

*I am a student at Columbia University. However, this comment to the Federal Trade Commission reflects my own personal opinions. This is not representative of the views of Columbia University or the Trustees of Columbia University.*

Reference: P131207

### **Summary:**

Telemedicine is a growing field whose widespread adoption promises to address inequalities in access to care, by both reducing costs and by remotely redistributing the supply of physicians. However, current regulatory policies at the state-level are hindering the expansion of cross-border medical practice. These regulatory barriers need to be removed if telemedicine is to serve as a key strategy in mitigating current and future healthcare delivery challenges.

### **Evidence:**

The evidence was collected from database searches of law review journals and from conversations with doctors in the field (not directly referenced). These sources influenced both the alternatives proposed and the conclusion reached.

### **Background:**

The Food and Drug Administration (FDA) defines telemedicine as the delivery and provision of healthcare and consultative services, including diagnosis, treatment and remote monitoring of patients, using telecommunications technologies.<sup>8,12</sup> When telemedicine is used in conjunction with peripheral activities to patient care, such as patient education and administration services, telemedicine is more broadly addressed as telehealth.<sup>4</sup> Telehealth projects are rapidly become more prominent, particularly with the evolution of the Internet in the past two decades.<sup>1</sup> Although the size of the domestic market for telemedicine remains unascertained, experts agree that the market is significant.<sup>1,2</sup> As of 2012, 42 percent of non-federal hospitals had fully implemented telehealth capabilities in at least one unit.<sup>3</sup> This growth in telemedicine is predicted to continue as new technologies, such as telesurgery, are developed and as research quantifies the cost-effectiveness of these programs.<sup>1,2,3,5</sup>

The two chief motives for the widespread adoption of telehealth are access and cost. It is widely believed that “when properly implemented, the broad adoption of connected health has the potential to extend care across populations of both acute and chronically ill patients and help achieve the important policy goals of improving access to high-quality and efficient health care.”<sup>4</sup> Specialists and advanced diagnostics are more readily accessible in urban than in rural settings.<sup>1,3,4,9</sup> By using telemedical services, isolated, immobile and remote populations would be able to access high-quality healthcare.<sup>1,3</sup>

Telemedicine has been cited as a strategy for achieving cost-effective care,<sup>2,4</sup> and policymakers are increasingly utilizing technology to mitigate rising healthcare costs.<sup>4,6</sup> Moreover, telemedicine not only reduces costs but also addresses the priorities set forth by the Affordable Care Act (ACA).<sup>1,3,4,8</sup> Nursing homes utilizing telemedicine services can save Medicare an average of \$120,000 per nursing home per year, while reducing hospitalization rates, and home telemonitoring data suggests a decrease in both readmission and mortality rates, in addition to savings of around \$10 million over a six-year period.<sup>3,4</sup>

As worded by Cleland (2002), “there is no reason to doubt that innovative technologies will develop to address existing professional obstacles. But telemedicine, particularly cross-border telemedicine, presents significant regulatory challenges that cannot be easily addressed”.<sup>11</sup> The federal government has been active in both providing funding and in passing

legislation to enable the advancement of telemedicine, as seen in these major federal laws:

- Telecommunications Reform Act of 1996<sup>1,10</sup> – requires the Federal Communications Commission (FCC) to construct and maintain suitable communication infrastructure in rural areas; mandates that service rates for the provision of healthcare services to rural regions in a state be comparable to rates charged for similar services in the urban regions of the same state
- Balanced Budget Act of 1997<sup>1,10</sup> – expands reimbursement option for telemedicine practitioners; following amendments improve previous reimbursement arrangements expanding geographic areas eligible for telehealth reimbursement
- Medicare Telehealth Validation Act of 2002<sup>1</sup> – expands access to Medicare telehealth; increases reimbursable types of originating sites (10)
- Food, Drug and Cosmetic Act<sup>10,12</sup> – regulates hardware and software that comprise telemedical devices

Despite efforts by the federal government to minimize barriers to the expansion of telehealth, historically, it is the states that have regulated the practice of medicine.<sup>1,11</sup> Regulatory challenges of telemedicine consist primarily of practitioner licensure and reimbursement laws.<sup>1,3,10,11</sup>

Research has shown that states that promote reimbursement for telemedical services are associated with a greater likelihood of telehealth adoption, while those states that require out-of-state providers to have a special license when delivering telehealth services are associated with a lower likelihood of telehealth adoption.<sup>1,3</sup> This “patchwork” of laws across all states has resulted in regulatory barriers to the uniform adoption of telehealth services. However, concerns about legal liability, financial disincentives, quality of care, and patient safety, remain obstacles to the removal of these barriers.<sup>1</sup> Additionally, lack of conclusive evidence, regarding cost of expansion of telehealth initiatives, has restrained the federal government from mandating broad changes in regulation.<sup>1</sup>

It is important to consider telemedicine as an important strategy in not only mitigating rising costs but also in accomplishing many of the priorities of the ACA, such as reduction in readmission rates and provision of high quality, patient-centric care.<sup>3,4</sup> Given that telemedicine is competitive only at high volumes,<sup>3,4</sup> new regulatory approaches must be considered in order to enable the widespread practice of telemedicine, while continuing to safeguard the safety and rights of the public.

### **Problem:**

The condition of inequality in access to high-quality care is driven primarily by costs and by the maldistribution of health professionals in the United States. The emergence of telemedicine has provided a cost-saving alternative to address professional shortages in underserved areas, turning this condition into a problem amenable to government action.<sup>1,3,4</sup> Framing this problem as an inequality urges government intervention in the form of public policy. Below three policy alternatives are offered that would enable the expansion of cross-border telemedicine services.

### **Policy options:**

#### The Federation of State Medical Boards (FSMB) Model

Originally proposed in 1996, the FSMB model regulates cross-border medicine practice; physicians holding a full and unrestricted license in any state would be able to practice cross-border medicine by obtaining a special license from the medical board in which the patient is

located.<sup>10,13</sup> This special license would ensure that the physician would be subject to the jurisdiction of the board in the patient's state, and therefore failure to appear in court, or produce records, could result in the suspension or revocation of the physician's medical license.<sup>11</sup> The FSMB further sets specification for cases exempt from this requirement, such as medical emergencies and practice done without compensation.<sup>11</sup>

The advantage of this regulation would be primarily that physicians are held liable in the state where the patient is located, which protects the rights of the consumers. Additionally, this model would provide incentive for states to participate through special license fees, and would allow the states, particularly the medical boards, to continue to regulate quality of care by establishing qualifications for the special licenses. Furthermore, having a special license from the state would facilitate reimbursement of telemedicine services, which could incentivize more practitioners to participate.

On the other hand, it is possible that this model will decrease the uptake of telemedicine adoption by making it more costly and difficult to participate in cross-border services.<sup>3</sup> Additionally, the providers might be reluctant to submit to the jurisdiction of the state where the patient is located.<sup>1</sup> Nevertheless, it is predicted that the uniform implementation of this model would result in an increased adoption of telemedicine practice.

There are some states, such as Texas, which are currently allowing cross-border practice using this model, however, the varying degrees of regulation set forth by the states has thus far impeded the cross-border use of telemedicine.<sup>3</sup> The alternative proposed would be a federal implementation of the FSMB Model in every state, regardless of current regulation.

#### Auto Insurance Model

The automobile industry tackled cross-border driving through the use of insurance, which protects the driver regardless of the state in which the accident occurs. Applying this model, any physician holding a full and unrestricted license in one state, could practice in any state so long as (s)he has sufficient malpractice insurance to cover potential losses in the state where the patient is located. Additionally, if quality of care remains an issue, further restrictions could be placed on the practice of free cross-border medicine, such as board certification in a specialty, which is an existing quality standard measure set at the national level.

The advantages of this model are that quality can be maintained and that it allows for essentially free competition of providers between states, which would drive down costs on a national level. Furthermore, a patient could sue the company no matter where it does business in the United States, and the company would have to produce the provider to defend the claim.<sup>3</sup>

On the other hand, though the malpractice insurance would cover the provider in the state where the patient is located, this model allows for less regulatory oversight and it might prove difficult to enforce state's jurisdiction on providers in different states. Additionally, this model provides no incentive for states to accept cross-border medicine or to provide appropriate reimbursement rates. Particularly, this last point needs to be addressed on a federal level because without a special license, current Medicare regulations prevent the distribution of funds to nonresident providers.<sup>2</sup>

#### Liability Shift Model

This model is based on the corporate liability model, in which the most powerful party in the transaction is responsible for internalizing the costs of safety and improving the quality of products or services.<sup>3</sup> Precedent shows that hospitals are more likely to be held liable by courts than the consulting specialists.<sup>2,11</sup> This alternative proposes an expansion of this model to private

physician offices in which the provider requesting the consultation is held liable, rather than the consulting physician.

The advantages of this alternative are that it eliminates the current challenges in determining liability to the patient; currently, hospitals/providers could use the “independent contractor” defense, and patients would have a hard time demonstrating sufficient contact with specialist in order to establish jurisdiction. Additionally, it is the treating physician that makes the final decision and for this reason the physician will not only seek a high-quality specialist, but will also review the diagnosis, and by doing so, ensuring high-quality care.<sup>2</sup>

On the other hand, if the courts rule that the physician cannot rely on the specialist’s diagnosis, this would require another specialist to review the diagnosis, resulting in redundancy and eliminating some of the benefits of teleconsultation.<sup>2</sup> Furthermore, the nature of this liability shift model would restrict the use of telemedicine to consultations and diagnoses (no treatment).

### **Recommendation: FSMB Model**

The FSMB Model seems both the most feasible, and the most appropriate in guaranteeing quality of care and patient’s rights. Historically the states and the medical boards have had the most expertise in regulating medical care, and though expansion of cross-border telemedicine will require some governmental action, the states continue to be best equipped in regulating this market; states are both able to enforce existing professional standards of the FSMD and manage violations through the revocation of licensure for physicians or accreditations for hospitals.<sup>2,3,10</sup>

Further actions in the enactment of this regulation would be:

- the establishment of minimum qualifying criteria for the special licenses by the FSMB (with oversight from the FTC to ensure fair competition)
- the amendment of the Balanced Budget Act to allow for easier and more generous reimbursements to more telemedicine services
- the involvement of the Federal Trade Commission (FTC) - while involvement of the FTC would be most relevant in the regulation of cybermedicine, the agency’s regulatory oversight would still apply to the proposed solution by ensuring that all states are abiding by the trade agreement. Since regulation of interstate medicine can inherently not be done on a state level, the FTC could serve as a higher regulatory authority in this process.

By enabling telehealth delivery across states, the specialist shortage and maldistribution would be addressed, quality of healthcare services would be improved, and service costs would be contained.

### **References:**

1. Mary Schmeida. Telehealth Innovation In The American States. Dissertation Submitted To Kent State University. (2005)
2. Thomas R. Mclean and Edward P. Richards. Teleradiology: A Case Study Of The Economic And Legal Considerations In International Trade In Telemedicine. *Health Affairs*, 25, No.5 (2006):1378-1385
3. Julia Adler-Milstein, Joseph Kvedar and David W. Bates. Telehealth Among US Hospitals: Several Factors, Including State Reimbursement And Licensure Policies, Influence Adoption. *Health Affairs*, 33, No.2 (2014):207-215
4. Joseph Kvedar, Molly Joel Coye and Wendy Everett. Connected Health: A Review Of Technologies And Strategies To Improve Patient Care With Telemedicine And Telehealth. *Health Affairs*, 33, No.2 (2014):194-199

5. Leihu Shi and Douglas A. Singh. *Delivering Health Care in America: A Systems Approach*. Fourth Edition. Jones and Bartlett Publishers. Sudbury, Massachusetts (2008)
6. Johnston Et Al. Outcomes Of Kaiser Permanente Telehome Health Research Project. *Archives Of Family Medicine* No.9 (2000):40-45
7. Field And Grisby. Telemedicine And Remote Patient Monitoring. *JAMA* 288 (2002):423-425
8. D. C. Grabowski And A. J. O'Malley. Use Of Telemedicine Can Reduce Hospitalizations Of Nursing Home Residents And Generate Savings For Medicare. *Health Affairs*, Feb. 2014 33(2):244-50.
9. Robert A. Berenson, Joy M. Grossman And Elizabeth A. November Does Telemonitoring Of Patients-The eICU-Improve Intensive Care? *Health Affairs*, 28, No.5 (2009):W937-W947
10. Richard L. Cleland. Cross-Border Telemedicine: An Uncertain Future. Saint Louis University School Of Law Saint Louis University Law Journal 46 (2002):149-156
11. P. Greg Gulick. E-Health and The Future Of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs. *Albany Law Journal of Science & Technology* 12 (2002):351-407
12. Peter S. Reichertz and Naomi J. L. Halpern. FDA Regulation Of Telemedicine Devices *Food And Drug Law Journal*. Vol. 52 517-523 1997
13. Gene C. Wunder. Telemedicine: An Overview. Washburn University At Topeka, Kansas. Allied Academies International Conference (1997)40-44