

The Impact of Laws Governing Telemedicine

Not all telemedicine is created equal and states have their preferences and their say-so

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EXECUTIVE SUMMARY

Telemedicine is having a profound impact on the evolving healthcare system in the United States. As many providers focus on carving out their place in a local and regional market, they are suddenly forced to consider the broader market as well.

There are some key players in the telemedicine space but most are at entry stages and their current models are likely not sustainable into the future. Technology will take center stage in healthcare delivery as it evolves.

We want to explore what the individual state and federal governments as well as physician groups and payors have to say about telemedicine and shed some light on the impact of their influence in its development; but first, let's take a brief visit into the history of telemedicine is needed.

The History of Telemedicine

The most prolific use of telemedicine in its early stages was at the National Aeronautics and Space Agency (NASA) as a means of monitoring the health status of astronauts as they completed their missions. NASA has been the source of significant invention over the years but the development of technology for the purpose of remote health status monitoring is one that is often over-looked. Even today we can and do learn from what NASA created to fulfill this mission-critical element. The need for portability, durability, high resolution, accuracy, accountability and simplicity could have been no greater than while orbiting the earth or on trips to the moon.

Even given the many advancements afforded by our space program, telemedicine has been slow to meld into the United States healthcare fabric. It has been more readily adapted overseas where healthcare is not nearly as accessible as it is in the U.S.

In 1924, a radio enthusiast magazine titled *Radio News* described and illustrated what it termed "The Radio Doctor" - a complete bedside unit that allowed a physician to remotely examine, diagnose, and treat a patient.

Mr. Hugo Gernsback was a noted science fiction author and would likely be shocked at the developments of what he alluded to in this 1924 *Radio News*



publication. What he reported therein has surprising parallels to actual telemedicine services in use today - having two way sound and video, an electronic remote stethoscope and monitors for vital signs and more. Mr. Gernsback, went on to notoriety as a publisher of popular science fiction through the coming decades and after his death, the [Hugo Award](#) for science fiction literature was named in his honor.

Telemedicine by radio was used until the mid-20th century, most frequently applied by doctors providing advice to ships at sea using maritime radio. As television emerged nationally beginning in the 1950's, telemedicine applications attempted using TV. In 1955, a Nebraska psychiatric institute created and operated a successful closed-circuit black and white television system to a hospital over 100 miles away.

Television projects became the mainstay of telemedicine through the mid-20th century. An additional notable project once again used black-and-white closed circuit TV to link the medical clinic at Boston's Logan International Airport to Massachusetts General Hospital just across the bay. Concerns over Logan Airport's limited road and train access led to the project, and a paper published after doctors had seen 1,000 patients over the link was the first positive evaluation of the diagnostic equivalency of a telemedicine link versus in-person care. (Source: http://www.philblock.info/hitkb/h/history_of_telemedicine.html)

In the late 1990's the popularity of the personal computer followed by the fast-paced expansion of the Internet created even more opportunity for telemedicine applications. By the year 2000, two factors began to drive a rapid expansion and exploration of new telemedicine applications:

- The development of low-cost solid-state devices with high performance.
- The rapid availability and popularity of the Internet

Federal grant support for telemedicine continued through the 1990's via many different US government agencies and with it, the number and complexity of telemedicine options grew so great that Congress requested a review of this activity by the US Department of Commerce, which led to the [1997 Telemedicine Report to Congress](#).

This report yielded no clear conclusions and made no specific recommendations, further muddying the already unclear waters regarding the value of telemedicine to national health care. A follow-up report was commissioned in 2001 ([2001 Telemedicine Report to Congress](#)). It is recommended that anyone with an interest in telemedicine read this 111 page report. This report identified five (5) areas of needed policy development:

- A lack of reimbursement
- Legal issues
- Safety and related standards
- Patient privacy and confidentiality
- Telecommunications infrastructure

Ironically, these issues are largely still unresolved with the exception of the reimbursement issues. Telemedicine has gained wide acceptance in the payor world as not only a cost-effective

method of healthcare delivery but a clinically effective delivery mechanism as well.

State Laws

As of April 2014, twenty-two (22) states have enacted laws that mandate coverage for telemedicine services and another fourteen (14) have proposed such laws. There are thirteen (13) states that have mandated Medicaid coverage for telemedicine and ten (10) that have proposed such coverage. If not for the impact of the Affordable Care Act on individual state Medicaid programs, adaptation would likely have been much higher. There are twenty-nine (29) states that have additional legislation that has been adapted or pending. Telemedicine is one of the most dynamic areas of legislative action across all states. For those states that have legislated approval of telemedicine in some respect, follow-up legislation has focused on expansion of telemedicine to additional areas such as: speech therapy, mental health, federally qualified health centers and more.

Keeping up on what the states are doing in this regard has become such a dynamic topic that The American Telemedicine Association publishes a monthly [Policy Matrix](#), detailing changes and proposed changes in public policy on the subject.

These changes largely focus on the five (5) challenges that had been identified in the 2001 Telemedicine Report to Congress as identified earlier herein.

Federal Government Role

The federal government has generally stepped aside to allow the individual states to address their interests in the matter of telemedicine. One of the major reasons is because each state has its own provider licensure board and policies governing the licensure and credentials of medical practitioners. The federal government has taken action to accept telemedicine as a viable delivery platform by approving payment by Medicare in the same manner as it pays for primary care services.

Though the federal government has a significant interest in telemedicine, it is unlikely that they will use any political capital stomping on the individual states to fulfill their agenda.

The United States government is not nearly as proactive in addressing healthcare trends and patterns as other nations or groups of nations have been. Europe, by example, established a task force called the European Health Telematics Association (“ETHEL”). Having identified the potential benefits of telemedicine early on, ETHEL produced a complete guide of engagement and policy to be used as a blueprint for engagement ([Sustainable Telemedicine: Paradigms for future-proof healthcare](#)).

Having taken no such like action in the United States, the Federal Government has left the market to evolve on its own which has had the affect of slowing the engagement and rollout process, creating an open forum for debate and conflict. Ideally, the Federal Government should have formulated a full policy statement like the European counterparts so as to set the stage for faster and more effective engagement. This is one of the downfalls of healthcare policy in the United States.

Medical Boards

Medical boards in all states are progressively more vocal regarding their opinions and thoughts on what constitutes safe and prudent deployment of telemedicine. The *Model Policy on the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, adopted by the Federation of State Medical Boards (FSMB), provides guidance that state boards can use to assess and act on relative to increasing activity in the telemedicine market. Their stated objective is to ensure that patients are protected from harm in a fast-changing health-care delivery environment. Here are the stated objectives of their policy:

- Place the welfare of patients first
- Maintain acceptable and appropriate standards of practice
- Adhere to recognized ethical codes governing the medical profession
- Properly supervise non-physician clinicians
- Protect patient confidentiality

The Model Policy:

- Discourages any physician from rendering medical advice and/or care using telemedicine technologies without:
 - fully verifying and authenticating the location
 - to the extent possible, identifying the requesting patient
- Encourages disclosure and validation of the provider's identity and applicable credential(s)
- Encourages obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telemedicine technologies

The policy goes on to state: *"Where appropriate, a patient must be able to select an identified physician for telemedicine services and not be assigned to a physician at random"*. Considering that huge amount of care is delivered every day in urgent care centers and emergency rooms to patients who were assigned to providers on a totally random basis, this position seems out-of-touch with current practice.

Of importance, the policy goes on to define the term telemedicine as: *"the practice of medicine using electronic communications, information technology or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider. Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support."*

Defining telemedicine in this manner severely limits its application when compared to what is actually occurring today. Though there are no actual numbers, it is estimated that over eighty percent (80%) of the telemedicine interactions today are "telephone only" connections (based on conversations with those active in the space). Several companies have built their entire models on telephone only interactions and with this interpretation could find themselves well outside the playing field.

Here are some other key elements of the KSMB standard:

- Licensure: A physician must be licensed by, or under the jurisdiction of, the medical board of the state where the patient is located. The practice of medicine occurs where

the patient is located at the time telemedicine technologies are used.

- Establishment of a Physician-Patient Relationship: Where an existing physician-patient relationship is not present, a physician must take appropriate steps to establish a physician-patient relationship consistent with already published guidelines.
- Evaluation and Treatment of the Patient: A documented medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.
- Informed Consent: Evidence documenting appropriate patient informed consent for the use of telemedicine technologies must be obtained and maintained.
- Continuity of Care: Patients should be able to seek, with relative ease, follow-up care or information from the physician [or physician's designee] who conducts an encounter using telemedicine technologies. Physicians solely providing services using telemedicine technologies with no existing physician patient relationship prior to the encounter must make documentation of the encounter using telemedicine technologies easily available to the patient, and subject to the patient's consent, any identified care provider of the patient immediately after the encounter.
- Referrals for Emergency Services: An emergency plan is required and must be provided by the physician to the patient when the care provided using telemedicine technologies indicates that a referral to an acute care facility or ER for treatment is necessary for the safety of the patient. The emergency plan should include a formal, written protocol appropriate to the services being rendered via telemedicine technologies.
- Medical Records: The medical record should include, if applicable, copies of all patient-related electronic communications, including patient-physician communication, prescriptions, laboratory and test results, evaluations and consultations, records of past care, and instructions obtained or produced in connection with the utilization of telemedicine technologies. Informed consents obtained in connection with an encounter involving telemedicine technologies should also be filed in the medical record. The patient record established during the use of telemedicine technologies must be accessible and documented for both the physician and the patient, consistent with all established laws and regulations governing patient healthcare records.
- Privacy and Security of Patient Records & Exchange of Information: Physicians should meet or exceed applicable federal and state legal requirements of medical/health information privacy, including compliance with the Health Insurance Portability and Accountability Act (HIPAA) and state privacy, confidentiality, security, and medical retention rules. Disclosures and Functionality on Online Services.
- Making Available Telemedicine Technologies: Online services used by physicians providing medical services using telemedicine technologies should clearly disclose:
 - Specific services provided
 - Contact information for physician
 - Licensure and qualifications of physician(s) and associated physicians
 - Fees for services and how payment is to be made
 - Financial interests, other than fees charged, in any information, products, or services provided by a physician;
 - Appropriate uses and limitations of the site, including emergency health situations;
 - Uses and response times for e-mails, electronic messages and other

- communications transmitted via telemedicine technologies;
- To whom patient health information may be disclosed and for what purpose;
- Rights of patients with respect to patient health information; and
- Information collected and any passive tracking mechanisms utilized. Online services used by physicians providing medical services using telemedicine technologies should provide patients a clear mechanism to:
 - Access, supplement and amend patient-provided personal health information
 - Provide feedback regarding the site and the quality of information and services
 - Register complaints, including information regarding filing a complaint with the applicable state medical and osteopathic board(s). Online services must have accurate and transparent information about the website owner/operator, location, and contact information, including a domain name that accurately reflects the identity. Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits, or incentives (other than the fees for the medical care services) is prohibited. Notwithstanding, online services may provide links to general health information sites to enhance patient education; however, the physician should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of preferred relationships with any pharmacy is prohibited. Physicians shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit from that pharmacy
- **Prescribing:** Telemedicine technologies, where prescribing may be contemplated, must implement measures to uphold patient safety in the absence of traditional physical examination. Such measures should guarantee that the identity of the patient and provider is clearly established and that detailed documentation for the clinical evaluation and resulting prescription is both enforced and independently kept. Telemedicine technologies should limit medication formularies to ones that are deemed safe.

The impact of these standards could be significant in defining the competitive battlefield in the coming years. Though not laws, the standards have already gathered enough attention by states so as to dramatically impact the form and substance of further laws governing telemedicine.

The definitions could be suspect of being somewhat self-serving given the agenda of individual licensure boards but they will be relied upon heavily non-the-less.

Tightening the regulations will begin to narrow the field of potential businesses equipped to take advantage of the emergence of telemedicine but it will not stop it. Technology will continue to evolve and refine the sector and as it does, look for it to expand and have significant impact on healthcare delivery.

Who Is Impacted the Most?

Telemedicine promotes access and thus those sectors suffering most from lacking access will be impacted the most, including:

- **Primary Care:** A huge portion of the typical primary care physician's office activity and the cost of healthcare is seeing patients for regular check-ups and follow up visits. Many of these could be done telemedically.
- **Urgent Care:** Urgent care has built itself upon an access model. Access is enhanced with telemedicine and thus it will have a huge impact on this sector.
- **Emergency Departments/Freestanding Emergency Rooms:** The abuse and cost of over use of the emergency rooms of America is well documented. Telemedicine can and will at least be a front line screening tool to reduce the volume and wait emergency departments everywhere.
- **Federally Qualified Health Clinics:** The waits in these clinics can be significant and recruitment of qualified providers is challenging. The most qualified of providers can and will be introduced to these markets via telemedicine in the future.

Look for additional developments in the following areas:

- **Home Care:** The quality and capability of in-home computers and their attachment will continue to be enhanced. As it is, look for the technology to be more and more capable of bringing high quality care into the home.
- **Travel Medicine:** Americans are highly mobile. Mobile devices are everywhere. It is only natural that telemedicine will be in the palm of the average traveler's hands so as to make it readily available.
- **School health:** The cost of school health clinics is unsustainable. Systems everywhere are looking for alternatives and telemedicine is a natural fit.
- **Employer health programs:** Employers are footing the majority of the healthcare spend in the United States. They are desperate for cost savings and telemedicine offers the ability to better manage chronic conditions to lesser cost and employees to greater productivity.
- **Pulmonary Monitoring/Sleep Apnea:** Obesity is growing problem in the United States and one of the problems that follows it is sleep apnea. Once diagnosed in expensive inpatient centers, sleep apnea is now diagnosed, monitored and treated remotely that connect in a meaningful way to telemedicine services.
- **End Stage Renal (ESRD) Care:** Patients in renal programs have a host of comorbidities that can and should be treated at home using telemedicine. Moving patients about for doctor appointments is both unnecessary and hard on the patient.
- **Patients in cancer treatment:** Patients receiving cancer treatment can and should have access to care by providers familiar with their treatments and condition. The ability to share medical records; therapy notes and outcomes allows providers treating their acute illnesses (potentially connected to their treatment) to take a more holistic approach with better results. This has been demonstrated in MD Anderson's cancer-focused urgent care center.
- **Mental Health:** There may be no better fit for the telemedicine venue than mental health services.
- **Specialty medical services in remote/underserved areas:** There are many areas of the United States that do not have sufficient specialty physician coverage. Providing access to these specialists to provide consults in conjunction with primary care remotely improves access and drives down cost.

Conclusion

Telemedicine is here to stay and patients and providers must come to grips with how it will be best deployed in order maximize its safe utilization. The driving factor is and will be cost. Our current model does not afford nearly enough access and is unsustainably expensive. There is a push on to define and promote best practices that prove to generate the best patient outcomes for the least cost. Telemedicine can help facilitate this and bridge the gap between urban and rural America.

No doubt regulations will be increasing and will be necessary but the technology will adapt and so will savvy providers.

The United States cannot continue to sport the most expensive healthcare in the world if we are to compete in a global economy. The World Health Organization, in its last report on global health, placed the United States as 37th of the developed nations in health outcomes, in spite of our exorbitant costs.

It seems like a perfect storm of opportunity for telemedicine today and those providers that position themselves correctly, should find great success in the next few years.
