

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?
<p>Venezuela allows telemedicine. The Telehealth Law (Telehealth Law) defines telemedicine as ‘the combined use of information and communication technology in a free software for the provision of long-distance medical attention services by healthcare workers, for the exchange of reliable information in the diagnosis, treatment and prevention of diseases, investigation, evaluation and continuous medical education, with the purpose of improving the health of individuals, families and communities.’ Furthermore, the Telehealth Law defines the Telehealth Network as establishments and services interconnected by information and communication technology, organised within the Public Health System at different levels, which relate and operate among each other, with provenances and specific parameters.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>Telemedicine’s legal framework is covered by the Telehealth Law, which was enacted in 2015 and was the first piece of legislation regulating telemedicine in Venezuela. Generally, the exercise of the medical profession is governed by the Law of the Practice of Medicine (enacted in 1982, amended in 2011 and 2020), the Partial Rules No 1 of the Law of the Practice of Medicine (1983) and the Medical Deontology Code (1985). The Ministry of the People’s Power for Health (Ministry of Health) is the governing authority in Venezuela.</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>According to the Telehealth Law, the Ministry, through the National Telehealth Commission (Telehealth Commission), is the entity in charge of regulating, controlling and evaluating all matters relating to the Telehealth Network.</p>
4. Was telemedicine authorized during the Covid-19 pandemic?
<p>The Venezuelan Executive Branch issued several emergency decrees throughout the pandemic. However, there was no specific mention or authorisation to telemedicine services. Most decrees restricted free transit and certain activities, and only provided a general authorisation to public and private sector healthcare providers to continue operating.</p>
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?
<p>A regulatory change in the current landscape seems unlikely. There have been no initiatives of this nature from the National Assembly.</p>
6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)
<p>The Telehealth Law provides very basic definitions, mostly around the technological side of telemedicine and fails to develop the more technical side from a health perspective.</p> <p>Although the Telehealth Law is not clear on the types of teleservices allowed, the spirit of the law aims to provide preventive medical assistance, including teleconsultation, telediagnosis, teletherapy and educational services. The teleservices allowed under the Telehealth Law should</p>

be developed by and included in the Rules of the Telehealth Law. However, such Rules have not been enacted to date.
7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.
Telemedicine services are open to the general public. Children, teenagers and individuals subject to interdiction require the consent of their legal representative.
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.
<p>The Telehealth Law provides very basic definitions, mostly around the technological side of telemedicine and fails to develop relevant concepts around the functioning of the system as such. Funding models and related provisions should be developed by the Telehealth Commission and included in the Rules of the Telehealth Law, yet such Rules have not been enacted to date. Certain insurance policies offer telemedicine services, but it is not a legal requirement.</p> <p>The Telehealth Network is organised from within the Public Health System, so any funding model for telemedicine should come from the same funding as the Public Health System.</p>
9. Please indicate whether any insurance requirements applicable to telemedicine services providers.
The Telehealth Law is silent with respect to insurance matters relating to telemedicine service providers. These matters should be developed by the Telehealth Commission and included in the Rules of the Telehealth Law. However, such Rules have not been enacted to date.
REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS
10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)
<p>The Telehealth Law is not clear as to which specific healthcare professionals are authorised to provide remote health services. It only refers to 'health sector workers'. These concepts should be developed by and included in the Rules of the Telehealth Law. However, such Rules have not been enacted to date.</p> <p>At least until further regulations are enacted, health sector workers should be understood to include doctors, nurses, psychologists and nutritionists. These professions are governed by their own specific laws, which should apply supplementary to the Telehealth Law (ie, the Medicine Law, the Law of the Professional Exercise of Nursing, the Law of the Exercise of Psychology, the Law of the Exercise of the Profession of Graduate in Nutrition and Diet).</p>
11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?
The Telehealth Law is not clear as to the specific education requirements or trainings that healthcare professionals need to provide telemedicine services. It only mentions that the Ministry of the People's Power for University Education (Ministry of University Education) has the obligation to incorporate telemedicine in their respective curricular programmes relating to these public services. Furthermore, both the Ministry of Health and the Ministry of University Education have the responsibility of supervising the formation, capacitation and accreditation of individuals who provide services within the Telehealth Network. These concepts should be developed by and included in the Rules of the Telehealth Law. However, such Rules have not been enacted to date.
12. Is there any registration requirement applicable to physicians that provide telemedicine services?

<p>The Telehealth Law is not clear as to any requirements applicable to physicians that provide telemedicine services. These matters should be developed by and included in the Rules of the Telehealth Law. However, such Rules have not been enacted to date. In the meantime, the provisions applicable to their specific professions will apply. These have been developed by the Medicine Law, the Law of the Professional Exercise of Nursing, the Law of the Exercise of Psychology and the Law of the Exercise of the Profession of Graduate in Nutrition and Diet.</p>
<p>13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.</p>
<p>The Telehealth Law is not clear as to any mandatory licences or authorisations applicable to institutional healthcare providers engaged in telemedicine services. The Telehealth Law only mentions that any public or private institution rendering services to the Telehealth Network shall do so under the parameters and directions set out therein and the Rules of the Telehealth Law. These matters should be developed by and included in the Rules of the Telehealth Law. However, such Rules have not been enacted to date. In the meantime, the licences or authorisations applicable to the specific professions of healthcare providers will apply (ie, those developed by the Medicine Law, the Law of the Professional Exercise of Nursing, the Law of the Exercise of Psychology and the Law of the Exercise of the Profession of Graduate in Nutrition and Diet).</p>
<p>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</p>
<p>14. Are there specific requirements applicable to the telemedicine platform?</p>
<p>According to the Telehealth Law, the Telehealth Commission shall set the technical rules to regulate the Telehealth Network and the offer of services nationwide, both within the public and private networks. The Telehealth Commission has not issued such technical rules to date, nor have they been included in the Rules of the Telehealth Law, which have not been enacted to date either. However, the Telehealth Law does mention that the IT and communication systems of the Telehealth Law must be developed under the technological protection measures that guarantee their confidentiality, integrity, privacy and availability. General principles on data privacy (explained in questions 20-23 below) must also be observed.</p>
<p>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</p>
<p>According to the Telehealth Law, the Telehealth Commission shall set the technical rules to regulate the Telehealth Network and the offer of services nationwide, both within the public and private networks. The Telehealth Commission has not issued such technical rules to date, nor have they been included in the Rules of the Telehealth Law, which have not been enacted to date either.</p>
<p>16. Does the legislation provide for specific rules concerning patients' medical records?</p>
<p>According to the Telehealth Law, consultations and other services provided under the Telehealth Network require the informed and written consent of its users or of the legal representative of children, teenagers and individuals subject to exclusion. In addition, the beneficiaries of the Telehealth Network are entitled to the private nature of the data provided, forbidding use other than that specified under the Telehealth Law. Health and IT workers are civil, criminal, administrative and disciplinary liable for any breach to the privacy, confidentiality and anonymity of such data. Doctors must also comply with the provisions set out in the Law of the Exercise of Medicine (Medicine Law), the Organic Health Law (Health Law) and the Medical Deontology Code (Deontology Code) regarding the doctor-patient privilege and confidentiality obligations.</p> <p>These matters should be further developed by the Telehealth Commission and included in the Rules of the Telehealth Law. However, such Rules have not been enacted to date.</p>
<p>17. Are there geographic location requirements applicable to the provision of telemedicine services?</p>

The Telehealth Law is unclear as to geographic location requirements. This should be further developed by the Telehealth Commission and included in the Rules of the Telehealth Law. However, such rules have not been enacted to date.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
Yes. According to the Telehealth Law, consultations and other services provided under the Telehealth Network require the informed and written consent of its users or of the legal representative of children, teenagers and individuals subject to exclusion.
19. Is there any other important requirement that should be highlighted?
N/A
DATA PRIVACY ASPECTS
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.
Yes. The beneficiaries of the Telehealth Network are entitled to data privacy, forbidding uses other than those provided for under the Telehealth Law. Health and IT workers are civil, criminal, administrative and disciplinary liable for any breach to the privacy, confidentiality and anonymity of such data. In safekeeping the data, the following principles governing data privacy in Venezuela (pursuant to Decision 1,318 of the Constitutional Chamber of the Supreme Court (2011)) must be complied with: (1) autonomy of the will; (2) legality; (3) purpose and quality; (4) temporality and preservation; (5) accuracy and self-determination; (6) foresight and integrity; (7) safety and confidentiality; (8) protection; and (9) responsibility. Doctors must also comply with the provisions set out in the Medicine Law, the Health Law and the Deontology Code regarding the doctor-patient privilege and confidentiality obligations.
21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?
According to Telehealth Law, the IT and communication systems of the Telehealth Law must be developed under the technological protection measures that guarantee their confidentiality, integrity, privacy and availability. The Telehealth Commission has not issued the corresponding specific technical rules to date, nor have they been included in the Rules of the Telehealth Law, which have not been enacted to date either.
22. Does the applicable regulation provide for requirements for the transfer of information abroad?
The Telehealth Law does not mention the transfer of information abroad. The general data principle on safety and confidentiality prohibits the transfer of the contents of databases to other countries that do not ensure the adequate protection of personal data. Consequently, data can only be transferred abroad provided the recipient country provides the same or a higher level of protection than Venezuela.
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?
There is no requirement for registration of databases that companies must observe. Regarding the recording of data in patient medical records, the Deontology Code and the Health Law provide that patient medical records must generally include: (1) the objective and subjective elements provided by the patient; (2) the findings, correlations and interpretations of the doctor; (3) the contributions from other doctors assisting in the diagnosis (if applicable); (4) documentation relating to complementary exploration tests, examinations, x-rays, etc; and (5) the patient's health condition on discharge.
LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
<p>The Telehealth Law is not clear as to the liability of healthcare professionals and institutions involved in telemedicine practices. It only mentions that health and IT workers are subject to civil, criminal, administrative and disciplinary liability for any breach to the privacy, confidentiality and anonymity of patient medical records. Generally, the civil, criminal, administrative and disciplinary liability provided in the Medicine Law and the Deontology Code will apply to healthcare professionals in the provisions of their services, regardless of whether they are rendered within telemedicine practices, in addition to legal precedents issued by Venezuela's Supreme Court of Justice.</p>
TELEMEDICINE NUMBERS AND TRENDS
25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?
<p>There is no official publicly disclosed information regarding the use and acceptance of telemedicine in Venezuela. This information should be provided by the Ministry of Health and the Telehealth Commissions. However, they have not published such information to date.</p>
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.
<p>A regulatory change in the current landscape seems unlikely at the moment. There have been no initiatives of this nature from the National Assembly. Eight years have passed since the enactment of the Telehealth Law and the Rules of the Telehealth Law, which will certainly be an important piece of legislation, has yet to be enacted. Furthermore, the Telehealth Commission has not been active in its role either. It seems that this is not a pressing matter within current government policies. Nevertheless, in practice telemedicine services are offered and practiced in Venezuela.</p>