

Telemedicine

What is telemedicine?

Telemedicine is the practice of medicine using electronic communications, information technology, or other means between a licensee in one location, and a patient in another location. In some instances, the term “telehealth” is used interchangeably. However, generally, telehealth denotes a more encompassing term that means interactive patient-physician teleconsultations.¹ While telemedicine refers to remote clinical services, telehealth can refer to non-clinical services, such as providing training, administrative meetings, and continuing medical education. The [Centers for Medicine & Medicaid Services](#) states that telemedicine seeks to improve a patient’s healthy by permitting two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site. At a minimum, electronic communications means the use of audio and video equipment.

States do not consistently distinguish between the terms “telemedicine” and “telehealth.” Some states, including Nebraska, do not provide an explicit definition of telemedicine. Under the Nebraska Telehealth Act, Neb. Rev. Stat. §§ 71-8501 to 71-8508, telehealth is defined as “any contact between a patient through telehealth” and requires that a written instrument be signed by a patient prior to an initial telehealth consultation. The act also covers telemonitoring which is defined as “remote monitoring of a patient’s vital signs, biometric data, or subjective data by a monitoring device which transmits data electronically to a health care provider for analysis and storage.”

Investment in the telemedicine industry

In 2019, telemedicine companies experienced a [55% increase](#) in funding year-over-year. The top funded categories in 2019 included digital health products powered by artificial intelligence which brought \$2 billion; telemedicine which brought \$1.8 billion; data analytics with \$1.6 billion; and mHealth apps with \$1.2 billion. In the first quarter of 2020, venture capital funding for telemedicine companies skyrocketed to [\\$788 million](#). Global venture capital funding into digital health companies in the first quarter of 2020 reached an unprecedented [\\$3.6 billion](#) in 142 deals compared to \$1.7 billion in 142 deals in the fourth quarter of 2019. Furthermore, in the first quarter of 2020, there were more than 41 merger and acquisition transactions involving digital health companies. For example, Teladoc Health acquired InTouch Health for \$600 million in January 2020. The former serves more than 450 hospitals and health systems, and InTouch Health’s software also supports communication between health care providers. The acquisition, as well as the data above, highlights that the health care industry is becoming increasingly reliant on digital health technologies.

¹ E-Health, Telehealth, and Telemedicine: A Guide to Startup and Success. At 3.
<https://books.google.com/books?hl=en&lr=&id=T8qwu1okBW4C&oi=fnd&pg=PR7&dq=legal+distinction+between+telehealth+and+telemedicine&ots=fM4Sv0dLsj&sig=5Z-gEa4W2zk0Z6Ob4YZwodskFQ4#v=onepage&q=legal%20distinction%20between%20telehealth%20and%20telemedicine&f=false>

Legal issues in telemedicine

Telemedicine implicates numerous legal issues regarding reimbursement of a physician's services, licensing, credentialing, prescribing, electronic health records (EHR), privacy, medical malpractice, and more. To complicate matters, because each state has a unique definition for what telemedicine is, it is important to begin analyzing the legal issue by understanding the definition of telehealth or telemedicine within the jurisdiction where the issue occurred. Below is a non-exhaustive list of some legal issues to consider.

Anti-Kickback Statute

- The federal Anti-Kickback Statute (AKS) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any "remuneration" to induce referrals of items or services reimbursable by any federal health care program.
- Telemedicine arrangements among telemedicine providers as well as with technology providers are reviewed for compliance with AKS.

Safe Harbors

- The AKS also includes several safe harbors to facilitate legitimate business arrangements.
- An arrangement will not be prosecuted under the AKS if that arrangement meets the requirements of an applicable safe harbor.
- Some common circumstances the safe harbors cover include where a physician receives free electronic prescribing technology or training or free electronic health records software, information technology, or training.
- It is best practice to consider safe harbors when structuring a telemedicine arrangement between health care entities or technology providers to potentially reduce kickbacks.

Stark Law

- The federal Stark Law prohibits physicians from referring Medicare beneficiaries for designated health services (DHS) reimbursed by Medicare to an entity in which the physician has a financial interest, or physician's immediate family member has a financial relationship, unless an exception applies.
- Unlike the AKS, penalties under the Stark Law are limited to civil, rather than criminal liability, and the Stark Law, unlike AKS which requires intent, is a strict liability statute.
- Similar to AKS, the Stark Law includes safe harbors applicable to telemedicine services.

Professional Liability Insurance

- Some states may require a health care provider to obtain a certain level of minimum coverage.
- A health care provider's existing malpractice insurance may not cover practice in another jurisdiction or may not cover the practice of telemedicine at all.

Telemedicine device technology

Telemedicine technologies are classified either as asynchronous (store-and-forward) or synchronous (in real time). For example, if a patient is using a mobile medical app to record their medical information and that information is stored in the app, and then accessed by a health care provider, that would qualify as an asynchronous telemedicine technology. On the

other hand, concurrent communication between a patient and health care provider over a video conference would constitute a synchronous telemedicine technology.

The Federation of State Medical Boards (FSMB's) created guidelines for the appropriate use of telemedicine technologies in medical practice related to issues of licensure, the establishment of a physician-patient relationship, the evaluation and treatment of the patient, and informed consent.

The Food and Drug Administration (FDA) has jurisdiction over all medical devices, including mobile health devices and mobile medical apps (MMAs). Instruments and objects intended to diagnose diseases or other conditions or intended to cure, mitigate, treat, or prevent diseases, including any components, parts, or accessories, qualify as a medical device. Note that not all MMAs qualify as devices. For an MMA to qualify, the device must transform the mobile platform into a device.

In general, the innovation of telemedicine technologies, such as Home Diagnostic Tools (HDTs) and self-monitoring devices, allow patients the ability to have greater access and agency in their medical care.

COVID-19 Impact on telemedicine

In the spring of 2020, Vandennack Weaver provided [guidance](#) on changes to federal regulations related to telehealth services. A quick summary of those changes related to telehealth, and by extension, telemedicine includes:

- Allow health care providers covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to communicate with patients and provide telehealth services through remote communication technologies that are non-public facing remote communication products with common video chat applications including Apple FaceTime, Facebook Messenger, Google Hangouts, and Skype.
- Practitioners subject to the anti-fraud provisions of federal health care programs are not subject to administrative sanctions for reducing or waiving obligations that a beneficiary may owe for telehealth services furnished during COVID-19.
- The Centers for Medicare & Medicaid Services (CMS) broadened access to telehealth services where Medicare will now cover office, hospital visits, evaluation and management visits, mental health counseling, and preventative health screenings furnished via telehealth for services starting March 6, 2020.

Additionally, on March 23, 2020 the Nebraska Department of Health and Human Services (DHHS) implemented an [exception](#) to certain requirements under the Nebraska Telehealth Act where health care providers are no longer required to obtain a patient's signature on a written agreement prior to providing telehealth services during COVID-19. Additionally, insurance claims for telehealth will not be denied solely on the basis of lack of a signed written statement.

A helpful Q&A for general statewide telehealth services during COVID-19 can be accessed [here](#).