

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>Telemedicine is allowed and is a common practice now in Argentina. Resolution 581/2022 of the Ministry of Health, by means of which the <i>Good Practice Guide for Teleconsultation</i> are established, defines 'telemedicine' as 'the modality of providing health services through information and communication technologies. It is a form of 'Telehealth'.</p> <p>In addition, Resolution 21/2019 of the Ministry of Health ('Resolution 21'), by means of which the National Telehealth Plan was approved, when referring to telemedicine said Resolution 21 refers to the definition given by the World Health Organization's (WHO) which defines telemedicine as 'The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities'.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>On 19 August 2020, Law No 27,553 on Electronic or Digital Prescriptions entered into force. In addition to incorporating in our health system that the prescriptions made by Health Care Professionals may be written in electronic or digital prescriptions and signed in handwritten, electronic or digital form, it also established the possibility of using tele-healthcare platforms throughout the national territory for the practice of medicine, dentistry and collaboration activities thereof, guaranteeing the patient's rights.</p> <p>It establishes that teleassistance can be developed only for the practices authorised for this purpose, according to protocols and platforms approved for it by the enforcement authority.</p> <p>Such law states that the enforcement authority shall be responsible for the custody of the databases connected with the electronic systems of electronic or digital prescriptions and with the electronic systems of health teleassistance platforms.</p> <p>Likewise, the enforcement authority shall have the obligation to outline the criteria for authorisation and access control to such databases, and to guarantee the strict compliance with the Law on Personal Data Protection (DP), among other regulations.</p> <p>With the purpose of continuing regulating telemedicine in the country, on 18 March 2022, the Ministry of Health issued Resolution 581/2022 by means of which the '<i>Good Practice Guide for Teleconsultation</i>' was established. In said document, a baseline of good practice is established, linked to the modality of provision of health services through information and communication technologies. Including, among others, that: (i) healthcare professionals using telemedicine shall be in a private place; (ii) the place shall have soft light so the patient can identify the professional; and (iii) the place shall have good acoustics.</p> <p>Please note that this Guide is not mandatory, but it is a 'reference document'.</p> <p>However, it is worth mentioning that Law No 27,553 has not been regulated yet, so there are many issues in relation to telemedicine that remain unregulated and unspecified.</p>

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

Notwithstanding Law No 27,553, there is still no specific regulation that thoroughly regulates telemedicine in Argentina. However, Law No 27,553 establishes that the enforcement authority will be determined by the National Executive Power and said authority must coordinate its actions with the corresponding jurisdictional authorities, as well as with the institutions that have competence in these matters.

Given that the National Executive Power has not yet established a specific enforcement authority, the key licensing body is the same as for general practice of medicine – this is the Ministry of Health and the Superintendence of Health Services (SHS).

The main function of the SHS is to regulate and control the National Social Security and Prepaid Medicine Entities to guarantee the rights of the users to health service, while the Ministry of Health's main function is to regulate all the medical and health activity in the country.

4. Was telemedicine authorised during the Covid-19 pandemic?

During the Covid-19 pandemic, by means of Resolution 282/2020, the SHS recommended that for as long as the mandatory, social, preventive isolation measures established by the National Executive Branch as a consequence of the Covid-19 pandemic were in place, the Health Insurance Entities should implement and encourage the use of teleassistance and/or teleconsultation platforms, in order to guarantee essential demand benefits.

To such end, during the Covid-19 pandemic the following resolutions were issued in connection to telemedicine:

1. Resolution No 723/2020 approved the 'Contingency project for on-site and permanent training through tele-education during COVID-19', which promotes new processes for the training of all members of the health team of the participating hospitals and services that attend critical patients in areas prepared for such purposes (intensive care, shock room, etc); and
2. Resolution No 696/2020 authorised, on an exceptional basis, the prescription of certain drugs for patients with oncological treatment or chronic non-communicable diseases (NCDs), as well as any other drug used under prescription, excluding narcotics, in the form of text messages or messages through messaging applications via web, email or fax.

As mentioned above, during the Covid-19 Pandemic, in August 2020, Law No 27,553, which incorporates electronic or digital prescriptions and tele-healthcare platforms nationwide, entered into force.

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?

There is no possibility for the regulatory landscape – which specifically provides for the use of telemedicine in the scope of our health system – to change in the post-pandemic scenario. In fact, in March 2022 when most of the pandemic measures were already lifted, the 'Good Practice for the Telemedicine Guide' was issued which shows the government's intention to keep regulating telemedicine.

6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis, telesurgery, among others)?

As explained above, the regulation on telemedicine is broad and does not provide for specifics. Therefore, there is no reference in the regulation to different types of teleservices allowed. However, it should be noted that the different dispositions and resolutions that address the topic refer to:

- telehealth as ‘all activities related to health, services, training, management or services provided through information and communication technologies’;
- telemedicine as ‘the modality of providing health services through information and communication technologies. It is a form of Telehealth’; and
- teleconsultation as ‘health care process, which as such involves the interpretation of medical information and decision making, through information and communication technologies between two or more health professionals, as well as between the health care team and the person receiving care.’ They distinguish two types of teleconsultation (i) between a doctor and a patient, and (ii) second opinion.

They also refer to tele-education and tele-investigation.

7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.

Law No 27,553 provides that tele-assistance is authorised for the practice of medicine, dentistry and other activities related to medicine; it does not specify who can use it.

However, it is to be understood that it is primarily intended for doctor-patient consultation.

The ‘*Good Practice Guide for Teleconsultation*’ approved by Resolution 581/2022 of the Ministry of Health, which is only a reference document, indicates that the teleconsultation can be performed by following ‘two modalities’ as required by each case: (i) teleconsultation with the patient; and (ii) second opinion teleconsultation between two or more doctors without the presence of the doctor. The Guide clarifies that its good practice recommendations are for the first modality and not the second.

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.

There is no specific regulation on the matter in Argentina. There are certain public health systems (national and provincial ones) that do have telemedicine available. In the private sector, telemedicine services are only offered by Health Coverage Entities (clinics or doctors) that voluntarily offer such service to their patients.

9. Please indicate whether any insurance requirements applicable to telemedicine services providers.

There is no specific insurance required to render telemedicine services and, therefore, the general principles of medicine will apply.

Although there is no legal obligation to have a professional liability insurance, some jurisdictions of Argentina require the payment of a fee which includes the social security contribution and the civil liability insurance to grant the licence to practice medicine in such jurisdiction,.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practise telehealth in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists, alternative health therapies providers, etc).

There is no specific certification to perform telemedicine. As indicated, Law No 27,553 enables the modality of teleassistance for the practice of medicine, dentistry and collaboration activities thereof. Teleassistance is also allowed for psychologists and/or interdisciplinary teams.

When performing telemedicine, medicine is being practiced and, therefore, telemedicine should be performed by healthcare professionals duly authorised to practice medicine in Argentina. The telemedicine services will be provided or performed by the healthcare professional, either directly or through health and medical facilities (which should also be duly authorised for such activity) or through Health Insurance Entities which should also be authorised by the SHS to act as such. There are also software or platforms that act as intermediaries between doctors and patients. Such intermediaries would require no authorisation or certification since they would not be practicing medicine themselves nor would they be providing health insurances services.

In Argentina, doctors, nurses, psychologists, nutritionists and traumatologists shall be duly authorised to practice their activity.

Please note that the practice of medicine is regulated by each provincial jurisdiction in Argentina. Each province has a different authority that regulates the practice of medicine in such jurisdiction according to its local rules. In order to practice medicine in each jurisdiction, the professional has to comply with registration and other requirements established in the jurisdiction where she/he wants to perform her/his activity.

11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?

There are no specific requirements that healthcare professionals shall meet to practice telemedicine.

The '*Good Practice Guide for Teleconsultation*' recommends the modality of provision of health services through information and communication technologies, including, among others: (i) that healthcare professionals using telemedicine shall be in a private place; (ii) the place shall have soft light so the patient can identify the professional; and (iii) the place shall have good acoustics.

Furthermore, said guide establishes that all members of the healthcare team involved in non-face-to-face telemedicine and teleconsultation telemedicine and teleconsultation activities must undergo prior training in the tool, processes, protocols and systems they will use, as well as in virtual communication skills and knowledge of digital transformation.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

There are no specific requirements to practice telemedicine in Argentina.

13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

There is no specific certification or licence to perform telemedicine in Argentina.

However, when performing telemedicine, medicine is being practiced and, therefore, telemedicine should be performed by healthcare professionals duly authorised to practice medicine in Argentina and in medical institutions authorised to offer medicine services (please see answer 10 above).

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

There are no specific requirements applicable to telemedicine platforms yet. This should be addressed in the regulation of Law No 27,553 or other rules to be issued in relation to such law, which have not been issued yet.

As long as the software or platform act only as intermediary between doctors and patients, such intermediary would require no authorisation or certification as the intermediary would not be practicing medicine themselves nor providing health insurances services.

However, the medicine practitioners that render services through the platform shall be authorised to provide the services in the respective jurisdiction.

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

There are no specific requirements related to electronic equipment or internet speed. This should be addressed in the regulation of Law No 27,553 or other rules to be issued in relation to such law, which have not been issued yet. However, the recommendations and the '*Good Practice Guide for Teleconsultation*' address the topic and give some non-binding recommendations.

In relation to the use of technology for the practice of telemedicine, the '*Good Practice Guide for Teleconsultation*' establishes that it should have adequate internet connection to ensure connectivity throughout the entire service. Systems are required to ensure that there are no interruptions in communication, both on the professional's side and on the patient's side.

16. Does the legislation provide for specific rules concerning patients' medical records?

Law No 27,553 provides that teleassistance can be performed 'guaranteeing the patient's rights' and that teleassistance platforms can be used in accordance with Law 26,569 which regulate the patient's rights.

Law No 26,529 sets forth: (i) the information that should be included in the medical records; (ii) the patient's rights in relation to its medical records; and (iii) the sanctions for not complying with points (i) and (ii) above.

Regardless of personal attendance or teleassistance, the doctor has to keep a medical history/record of the patient in which the doctor should record, among other medical information of the patient and the treatment, what drugs he/she has prescribed. Said records shall be available for patients.

According to such law, the content of the medical information can be recorded in 'magnetic support' provided that all means are taken to ensure the preservation of the integrity, authenticity, inalterability, durability and recoverability of the data contained therein in a timely manner. To this end, the use of restricted access with identification keys, non-rewritable storage media, field modification control or any other suitable technique to ensure its integrity must be adopted.

Furthermore, the doctor has to comply with the Data Protection regulation related to all and any information received from patients.

17. Are there geographic location requirements applicable to the provision of telemedicine services?

There is no specific national regulation on this matter in relation to telemedicine; however, each province of Argentina has the authority to regulate all matters related to health in its own territory. As mentioned above, in order to practise medicine in a determined province, the healthcare professional must be licensed before the correspondent authority of such province to practise his/her activity within such territory. Therefore, in principle, for example, a doctor located in the city of Buenos Aires licenced to practice medicine there but not licenced to practise

medicine in the province of Santa Fe, could not legally practise medicine in the province of Santa Fe.

18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?

There is no regulation that requires that the healthcare professional needs to obtain patient's consent to engage in telehealth. Therefore, general principles on the need of informed consent from patients both for medical treatment and for use/treatment of his/her medical information/images would apply.

Section 59 of the Argentine Civil and Commercial Code states that an informed consent for medical acts and health research shall be obtained prior to any medical act.

Additionally, Law No 26,529 establishes that all professional actions in the medical-health field, whether public or private, require, in general and within the limits established by regulation, the prior informed consent of the patient.

Finally, although as mentioned above there is no specific regulation related to telemedicine, the *Good Practice Guide* establishes that the healthcare team must require the patient's prior informed consent and inform and exchange with the patient about the expectations regarding the management of teleconsultations, as well as issues related to emergencies during and between teleconsultations. Additionally, it states that informed consent should be expressly required for the use of the telemedicine modality, as well as for the healthcare consultation itself.

19. Is there any other important requirement that should be highlighted?

The main points have already been addressed in the previous questions.

DATA PRIVACY ASPECTS

20. Are there data privacy issues that should be considered for the exploitation of such market? If your answer is positive, please provide a short description.

Yes, there are data privacy issues that should be considered for the exploitation of such market. In this regard, when processing personal data, the provisions of the Personal Data Protection Law No 25,326 (the 'DP Law') and complementary regulations should be borne in mind. Please note that the DP Law defines 'personal data' as information of any kind referred to identified or identifiable individuals or legal entities. Particularly, personal data includes, but is not limited to, 'sensitive data', defined as personal data that reveal racial and ethnic origin, political opinions, religious, philosophical or moral convictions, union affiliation and information regarding health or sexual life.

Sensitive data has an accentuated protection in our country. According to the DP Law, no one can be forced to provide sensitive data. In this sense, sensitive data can only be processed: (i) when there are reasons of general interest authorised by law; or (ii) for statistical or scientific purposes when the interested parties cannot be identified. However, the Data Protection Authority (DPA) has interpreted in various opinions that sensitive data can also be processed if the data subject has given prior, express and informed consent, since although no-one can be forced to provide sensitive data, nothing prevents them from doing so voluntarily.

Moreover, Resolution No 4/2019 which approved the mandatory guiding criteria and indicators of best practices in the application of the DP Law, establishes that 'biometric data' that identify a person will be considered sensitive data when they can reveal additional data, the use of which could be potentially discriminatory for the data subject (eg, data revealing ethnic origin or health information).

Lastly, section 8 of the DP Law states that health institutions, as well as medical science professionals, are entitled to collect and process personal data related to the physical or mental

condition of patients who make use of their services or who are or may have been under their care. These institutions and professionals are subject to professional secrecy duties when processing health-related data.

21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?

Yes, the applicable regulation provides for criteria and requirements for the security systems to protect the patient's information. In this sense, the data controller must take all technical and organisational measures which are necessary to guarantee the security and confidentiality of personal data, in order to avoid their alteration, loss, unauthorised consultation or processing (pursuant to Section 9 of the DP Law). The DP Law prohibits the recording of personal data in files that do not meet the technical requirements of integrity and security.

In addition, the Data Protection Authority's Resolution No 47/2018 provides the 'Recommended Security Measures for the Processing and Conservation of Personal Data'. This resolution reaches the entire cycle of processing and conservation of personal data, from its collection to its destruction, passing through access controls, actions aimed at its backup and recovery, the management of vulnerabilities and data breaches.

Although these measures are not mandatory, it is highly advisable to adopt the recommended security measures approved by Resolution 47/2018, or other equivalent ones, taking into consideration that implementing such measures is an efficient way to give evidence that the company is complying with the security and confidentiality obligations set forth in sections 9 and 10 of the DP Law.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

Yes, the applicable regulation provides for requirements for the transfer of information abroad. In principle, Argentine data protection regulations (ADPR) prohibit the transfers of personal data to countries that do not provide an adequate level of protection. To date, the countries that are considered by the DPA to provide an adequate level of protection are: Andorra, Canada (only for the private sector), the member states of the European Union and members of the European Economic Area, the Faroe Islands, Guernsey, the Isle of Man, Israel (only for data receiving automated processing), Jersey, New Zealand, Switzerland, the United Kingdom and Uruguay.

Notwithstanding the foregoing, the ADPR set forth that the prohibition is not applicable when either:

1. the data subject has expressly consented to such transfer;
2. data is exported for outsourcing purposes by means of an international transfer agreement (IDTA) between the transferor and the transferee, under which the latter undertakes to comply with ADPR, amongst other obligations; and
3. the transfer is among companies of the same economic group who have executed binding corporate rules (BCRs) with the minimum content set forth by the DPA or approved by the DPA.

In view of the above, in case data is transferred abroad for outsourcing purposes (controller to processor), data subjects' consent is not necessary. However, an IDTA will be necessary when transferring data to countries that do not have an adequate level of protection.

On the contrary, in case of assignment of data (controller to controller), data subjects' consent is in principle required (with some exceptions mentioned below), which renders the execution of an IDTA unnecessary, regardless of whether the transfer is to countries that have an adequate level of protection or not. However, the DPA still considers the execution of an IDTA as a 'good practice' if the transfer is made to a country that does not have an adequate level of protection.

On the other hand, if consent was not granted due to one of the exceptions set forth in the DP Law, an IDTA is necessary when data is transferred to countries that do not have an adequate level of protection.

By means of Provision 60/2016, the DPA approved two sets of standard contractual clauses (SCCs) for both 'outsourcing' (controller to processor) and 'assignment' (controller to controller) IDTAs. If these SCCs are used, it is not necessary to submit the IDTAs to the DPA for authorisation. In case the approved SCCs are not used and other types of IDTAs are used, if these do not contain the SCCs main principles, they must be submitted to the DPA for approval within 30 days of execution.

Consent for assignment of personal data is not required:

- when so established by law;
- when it is not required for the collection;
- when carried out directly between dependencies of state bodies, to the extent of the compliance with their respective competencies;
- when it is personal data related to health and is necessary for reasons of public health, emergency or for conducting epidemiological studies, while preserving the identity of data subjects through appropriate dissociation mechanisms; and
- when a dissociation procedure has been applied, so that the data subjects are unidentifiable.

In addition, Resolution No 159/2018 of the DPA approved the '*Guidelines and Basic Contents of Binding Corporate Rules*' in the context of international data transfers of Argentinean companies to companies that belong to the same economic group located in countries without adequate level of protection for personal data.

Said Guidelines set forth that binding corporate rules (BCRs) that seek to achieve an adequate level of protection for personal data must be mandatory and enforceable for all companies that are part of the economic group (through corporate resolutions that compel the company to comply with such rules,) as well as for employees, subcontractors and third-party beneficiaries (through specific clauses). It also requires the provision of judicial and administrative remedies of an independent, effective and accessible nature. Likewise, the BCRs must include a series of minimum contents which must be interpreted within the scope of the DP Law. In case the self-regulation rules set forth by an economic group differ from the guidelines outlined in the resolution, they shall be submitted for approval by the DPA within 30 days of the transfer.

Moreover, please note that ADPR also consider that: (i) sharing of personal information with companies from the same group is the same as sharing information with absolutely independent third parties; and (ii) cloud storage is considered an international data transfer of data (pursuant to Provision No 18/2015 of the DPA).

**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?**

Yes, there is a databases registration requirement that companies must observe. According to sections 3 and 21 of the DP Law, all those who form databases are obliged to register them with the Registry that the DPA created for this purpose. The registration process must be performed through a platform operated by the State called 'Remote Procedures' (TAD by its Spanish acronym).

The DPA's criterion is that the duty to register databases is only applicable to companies that are registered with the General Inspection of Justice (IGJ by its Spanish acronym) and that have a local tax identification number (CUIT by its Spanish acronym).

Please note that the DPA does not require any sort of disclosure of the content of the databases, but only some general information about the creation and maintenance of the latter and compliance with ADPR. Registration can be accomplished through a simple, online process.

Although there is no obligation to renew the registration annually, it is mandatory to report any update or amendment that takes place related to the data controller or the data. The lack of registration may give rise to sanctions such as warnings, suspensions, fines, closure or cancellation of the databases.

On the other hand, regarding the recording of data in the patient's medical records, please note that, as mentioned above, doctors shall comply with Law No 26,529 which establishes that: (i) the information that should be included in the medical records; (ii) the patient rights in relation to its medical records; and (iii) the sanctions for not complying with points (i) and (ii) above.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

Since there is no specific regulation for telemedicine, the general legal framework that can be found in the Consumer Protection Law and in the Civil and Commercial Law will apply.

It is worth mentioning that in Argentina consumer protection law does not apply to liberal professions, such as the practice of medicine and related activities.

To such activities, section 1768 of the Civil and Commercial Code, which establishes that the activity of the liberal professional – as medicine and related activities – is subject to the rules of the obligations to do (and not obligation of result), will apply. Healthcare professionals' liability is subjective and, therefore, the healthcare professionals will answer for fault or malice. Basically, the victim who is claiming compensation for the damage caused by a healthcare professional has to prove fault, gross negligence or wilful misconduct of the healthcare professional, regardless of whether telemedicine was used for the practice of medicine or not. In other words, the healthcare professional is not liable for providing service/practising medicine through the telemedicine system used but only for his/her decisions.

Regarding the healthcare institution liability, section 40 of the National Consumers Law establishes that 'if the damage to the consumer results from the defect or risk of the thing or from the rendering of the service, [...] the supplier, the seller and whoever has put his mark on the thing or service shall be liable [...]'. Therefore, liability of healthcare institution is joint and several. Only the person who proves that the cause of the damage was not his fault shall be released in whole or in part.

TELEMEDICINE NUMBERS AND TRENDS

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

There is no publicly available information 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.

Although, passing Law No 27,553 was a major step for Argentina's legal framework on the matter, so far, no specific regulation has been approved and, therefore, although legal and allowed, there are many unregulated matters in relation to telemedicine, especially concerning the platforms, their designs, their functionalities, their safeties and liabilities deriving from the use of same. Notwithstanding this, day-by-day telemedicine is increasingly used and is seen as a way to provide medicine in those areas not accessible to doctors. It is becoming more and more common to hear in the projects of the different political parties and the current government that telemedicine is an area that should continue to expand and that will help to democratise

medicine. The government's interest in its development is demonstrated by the recently published good practice guidelines for its practice. That is why we believe that within a short period of time we will have some regulation that deals specifically with telemedicine and its practice in the country.