

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Carla Sosa, Ignacio Serrati and Giuliano Busnes, Berkemeyer

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LAWS AND REGULATIONS ON TELEMEDICINE

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

Yes, it is allowed. Law No 5.482/2.015 'Which Creates the National Telehealth Program' defines telemedicine as 'the provision of health services at a distance in the components of promotion, prevention, diagnosis, treatment and rehabilitation, by health professionals using information and telecommunication technologies, which allow them to exchange data with the purpose of facilitating access and timeliness in the provision of services to the population with limitations of supply, access to services or both in their geographic area'.

Regarding this item, we would like to point out the definition that the referred law establishes for telehealth, which is 'The group of health-related activities, services and methods, which are carried out remotely with the help of information and telecommunication technologies. It includes, among others, telemedicine and tele-education in health.'

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

In addition to the general regulation for healthcare services, in our country, the legal framework for telemedicine is basically composed of one law and two resolutions from the Ministry of Public Health and Social Welfare (Ministerio de Salud Pública y Bienestar Social or 'MSPyBS'). The law is the already mentioned Law No 5.482/2.015 'Which Creates the National Telehealth Program', and the resolutions are Resolution No 139/2.020 'Which Authorises Health Service Providers and Medical Professionals to Provide Remote Health Services in the Components of Promotion, Prevention, Diagnosis, Treatment and Rehabilitation, Through the Use of Information and Telecommunication Technologies', and Resolution No 367/2.020 'By Which Law No 5.482/2.015 "Which Creates The National Telehealth Program" Is Regulated, Providing Rules For Its Compliance'.

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

Telemedicine providers and personnel must comply with the general requirements for healthcare providers and personnel, including in the aspect of registration and licensing provided by the respective institutions. These requirements are established in the following legal framework:

- Law No 836/1.980 – Sanitary Code;
- Law No 1.032/1.996 – which creates the National Health System; and
- Law No 2.319/2006 – which regulates the functions of the Superintendence of Health.

However, in addition to that, specifically for the type of services in question, they must also complete a specific registration for the telemedicine modality.

These providers and personnel, within the framework of Law No 5.482/2.015 are required to register in the 'Unique Registry for the Authorisation of Services in the Telemedicine modality'.

Having explained that, the key specific licensing body for telemedicine providers and personnel is the General Directorate for the Control of Health Professions, Establishments and Technology, which is part of the MSPyBS. This is pursuant to Article 5° of the already cited Resolution No 367/2.020, which establishes that said Directorate is in charge of the registration of these health service providers and health personnel in the telemedicine field.

4. Was telemedicine authorised during the Covid-19 pandemic?
<p>Yes, it was authorised. It was a useful and helpful tool, considering that through telemedicine services, it was possible to continue providing diagnostic services for chronic pathologies that could not be treated in hospitals and clinics due to the social-distancing measures implemented by the government. However, despite that, this is not yet frequently used, and has a lot of space to grow and evolve.</p>
5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?
<p>The most complete and detailed norm on the matter, Resolution No 367/2.020 from the MSPyBS, was issued during the pandemic, taking into consideration the circumstances of the pandemic.</p> <p>Before this, there were no specific regulations regarding how to implement telemedicine. Therefore, it is not likely that there will be post-pandemic changes in the regulatory landscape.</p> <p>However, considering the evolution of this tool and, generally, of technology, it is reasonable to think that the regulation will evolve. Even more so because there is room to expand and improve the regulation on this matter.</p> <p>In regard to the second question, there has not been any change in the regulation in the post-pandemic scenario. Nevertheless, it should be mentioned that Article 4° of Resolution No 367/2.020 provides that the National Telehealth Plan will be updated every five years, with the participation of other public and private entities related to telehealth.</p>
6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis and telesurgery)?
<p>Resolution No 367/2.020 establishes that telemedicine applies to all areas of action in the field of health and medical specialties for promotion, prevention, recovery (diagnosis and treatment) or rehabilitation, including teleconsultation, tediagnosis support, telematics, telemetry with the application of artificial intelligence (machine learning) and other technological methods approved by the Ministry of Public Health and Social Welfare.</p>
7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.
<p>Any person who has accepted the terms of the telemedicine regulation, especially regarding 'informed consent' established in Resolution No 367/2.020, can use telemedicine, as long as the healthcare professional who is attending or treating the patient does not indicate otherwise.</p> <p>The said resolution allows both doctor-doctor and patient-doctor telemedicine services, and expressly makes reference to them.</p>
8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.
<p>The telehealth regulation (in which telemedicine is contemplated), specifically Law No 5.482/2.015, provides that the financial resources required by the National Telehealth Program, such as for the purchase of equipment, training of specialised human resources, and generation of educational and information dissemination activities, should be included as a separate budget item within the MSPyBS.</p> <p>It is available as a public health service and its funding is included in the MSPyBS general budget.</p> <p>In addition, it can be considered to be covered in insurance that covers face-to-face or in-person medical consultation (subject to its conditions and respective availability) because, in that sense, there is no differentiation between the services.</p> <p>This is supported by the provision of Article 8° of Resolution No 367/2.020, which</p>

<p>incorporates telehealth (that, as it is expressed, includes telemedicine) in the Organization of Health Services, within the framework of the Integrated and Integral Health Services Networks (Redes Integrales e Integradas de Servicios de Salud or RIIS), according to the levels of care.</p>
<p>9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.</p>
<p>Currently, there are no established insurance requirements applicable to telemedicine providers. However, with the evolution of this kind of healthcare service, it is reasonable to think that there will be requirements on that aspect.</p>
<p>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</p>
<p>10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists and alternative health therapy providers).</p>
<p>According to Resolution No 367/2.020, health professionals, and technical and auxiliary healthcare personnel involved in the patient care process can practise telemedicine. The said resolution does not list the types of professionals, but rather makes general provisions. On this point, it should be noted that any health professional practicing telemedicine must be registered and authorised by the MSPyBS. Lastly, there is no specific public regulation regarding each healthcare professionals.</p>
<p>11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?</p>
<p>Yes, there are. In Article 12°, Resolution No 367/2.020 establishes that healthcare professionals who provide telemedicine services must: (1) have knowledge of the use of information and telecommunication technology (ICT) for this service; (2) comply with the requirements for professional practice; and (3) provide telemedicine services within the scope of their professional competencies, including those related to the prescription of medicines in accordance with the provisions of the regulations in force. Regarding (1), the resolution contemplates 'telecapacitation', defining it as the learning process related to ICTs and its use carried out by technological support personnel, aimed at expanding the knowledge, skills, abilities and aptitudes of healthcare professionals and personnel.</p>
<p>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</p>
<p>As explained in item 3, physicians must comply with general requirements for healthcare providers and personnel, and those specific to their area of specialism. However, in addition, they must also complete a specific registration for the telemedicine modality. They are required to be registered by the General Directorate for the Control of Health Professions, Establishments and Technology in the Unique Registry for the Authorization of Services in the Telemedicine Modality.</p>
<p>13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</p>
<p>As noted above, both telemedicine providers and personnel must complete a specific registration for the telemedicine modality. They are required to be registered by the General Directorate for the Control of Health Professions, Establishments and Technology in the Unique Registry for the Authorization of Services in the Telemedicine Modality.</p>

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
<p>There are no specific requirements as for the platform itself, just the referenced requirements for the provider.</p> <p>It is reasonable to think that as these services become more used in Paraguay, there are going to be new, expanded, and specific regulations and requirements.</p>
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
<p>There are no legal requirements regarding electronic equipment and/or internet speed for telemedicine services. However, with the evolution of this kind of healthcare service, it is reasonable to think that, in future, there will be requirements on this aspect as well.</p>
16. Does legislation provide for specific rules concerning patients' medical records?
<p>Resolution No 367/2.020 is the norm that establishes provisions in this regard. Article 14° states that telemedicine service providers must record, in the patient's clinical history, every act performed in the framework of telemedicine services, according to the current regulations established by the MSPyBS.</p> <p>Article 25° establishes that the communication and information storage media and system chosen for the provision of telehealth services must guarantee trust, confidentiality, respect for privacy and protection of patients' personal data, in accordance with the general regulations currently in force. This entails that the management of information at the national, regional or local level, obtained within the framework of telehealth services, will be carried out in a statistical, anonymous and dissociated manner. Telemedicine service providers will be responsible for maintaining the confidentiality of personal data submitted to them for telehealth services.</p>
17. Are there geographic location requirements applicable to the provision of telemedicine services?
<p>There is a requirement on the location applicable to telemedicine services, implicitly, because the requirements for medicine service providers apply in that sense. The requirement is that telemedicine services must be seated or established in the country. In this regard, it may also be mentioned that there is no reference to the size, type of building or similar requirement for the place from where the service will be provided or for the administrative office.</p> <p>No other requirements on this aspect are found in the regulations.</p>
18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?
<p>The professional does need the patient's consent. This is pursuant to Article 15° of Resolution No 367/2.020, which provides that the telehealth service provider must obtain informed consent from the patient, user or his/her representative and inform them of how the service works through the use of ICT; the scope, risks, benefits, responsibilities, privacy and confidentiality management; the handling of their personal data; the contact protocols according to each telemedicine specialty area used; the conditions for prescribing health technology; the procedures to follow in emergency situations; the procedures to follow in the case of technological failures, including communication failures; and the risks of confidentiality violations during virtual consultations, among others.</p> <p>Consent will be recorded in the patient's medical record (only once). The patient will with his/her digital or handwritten signature declare that he/she understood the information</p>

provided and that he/she agreed to be treated in the remote modality.
19. Is there any other important requirement that should be highlighted?
A requirement that may also be important to highlight is the fact that telemedicine service providers are required to ensure the sustainability of the service.
DATA PRIVACY ASPECTS
20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description.
Yes, there are provisions regarding data privacy. Article 25° of Resolution No 367/2.020 establishes that the communication and information storage media and system chosen for the provision of telehealth services must guarantee trust, confidentiality, respect for privacy and protection of patients' personal data, in accordance with the general regulations currently in force. This circumstance entails that the management of information at the national, regional or local level, obtained within the framework of telehealth services, will be carried out in a statistical, anonymous and dissociated manner. Telemedicine service providers will be responsible for maintaining the confidentiality of personal data submitted to them for telehealth services.
21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?
The regulation does not establish specific criteria or requirements for security systems. It just makes reference to the general efficiency and safety of the system and media chosen by the provider, stating that the system must guarantee trust, confidentiality, respect for privacy and protection of patients' personal data, in accordance with the general regulations currently in force.
22. Does the applicable regulation provide for requirements for the transfer of information abroad?
The applicable regulation does not make any reference to requirements regarding the transfer of information to other countries, just the general requirements mentioned in the previous answer. Despite that, as stated in the previous responses, it is reasonable to think that there will be new requirements on these services as they evolve and become more used in Paraguay.
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?
In this case, again, there are just the general requirements set forth with regards to the communication and information storage media and system chosen for the provision of telehealth services, that must guarantee trust, confidentiality, respect for privacy and protection of patients' personal data.
LIABILITIES
24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
The liability of healthcare professionals involved in telemedicine practices is the same or equivalent to the liability of professionals providing face-to-face services, as there is no differentiation between these services. Healthcare professionals involved in telemedicine do have additional liability regarding obtaining informed consent, which includes the explanation of the service modality and its implications to the patient.

In general, healthcare providers have civil, criminal and administrative liability regarding their actions and conduct when it produces a harm to the patient, and if it is proven that the harm was derived from negligence, imprudence or malpractice of the professional.

The provisions on this matter are mainly contained in the following legal framework:

- Law No 836/1.980 – Sanitary Code;
- Law No 1.032/1.996 – which creates the National Health System;
- Law No 2.319/2006 – which regulates the functions of the Superintendence of Health;
- Law No 1.183/1.985 – Civil Code, with its subsequent amending laws; and
- Law No 1.160/1.997 – Penal Code, with its subsequent amending laws.

Common cases of malpractice include:

- deviating from the protocols determined by the competent authority;
- delay or error in the diagnosis of a patient: the time factor can be critical in employing proper medical processes; late diagnosis can have serious and harmful consequences for the patient's health, such as a worsening of the patient's general state of health;
- providing an inadequate prescription of medication;
- contagion of a serious infection due to a lack of hygiene in the hospital centre;
- performing a surgical intervention with harmful results for the patient;
- failure to provide emergency healthcare;
- lack of postoperative supervision; and
- lack of information to the patient. Failure to provide this information, before obtaining the patient's consent entails penalties for the hospital centre and intervening personnel.

It should be pointed out that most of the errors of healthcare service providers and physicians fall under administrative and civil law, not necessarily under criminal law, provided there is inevitably damage to the patient's health and this damage must have been caused by the careless action of the health agent in question.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

There is little information concerning the use and acceptance of telemedicine in Paraguay. This is mainly due to the fact that telemedicine is not yet a tool used regularly or frequently, and still has a lot of room to grow and evolve. However, there is some information (not up to date) published on the MSPyBS website, which refers to certain statistics on the matter, and how telemedicine helped during the social-distancing measures that were in force during the pandemic. Nevertheless, it is not easy to find and, we repeat, it is not up to date.

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.

As mentioned above, this type of healthcare service is not frequently used in Paraguay currently. However, several interested people are starting to inquire about the matter, which is a good indicator of the more widespread adoption of telemedicine, which will entail benefits, mainly regarding access to healthcare. As for unresolved issues, considering the above, it is notable that there is a lack of further detailed regulations on the implementation of telemedicine. These will entail, with no doubt, better accessibility to healthcare, especially for people that do not have it now.