

## TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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### LAWS AND REGULATIONS ON TELEMEDICINE

#### 1. Is telemedicine allowed in your country? If so, how is it defined?

Yes. Telemedicine is not regulated at the federal level, but it is generally understood to mean the use of telecom technologies to support the delivery of medical, diagnostic and treatment-related services by healthcare practitioners.

Because the United States regulates telemedicine in a state-by-state patchwork, there are varying definitions imposed by state laws.

For example, in New Jersey, telemedicine is defined as the delivery of a healthcare service using electronic communications, information technology, or other electronic or technological means to bridge the gap between a healthcare provider who is located at a distant site and a patient who is located at an originating site, either with or without the assistance of an intervening healthcare providers, and in accordance with the provisions of P L 2017, c 117 (c 45:1-61 et al). Email, instant messaging, texting or facsimile alone will not suffice to qualify as a telemedicine visit, but these may be used in conjunction with either a real-time two way or 'store & forward' technology interaction. A 'store & forward' interaction involves the acquisition and transmission of images, diagnostics, data and medical information either to or from a healthcare provider at a distant site and allows the patient to be evaluated without being physically present.

In New Jersey, unless the provider has established a proper provider-patient relationship with the patient, the provider shall not issue a prescription to a patient based solely on responses to an online static questionnaire. In addition, some products (such as some controlled substances) may typically only be prescribed after an in-person consultation.

If a healthcare provider determines that telemedicine or telehealth services would not be consistent with the standard of care or practice standards applicable to an in-person setting, the healthcare providers shall direct the patient to seek in-person care.

#### 2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

Telemedicine is not specifically regulated at the federal level, but the same legal framework governing healthcare applies to telemedicine, including the Federal Food, Drug and Cosmetic Act, 21 USC 321 et al, which regulates the drugs and medical devices that may be prescribed by healthcare practitioners, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which ensures that healthcare providers protect patients' personal health information.

Each of the 50 states impose their own standards and requirements governing the telemedicine encounter, including the requirements for prescribing medicines or ordering tests.

#### 3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

The key licensing bodies for telemedicine are the same bodies responsible for the general licensing of healthcare practitioners and differ by state.

Generally, each state requires practicing healthcare providers to be licensed to practice in the state, and some states require providers using telehealth technology across state lines to have a valid state licence in the state where the patient is located.

As of 30 November 2022, according to the Center for Connected Health Policy, nine state boards issue licences related to telehealth allowing an out-of-state licensed provider to render services to patients within the state via telehealth (see [https://www.cchpca.org/2021/04/Spring2021\\_Infographic-1.pdf](https://www.cchpca.org/2021/04/Spring2021_Infographic-1.pdf)). Physicians also can practice medicine across multiple state lines if they meet the Interstate Medical Licensure Compact eligibility requirements, which 27 states have signed.

Licensure for other healthcare providers (eg, nurse practitioners, physical therapists, psychologists, speech therapists, emergency medical services personnel) are led by state regulatory boards for each specific speciality.

#### **4. Was telemedicine authorized during the Covid-19 pandemic?**

Telemedicine was available before the Covid-19 pandemic, but its use expanded during the pandemic when the US federal government implemented temporary measures under the Covid-19 public health emergency declaration to support providing and receiving telehealth services (see <https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID-15Oct21.aspx>).

States also granted additional flexibility in their laws and rules to increase access to telehealth during the Covid-19 pandemic. Key legislative updates enabled telemedicine to flourish. For example, New Jersey required that health plans (providing insurance coverage for healthcare services) offer telemedicine services as an option for patients. Such telemedicine services must be reimbursed to the healthcare provider at the same rate that would be paid for an in-person visit. In addition, the patient's out-of-pocket payment (such as a co-pay or deductible) must also be no greater than what would be required at an in-person visit.

#### **5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?**

Many of the federal telemedicine flexibilities afforded during the Covid-19 are temporary and will lapse at the end of the Covid-19 public health emergency. The Consolidated Appropriations Act of 2022 outlines the federal telehealth policies set to expire or have a transition period. For example, the following policies will be phased out after a 151-day waiting period:

- flexibility regarding where the patient receives Medicare telehealth services, as well as where the services originate;
- Medicare reimbursement for mental health telehealth services will now require an in-person visits within six months of initial assessment and every 12 months following;
- Medicare reimbursement for telehealth services by physical therapists, occupational therapists, speech language pathologists, and audiologists; and
- Medicare coverage for audio-only visits.

In 2021, some states revoked the temporary changes to state health laws and rules whereas other states made their temporary changes more enduring. In New Jersey, as an example, the Governor (in December 2021) extended by two years the requirements that had been adopted at the outset of the Covid-19 pandemic. In addition, however, the state commissioned an in-depth review of telehealth and telemedicine services to assess their effect on patient outcomes, quality and satisfaction, and access to care, to inform future decisions on payment structure for these services.

#### **6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)**

Telehealth services include diagnosing, monitoring, prescription management, urgent-care issues, and mental health treatment. According to HHS, the following services can be provided through telehealth:

- lab test or x-ray results;

<ul style="list-style-type: none"> <li>• mental health treatment, including online therapy, counselling, and medication management;</li> <li>• recurring conditions like migraines or urinary tract infections;</li> <li>• skin conditions;</li> <li>• prescription management;</li> <li>• urgent care issues like colds, coughs, and stomach aches;</li> <li>• post-surgical follow-up;</li> <li>• treatment and follow-up appointments for attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD);</li> <li>• physical therapy and occupational therapy; and</li> <li>• remote monitoring services that help you track your health goals and manage chronic conditions like diabetes, high blood pressure, and high cholesterol.</li> </ul>
<p><b>7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.</b></p>
<p>There is no limitation on who can use telemedicine services, and the US specifically permitted the use of telemedicine to facilitate the patient-doctor remote relationship during the Covid-19 pandemic.</p> <p>State regulations must also be considered. New Jersey, as one example, permits cross-coverage remote medical evaluation without in-person contact at the request of another healthcare provider who has established a proper provider-patient relationship with the patient. Some healthcare providers' consultations are permitted to occur through remote means, but such consultations may not benefit from reimbursement parity protections.</p>
<p><b>8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.</b></p>
<p>Medicare, the federal health insurance plan for people 65 or older, and Medicaid cover telemedicine services. The Coronavirus Aid, Relief, and Economic Security (CARES) Act, H R 748, Pub L No 116-136 (see <a href="https://www.congress.gov/bill/116th-congress/house-bill/748">https://www.congress.gov/bill/116th-congress/house-bill/748</a>), includes additional funding to the Telehealth Network Grant Program (TNGP) to promote rural telehealth services by enhancing telehealth networks. The Centers for Medicare &amp; Medicaid Services details the requirements for reimbursement and coverage to providers for healthcare services (see <a href="https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf">https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf</a>).</p> <p>Forty-two states and the District of Columbia require private insurance providers to reimburse telemedicine. The US Department of Health and Human Services references the Policy Finder tool maintained by the Center for Connected Health Policy to identify the most up-to-date requirements by state. For example, Connecticut law requires certain commercial health insurance policies to cover medical advice, diagnosis, care, or treatment provided through telehealth to the same extent that they cover those services when provided in person. CGS ss 38a-499a and 38a-526a.</p>
<p><b>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</b></p>
<p>Most insurance providers cover at least some form of telehealth service. The restrictions applicable to insurance coverage relate to the specialty that the telemedicine service provides, the type of service that is offered (eg, inpatient office, consult), and the type of provider (eg, physician, nurse practitioner). Most states have laws that require reimbursement by private payers to be equal to in-person coverage, but do not necessarily require reimbursement coverage parity.</p>
<p><b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b></p>
<p><b>10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the</b></p>

<b>applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)</b>
Physicians, nurse practitioners, physical therapists, psychologists, speech therapists, emergency medical services personnel, social workers, and occupational therapists, all are permitted to provide telemedicine services during the Covid-19 pandemic. Some states also permit chiropractors, optometrists, pharmacists, physician assistants, or dentists, to provide telehealth services.
<b>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</b>
There is no further education or training required for healthcare professionals to provide telehealth services.
<b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b>
There are no registration requirements, but there are licensing requirements as discussed in response to Question 3.
<b>13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
Some states may require that providers using telehealth technology across state lines have a valid state licence in the state where the patient is located.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>
Telehealth technology should maintain privacy and security according to the Healthcare Insurance Portability and Accountability Act of 1996 (HIPAA).
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>
<p>Under HIPAA, a healthcare provider typically can use non-public facing applications that meet the requirements of the HIPAA privacy, security, and breach notification rules.</p> <p>During the Covid-19 pandemic, the government permitted health care providers to use any non-public facing remote communication product available to communicate with patients and stated that it would exercise enforcement discretion to not impose penalties for noncompliance with HIPAA during the public health emergency (see <a href="https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html">https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html</a>). A 'non-public facing' remote communication product is one that, as a default, allows only the intended parties to participate in the communication. These platforms typically employ end-to-end encryption and other features (eg, logins and passcodes) to help limit access and verify participants. Enforcement discretion did not extend to public facing applications, like Facebook Live, Twitch, or TikTok.</p> <p>For purposes of reimbursement, certain payers, including Medicare and Medicaid, may impose restrictions on the types of technologies which can be used.</p>
<b>16. Does the legislation provide for specific rules concerning patients' medical records?</b>
HIPAA requires that covered entities apply reasonable safeguards to protect the privacy of protected health information (PHI) from impermissible uses or disclosures, including when providing telemedicine services. Regulations require that only authorised users should have access to electronic PHI (ePHI) and that a system of secure communication be implemented to protect the integrity of ePHI.
<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>

It depends on the state. Some states require that providers using telehealth technology across state lines have a valid state licence in the state where the patient is located. For example, in New Jersey, the individual providing telehealth services must be validly licensed, certified or registered to provide such services in New Jersey. The healthcare provider is subject to regulations by the appropriate New Jersey licensing board or other NJ state professional regulatory entity and is expected to act in compliance with existing regulations, including maintaining liability insurance.
<b>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</b>
The majority of states and the District of Columbia expect healthcare services to be provided with the informed consent of the individual receiving that care. In addition, additional requirements may apply for individuals receiving mental health services.
<b>19. Is there any other important requirement that should be highlighted?</b>
N/A
<b>DATA PRIVACY ASPECTS</b>
<b>20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.</b>
Yes. The Healthcare Insurance Portability and Accountability Act of 1996 (HIPAA) applies to a patient's protected health information (PHI) that is collected during the provision of telemedicine services. A covered entity must have in place policies and procedures regarding the transfer, removal, disposal, and re-use of electronic media, to ensure appropriate protection of PHI. A covered entity must also implement technical security measures that guard against unauthorised access to PHI that is being transmitted over an electronic network. See response to Question 16 above for further information.
<b>21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?</b>
<p>Yes. The Security Rule implemented under HIPAA establishes a national set of security standards for protecting certain health information that is held or transferred in electronic form. The goal of the Security Rule is to protect the privacy of individuals' health information while allowing covered entities to adopt new technologies to improve the quality and efficiency of patient care. The Security Rule does not dictate the security measures to be used, but requires a covered entity to consider:</p> <ul style="list-style-type: none"> <li>• its size, complexity, and capabilities;</li> <li>• its technical, hardware, and software infrastructure;</li> <li>• the costs of security measures; and</li> <li>• the likelihood and possible impact of potential risks to e-PHI.</li> </ul> <p>See also responses to questions 16 and 20 above.</p>
<b>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</b>
There is no specific requirement for transfer of information abroad.
<b>23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?</b>
There are no registration requirements for databases containing protected health information. There are no specific requirements regarding the recording of data in a patient's medical records other than the informed consent requirements described in Question 18.
<b>LIABILITIES</b>

<b>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</b>
Liability risks include privacy, security, licensure, and telehealth malpractice. The standard of care remains the same whether a healthcare provider is seeing a patient in person or using telehealth. Healthcare providers must be aware of the changing telehealth-related federal and state laws, regulations, and other relevant statutes to understand medical liability risks.
<b>TELEMEDICINE NUMBERS AND TRENDS</b>
<b>25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?</b>
Multiple organisations trend and report on the use and acceptance of telehealth, including the Centers for Disease Control and Prevention (CDC), the American Medical Association, and the Center for Connected Health Policy's National Telehealth Policy Resource Center. Several states maintain websites detailing the telemedicine requirements in each state.
<b>26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.</b>
Many of the federal telehealth flexibilities provided during the Covid-19 are temporary and will lapse at the end of the Covid-19 public health emergency. The current Covid-19 public health emergency is effective until at least April 2023. Once the public health emergency ends, the Consolidated Appropriations Act of 2022 has ensured a 151-day extension before many of the policies outlined in the public health emergency are set to expire, including the federal telehealth policies set to expire or have a transition period. There are also other federal telehealth bills (Ensuring Telehealth Expansion Act, Advancing Telehealth Beyond Covid-19) that are awaiting congressional decision. In addition, as previously noted, individual state law updates will directly affect the availability of telehealth services in the future.