telecommunications law is primarily economic legislation, and that Congress did not intend it to be the "complete regulation of an industry for health and safety of the general public."<sup>270</sup> As a result, to the extent that telemedical legislation relies on federal telecommunications law for validity, it will be difficult to predict how courts will interpret the overlapping jurisdictions of federal and state governments.

The newly signed Telecommunications Act of 1996<sup>271</sup> may contribute to increased federal-state friction in this area. It seeks to promote competition, encourage rapid deployment of new technology, and *reduce* regulation. It will accomplish these goals, in part, by requiring local telecommunications exchanges to make infrastructure, technology, information, facilities, and functions available to other carriers in order to expand telecommunications and information services to local populations.<sup>272</sup>

In this move toward deregulation, the federal government did not cede power to the states. Rather, it expressly forbids states from enforcing provisions of the law or regulations promulgated under it that are determined by the Commission to be inconsistent with the public interest.<sup>273</sup> Regulatory forbearance provisions require biennial federal review of regulations for this purpose.<sup>274</sup> Promoting competitive market conditions among providers of telecommunications services is a principal focus of "public interest" under this legislation.<sup>275</sup> In addition, carriers can petition for a review of offensive regulations.<sup>276</sup> Thus, fed-

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267. 47 U.S.C. § 151 (1994).

268. *Louisiana Pub. Serv. Comm'n*, 476 U.S. at 375 n.4.

269. *Public Serv. Comm'n of Md. v. FCC*, 909 F.2d 1510, 1515 (D.C. Cir. 1990), (quoting *National Ass'n of Regulatory Util. Comm'rs v. FCC*, 880 F.2d 422, 429 (D.C. Cir. 1989)).

270. *Air Transp. Ass'n of Am. v. Public Util. Comm'n of Cal.*, 833 F.2d 200, 204 (9th Cir. 1987), *cert. denied*, 487 U.S. 1236 (1988).

271. Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996).

272. *Id.* at § 259(a), 110 Stat. at 77-78.

273. *Id.* at § 401(e), 110 Stat. at 128.

274. *Id.* at § 402(a), 110 Stat. at 129.

275. *Id.* at § 401(b), 110 Stat. at 128.

276. *Id.* at § 401(c), 110 Stat. at 128.

eral deregulation does not mean that states will be allowed to step in and fill the void.

The telecommunications aspects of telemedicine make direct federal involvement obvious. However, there is precedent for federal input into other aspects of telemedicine. For example, *federal* professional licensure regulation is not new. In 1994, Congress enacted a law mandating minimum standards for “testing and ensuring the fitness” of individuals operating commercial motor vehicles in interstate commerce.<sup>277</sup> Although states still issue driver’s licenses to these individuals, they may do so only if the drivers demonstrate compliance with the minimum federal standards,<sup>278</sup> and, for this purpose, federal law controls over inconsistent state law.<sup>279</sup> Like Medicaid, this law is another example of federal incentives to induce state cooperation; however, the law provides a negative incentive because federal highway dollars can be withheld if states do not comply.<sup>280</sup>

The federal driver’s license law also creates a federal clearinghouse and depository of information about drivers, their licensing, and their disqualification.<sup>281</sup> This is somewhat akin to the federal medical practitioner database established under the Health Care Quality Improvement Act of 1986 (the HCQIA),<sup>282</sup> which tracks on a nationwide basis medical malpractice payments,<sup>283</sup> state medical board disciplinary actions,<sup>284</sup> and adverse professional review actions made by health care entities.<sup>285</sup> However, the HCQIA does not address physician licensure.

Congress has shown a willingness to legislate in matters of health and safety traditionally relegated to the states by imposing minimum federal requirements for state-licensed commercial drivers when they travel roads outside their home state. Teledoctors can “travel” to other states via the information superhighway. The potential for loss of human life exists in both cases. This precedent may give Congress the impetus to become

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277. 49 U.S.C. § 31305 (1994).

278. *Id.* at §§ 31311(a)(2), (a)(4) (1994).

279. *Id.* at § 31306(g) (1994).

280. *Id.* at 49 U.S.C. § 31314 (1994).

281. *Id.* at 49 U.S.C. § 31309 (1994).

282. 42 U.S.C. §§ 11101 (1995).

283. *Id.* at § 11131 (1995).

284. *Id.* at § 11132 (1995).

285. *Id.* at § 11133 (1995).

involved in another interstate licensing effort for telemedical practitioners.<sup>286</sup>

### *b. Legislative Restrictions*

In addition to the federal government's power to legislate, the Commerce Clause prohibits restrictive state regulatory schemes that place incoming commerce at a competitive disadvantage or that burden the free flow of commerce through a state's borders.<sup>287</sup> This federal power operates indirectly, through judicial scrutiny of state legislation. Notwithstanding that states have broad powers to protect their citizens against perils to health and safety, federal courts can use this principle to invalidate state laws that promote economic favoritism for state citizens. This means that a state's relatively free hand can be constrained by a finding of improper motive.

A famous "milk case"<sup>288</sup> provides an example of how the Commerce Clause is applied to state legislation. The State of New York enacted a law intended to assure an adequate supply of pure milk for its citizens by requiring milk dealers to pay a minimum price to milk producers. However, New York refused to grant a permit to a Vermont dairy because it was willing to accept a price lower than the state-mandated minimum. While the Supreme Court found the required minimum price permissible between New York dealers and producers,<sup>289</sup> it ruled that as applied to out-of-state producers, the law amounted to economic protectionism by mandating a minimum price for out-of-state milk purchases.<sup>290</sup> This example demonstrates that a state law that is a valid means of regulating an industry carried on

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286. The commercial driver's licensing statute exacts state cooperation by threatening to withhold federal highway dollars. By comparison, the federal government does not routinely hand health care dollars to the states outside programs such as Medicaid, and those programs serve a limited clientele and thus affect a limited number of physicians. In addition, future federal health care funding may be sharply curtailed. See, e.g., Hilary Stout, *Clinton, After His Veto, Will Have Tricky Job of Trying to Strike a Budget Deal on His Terms*, WALL ST. J., Oct. 30, 1995, at A20. Current House and Senate versions of the proposed fiscal 1995 budget promise to cut some \$170 billion from the Medicaid budget over seven years. *Id.* And there may be little new spending for telemedical infrastructure and programs. Thus, there may not be the same potential for broad-based economic incentives for a telemedical physician licensure statute as there are for the federal driver's license law.

287. See *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 532 (1949).

288. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935).

289. See *Nebbia v. New York*, 291 U.S. 502, 518-20 (1934).

290. *Baldwin*, 294 U.S. at 523-24.

wholly within a state can be invalid under the Commerce Clause when it restricts out-of-state entities from doing business there.

The Privileges and Immunities Clause also prohibits certain state regulatory schemes. It targets state laws that attempt to treat citizens and noncitizens differently. Professional pursuits such as the practice of medicine, a “common calling,” fall within the clause’s protections.<sup>291</sup> As a result, laws purporting to deny nonresidents a professional license in other states have been held unconstitutional.<sup>292</sup> Thus, this Clause also works by scrutinizing state law and negating offensive provisions.

### 3. Some Specific Tests in a Health Care Context: Licensure

The following discussion looks at four tests established under the Commerce Clause and Privileges and Immunities Clause in the context of physician licensure. *If* states are permitted to retain their historical jurisdiction in this area for telemedicine, they will have to maneuver through these tests to assure the validity of their legislation.

#### a. *Overt Economic Protectionism*

State regulation in the health care arena has often sought to achieve multiple goals. For example, state licensure may principally seek to assure the competence of persons practicing the healing arts.<sup>293</sup> However, some commentators note that this ostensibly citizen-centered goal conceals other goals that favor practicing professionals. Thus, licensure laws can control health care delivery, eliminate competition, control and restrict supply, enshrine orthodoxy, and assure high levels of payment for physician services.<sup>294</sup> These results could be legitimate, particularly when they are by-products of an important state goal such as assuring competent patient care. In this case, state licensure os-

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291. See *United Bldg. & Constr. Trades v. Mayor of Camden*, 465 U.S. 208 (1984). The Court stated that “the pursuit of a common calling is one of the most fundamental of those privileges” protected by the Privileges and Immunities Clause. *Id.* at 219.

292. See *Supreme Court of N.H. v. Piper*, 470 U.S. 274, 288 (1985) (holding that a New Hampshire regulation that prohibits nonresidents from obtaining a law license in that state violates the Privileges and Immunities Clause).

293. See, e.g., 225 ILCS 60/11, 60/12 (1993) concerning minimum educational qualifications and examination requirements.

294. PROPOSAL FOR REVISION OF SECTION 2052 OF THE MEDICAL PRACTICE ACT (Cal. Bd. of Medical Quality Assurance) §§ 3-5, 8-9 (1982), *reprinted in* WILLIAM J. CURRAN ET AL., *HEALTH CARE LAW, FORENSIC SCIENCE, AND PUBLIC POLICY* 261 (4th ed. 1990).

tensibly weeds out the unfit<sup>295</sup> and, incidentally, assures a limited supply of practitioners.

Although permissible at a state level, any such professional-centered goals that restrict out-of-state competition may fail under *federal* principles since they are likely to promote local economic advantage. They may also impermissibly impact the rights of nonresidents to practice a common calling within the state. Telemedicine promises to make out-of-state medical care more possible. State regulatory schemes that are intentionally or inadvertently designed to close state borders will likely fail under these principles.

### *b. Reciprocal Agreements*

As noted earlier, a state can enter into agreements with other states so that its regulations can achieve extraterritorial effect. However, if such arrangements impose a mandatory condition on state citizens doing business in other jurisdictions, they will likely fail as impermissible reciprocal agreements.

Another "milk case" illustrates this point. A Mississippi regulation allowed the sale of out-of-state milk and milk products in Mississippi only if the other state signed a reciprocity agreement to accept Mississippi products. The purported reason for the regulation was to guarantee safe milk imports into the state. A Louisiana milk producer was denied a Mississippi license because the state of Louisiana had not signed a reciprocity agreement for this purpose. Noting that the regulation did nothing to test the quality of the milk coming into the state, the Supreme Court held that the real purpose of this law was to protect markets for Mississippi milk.<sup>296</sup> Thus, the court struck down the regulation.

As a result, courts will likely find it impermissible for State A to allow State B's teledoctors to practice in State A if the compulsory quid pro quo is entry of State A teledoctors into State B. Even if such a regulation were enacted for ostensible health and safety purposes, courts would likely find that the regulation's real purpose was to protect markets for State A teledoctors.

295. Some state licensing boards are better than others in culling bad doctors. See, e.g., Timothy S. Jost et al., *Consumers, Complaints, and Professional Discipline: A Look at Medical Licensure Boards*, 3 HEALTH MATRIX 309, 337 (1993) (concluding from a study of the Ohio State Medical Board that public complaints "rarely lead to formal disciplinary actions").

296. *Great Atl. & Pac. Tea Co. v. Cottrell*, 424 U.S. 366 (1976).

### c. *Least Restrictive Means Test*

The least restrictive means test is a judicial principle that requires states to employ reasonable nondiscriminatory alternatives wherever possible to achieve legitimate local interests. Although economic protectionism is not a valid local interest, concerns that nonresidents pose a “peculiar source of the evil at which the statute is aimed”<sup>297</sup> may be legitimate. Unsubstantiated assumptions about such evils are not valid grounds for restricting those from out of state, however. Without satisfactory evidence, state lawmakers may not merely suspect that nonresidents are less diligent about local rules and procedures, are less ethical, or will be unavailable for in-state proceedings or for pro bono and volunteer work in the state.<sup>298</sup>

Even if nonresidents are guilty of these failings, absolute prohibitions against out-of-state business are inappropriate if alternative regulations can allow out-of-state participation on some basis. For example, concern that nonresident practitioners lack the same quality of training as in-state professionals might be addressed by requiring comparable education before nonresidents are allowed to practice in the state.<sup>299</sup> Concern about out-of-state practitioners’ knowledge about local rules and procedures might be ameliorated with mandatory attendance at state practice seminars.<sup>300</sup> The mere fact that local citizens have some economic or regulatory advantage is not fatal. Thus, in a telemedical context, State A may not stop State B teledoctors from practicing there, although its regulations may have the effect of making it more burdensome and possibly more costly for nonresident teledoctors to qualify there. This result is permissible if the more stringent requirements are reasonably related to achieving legitimate state goals.<sup>301</sup>

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297. *Toomer v. Witsell*, 334 U.S. 385, 398 (1948).

298. *Supreme Court of N.H. v. Piper*, 470 U.S. 274, 285 (1985).

299. *See, e.g., Lupert v. California State Bar*, 761 F.2d 1325, *cert. denied*, 474 U.S. 916 (1985). In *Lupert*, a California statute required students attending unaccredited law schools to pass a special examination before continuing their education. The court found that the statute bore a rational relationship to legitimate state interests of protecting the quality of training and education in that state. *Id.* at 1328.

300. *Piper*, 470 U.S. at 285 n.19 (suggesting that these seminars would be a “less restrictive alternative” to imposing a residency requirement on members of the state bar).

301. Yet another milk case illustrates this point. In *Dean Milk Co. v. City of Madison*, 340 U.S. 349 (1951), the Supreme Court invalidated a Madison, Wisconsin, ordinance that required pasteurization of locally sold milk at a milk plant located within a stipulated radius of the city’s center. This regulation had the effect of banning milk from plants located outside the arbitrary boundary, including the Illinois



#### *d. Evenhandedness*

There is one regulatory technique that might stop State B teledoctors at State A's borders. However, the state adopting such a regulation would have to determine that telemedical practice is potentially harmful to its citizens and, on that basis, would also have to prohibit telemedical practice by in-state doctors. Essentially, this regulatory scheme depends upon finding that telemedical practice constitutes a health menace, which must be eliminated.<sup>302</sup> If a health menace is legitimately found to require elimination, then the state must eliminate it entirely and cannot allow potentially harmful activities to be carried on within its borders while prohibiting nonresidents from conducting those same activities there. Thus, there must be an evenhanded approach to the perceived menace.

This principle is illustrated by two quite different cases. In the first, the State of New Jersey closed its borders to out-of-state waste, purportedly to protect the environment. Yet, it permitted the burial of treated waste generated within the state even though the waste had the same potential hazardous impact. The Supreme Court struck down the regulation.<sup>303</sup> In the second case, a State of Wisconsin regulation prohibited the retail sale of milk in plastic nonrefillable containers to conserve energy and local resources. The ban governed both in-state and out-of-state retailers. The Supreme Court found the regulation to be evenhanded and thus nondiscriminatory to interstate commerce.<sup>304</sup>

Note that an evenhanded approach can work to a state's benefit. For example, absent federal preemption, a state is not obligated to *lower* any high qualifications it may impose on its own residents or vary its own rules. That is, a state need not accommodate nonresidents simply because its rules differ from an-

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plaintiff. The state argued that the regulation promoted convenient, economical, and efficient plant inspection. *Id.* at 352-53. However, the Supreme Court invalidated it because less restrictive alternatives were available. *Id.* at 354. For example, the city might levy higher inspection fees for more remote processing plants or adopt the United States Public Health Service's system of verifying the quality of those plants. *Id.* at 355.

302. See *id.* at 354.

303. *City of Philadelphia v. New Jersey*, 437 U.S. 617, 625-26 (1978) (holding that the New Jersey regulation violated the Commerce Clause).

304. *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 471-72 (1981). Although local pulpwood manufacturers were likely to be benefited to the detriment of out-of-state plastic manufacturers, the Court found the potential benefit to be an incidental burden on commerce outweighed by the local health benefits. *Id.* at 473.

other state's rules.<sup>305</sup> It is only where the qualifications have no relation to the calling or profession or where they are unattainable that they can operate to impermissibly deprive a nonresident of the right to pursue an occupation.<sup>306</sup> In addition, states may impose new regulatory conditions from time to time to reflect innovation and advancement in a field.<sup>307</sup> Thus, and despite some constraints, states have considerable latitude in regulating occupations to root out ignorance, incapacity, fraud, or deception.<sup>308</sup>

This latitude will no doubt apply to telemedical practitioners seeking the right to practice within a state. If such regulations pertain to the learning and skill necessary to perform an occupation and are generally applicable to the state's *own* practitioners,<sup>309</sup> federal constitutional provisions will not completely restrain state lawmakers from regulating the occupation to assure local health and safety. Accordingly, one state's regulatory scheme will not be invalid merely because it requires greater qualifications for practitioners who treat its citizens than another state requires for its own practitioners.

## CONCLUSION

Telecommunications technology is becoming increasingly important to health care delivery in the United States. Telemedicine promises to send voice, video, and data along airwaves, enabling the physician and patient to reach out to each other across state borders on a real-time basis. Various specialties such as teleradiology, telepathology, telepsychiatry, and even telesurgery could be practiced in this manner. Telemedicine seeks to reduce cost, improve patient outcomes, and provide greater access to high-quality medical care to unserved and underserved populations.

Commentators have drawn attention to the legal barriers that may impede telemedicine, such as the current scheme of state-

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305. *See, e.g., Dent v. West Virginia*, 129 U.S. 114 (1889). The plaintiff was denied a license to practice medicine because he lacked the statutory qualifications. He attacked the regulation as a deprivation of his right to practice under the Due Process Clause. The Supreme Court rejected his claim, observing that there is no deprivation of this right if he fails to comply with conditions appropriately imposed by the state "for the protection of society." *Id.* at 121-22.

306. *Id.*

307. *Id.* at 123.

308. *Id.* at 122.

309. *Id.*

by-state licensure, which can stop physicians at state borders. In response, legislators and others are calling for *federal* measures to facilitate nationwide telemedical practice, contending that interstate commerce is a topic squarely within federal jurisdiction, that the telecommunications industry is already federally regulated, and that Congress recently enacted for health and safety reasons a federal licensing statute affecting an interstate industry. Yet, medicine has been traditionally regulated by the states, and states will likely resist federal incursions into this domain. The recently reinvigorated "New Federalism" movement, which demands a more faithful interpretation of the United States Constitution's Tenth Amendment, may empower states in these efforts.

In the absence of prompt federal legislation, states might legislate individually on telemedical issues, but the result may be a hodgepodge of laws that impedes multistate cooperation. Alternatively, states could wield their power collectively, in a more comprehensive manner short of federal involvement. Extraterritorial tools for this purpose include reciprocal agreements, uniform laws, and interstate compacts. Such efforts for telemedicine may be delayed or may fail, however, because of policy differences, unequal resources, and the need to marshal numerous individual state legislatures and governors in the cause. Collective state efforts might also fail because the interstate potential of telemedicine permits federal input.

A single legislative body—Congress—might adopt telemedical legislation instead. And even if the federal government permits states to retain some jurisdiction, certain federal principles will restrict anything individual states might do. Constitutional provisions require states to open their borders to out-of-state practitioners, to regulate the activities of resident and nonresident professionals in an evenhanded manner, and to ensure that any increased burden on nonresidents doing business in their state is incidental only, justified to weed out incompetence and potential health menaces. Simply put, states may not favor their local businesses over those of outsiders and must allow citizens in other states the same privileges afforded to their own citizens.

Right now, there may be more telemedical demonstration projects than use of telemedicine on a routine basis, standards for telemedical applications are unfinished, satellite systems for

telemedical transmissions are still in the development stage,<sup>310</sup> the “information superhighway” may currently have an infrastructure equivalent to that of “dirt roads,”<sup>311</sup> and cost efficiencies of telemedical applications are still being examined. It is too soon to predict whether state constraints or federal interest will dictate a federal solution to one or more of the many practice issues pertinent to telemedicine. However, interstate aspects of telemedicine and its potential to significantly alter the traditional medical encounter will likely focus attention on this topic in the coming years.

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310. Jeff Cole, *Star Wars: In New Space Race, Companies Are Seeking Dollars From Heaven; Satellite Transmission of Data and Images Spark Fight for Piece of Sky's Pie; 'That's Where the Money Is,'* WALL ST. J., Oct. 10, 1995, at A1.

311. Audrey Choi, *Netcom Will Upgrade Internet Services by Using High-Speed Network Switches*, WALL ST. J., Oct. 30, 1995, at B3 (quoting Daniel E. Smith, President of Cascade Communications Corp.).