

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Renata Fialho de Oliveira, Mauro Hiane de Moura, Beatriz Marconi, Juliana Marcussi and Isabel Hering, Veirano Advogados

Date of completion: 4 October 2022 (updated 29 December 2022)

LAWS AND REGULATIONS ON TELEMEDICINE

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

Telemedicine is allowed in Brazil. The Federal Medical Council (CFM) Resolution No 2,314/2022 ('Telemedicine Resolution') defines telemedicine as 'the practice of medicine mediated by digital, information and communication technology (DICTs), for the purposes of assistance, education, research, disease and injury prevention, healthcare management and promotion of health'.

More broadly, Federal Law No 14,510/2022 ('Telehealth Law') defines 'telehealth' as 'the rendering of remote health services, by means of communication and information technologies, involving, among others, the secure transmission of data and health information, by means of texts, sounds, images or other appropriate forms'.

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

The current legal framework that applies to the practice of telemedicine in Brazil includes (among others):

- Federal Law No 14,510/2022 ('Telehealth Law'), which amends Federal Law No 8,080/1990 ('Organic Health Law') and Federal Law No 13,146/2015 ('Statute for Disabled Persons'), to regulate the possibility of providing remote services related to all health professions (whether through texts, sounds, images, or other suitable forms). The Telehealth Law, thus, does not provide only for the practice of medicine; rather, it encompasses regulated health professions as a whole, delegating competence to their respective professional councils in relation to the ethical standards that should be observed for the provision of this type of services. It should be highlighted that the Telehealth Law aims at expanding access to health in Brazil, especially within the Brazilian public health system (*Sistema Unico de Saúde – SUS*), and, consequently, promote a better offer of services to the population;
- Telemedicine Resolution, issued by CFM in April 2022;
- Ministry of Health (MoH) Ordinance No 1,348/2022, which provides for telehealth practices and services within the Brazilian public health system (SUS);
- Federal Law No 12,842 of 2013, which provides for the exercise of the medical profession;
- The Medical Code of Ethics (CFM Resolution No 2,217/2018);
- CFM Resolution No 1,638 of 2002, concerning medical records;
- CFM Resolution No 2,311/2022, governing robotic telesurgery;
- Law No 8,078 of 1990 ('Consumer Defence Code' or CDC);

- Law No 13,709 of 2008 ('General Data Protection Law'); and
- Law No 12,965/2014 ('Internet Civil Framework').

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 both institutional healthcare providers as well as physicians, as detailed below.

In Brazil, all institutional healthcare providers must obtain and maintain a licence granted by the applicable sanitary surveillance authority. This licence may be granted on a municipal or state level, according to the location of the healthcare provider. The National Healthcare Facility Enrolment (*Cadastro Nacional de Estabelecimento de Saúde* (CNES)) is a general registry before which all healthcare facilities must register. Medical institutional healthcare providers shall further enrol with the Regional Medicine Council (*Conselho Regional de Medicina* (CRM)) of the states in which they have a seat and register before such body(ies) the medical professional who will officially be responsible, before the administrative authorities, for all the services rendered by such healthcare provider. Only domestic companies (ie, companies established and organised in accordance with Brazilian laws) may hold sanitary licences for the provision of health-related services.

Physicians may only render health services if their titles, certificates or diplomas are duly registered with the Ministry of Education and if they are enrolled with the applicable CRM (Federal Law No. 3,268, Decree No 44,045 and Law No 12,842 of 2013).

The Telemedicine Regulation expanded the list of entities subject to the Regional Medical Councils' surveillance, listing, in addition to institutional healthcare providers, also 'communication platforms and data filing services', requiring those to be headquartered in Brazil, registered with the CRM of the state where they are headquartered, with annotation of technical responsibility of a physician registered with the same council.

Pursuant to the Telemedicine Regulation, individual telemedicine providers must be licenced doctors registered with the CRM of their respective jurisdiction. They must opt-in and inform such body about the use of telemedicine to render medical services. The Telehealth Law exempts physicians of a secondary registration in cases they only render services in States different from their original registration states remotely, that is, in telehealth form.

At the national level, the Brazilian MoH is the highest sanitary authority. The Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária* (ANVISA)) is the agency responsible for regulating health related services. The Organic Health Law and Law No 9,782/1999, which instituted the National Sanitary Surveillance System, set forth that regulation, standardisation, control and sanitary surveillance are incumbent to institutions of direct and indirect public administration of the Federal Government, the States, the Federal District and Municipalities.

MoH's Consolidation Resolution No 04/2017 organised the distribution of authority among such governmental entities. Sanitary surveillance at all such levels is exercised through the issuance of regulations, execution of actions and services and political and administrative inter-sectorial articulation. In general, municipalities have more executory roles.

The Federal Medical Council has national jurisdiction and is responsible for regulating and supervising the activities of the CRMs. The CRMs, in turn, are responsible for the closer supervision of the medical practice, deciding on ethical questions, ruling conflicts and inspecting the activities.

4. Was telemedicine authorised during the Covid-19 pandemic?
During the Covid-19 pandemic telemedicine was authorised in an exceptional manner and for the duration of the Covid-19 health crisis in Brazil through Ordinance No 467/2020, issued by the Ministry of Health, and Federal Law No 13,989/2020.
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?
In the post-pandemic scenario, telemedicine became regulated on a definitive basis by the Telemedicine Resolution, Telehealth Law, Resolution CFM No 2,311/2022 and MoH Ordinance No 1,348/2022.
6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis, telesurgery, among others)?
Telemedicine Resolution expressly allows for: (i) teleconsultation; (ii) remote discussions between physicians; (iii) telediagnosis; (iv) telesurgery; (v) telemonitoring or tele-surveillance; (vi) tele-screening; and (vii) tele-consultancy.
7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.
Anyone who has expressly consented to telemedicine consultation can enjoy telemedicine services, as long as the responsible physician does not refuse to offer telemedicine and indicates instead the need of an in-person medical consultation. In other words, the regulation ensures the physician autonomy to decide on the best consultation method. Both doctor-doctor and patient-doctor telemedicine services are allowed.
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>In Brazil, telehealth (including telemedicine) is available within the public health system (SUS), as provided for the Telehealth Law and MoH Ordinance No 1,348/2022. The Ordinance, specifically, determines the actions, services and limits of telehealth within SUS.</p> <p>Telehealth is under mandatory insurance coverage, according to the respective plan agreement coverage, because it is considered as a valid method of consultation. Technical Note No 6/2020 issued by the National Supplementary Health Agency (ANS) clarifies this matter by indicating that '[...] services carried out through distance communication are not characterised as new procedures, but only as a form of non-face-to-face service, [...] telehealth services already enjoy mandatory coverage [...].'</p>
9. Please indicate whether any insurance requirements applicable to telemedicine services providers.

There are currently no insurance requirements applicable to telemedicine services providers.

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).

The regulation regarding licensing healthcare professionals is extensive in Brazil. Doctors, nurses, dentists, physiotherapists, psychologists and pharmacists, for instance, all must comply with a long list of requirements to be eligible to exercise their profession. Brazilian legislation is categorical when it comes to enforcing the mandatory enrolment with the competent authorities for all healthcare professionals.

Each medical profession in Brazil is regulated or supervised by its specific professional council, that defines the standards of the professional practice, supervises the professional ethics and the good practices in the services.

Authorisation for the provision of remote service varies according to regulation issued by each professional council. Currently, the following professionals may provide remote services through telecommunication means:

- nurses (Resolution No 696/2022 issued by the Federal Nursing Council);
- psychologists (Resolution No 11/2018 issued by the Federal Council of Psychology);
- nutritionists (Resolution No 666/2020 issued by Federal Council of Nutritionists);
- physiotherapist or occupational Therapist (Resolution No 516/2020 issued by the Federal Council of Physiotherapy and Occupational Therapy); and
- pharmacists (Resolution No 727/2022 issued by the Federal Pharmacy Council).

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

Except for robotic telesurgery, there is no further education or training required for physicians to provide telemedicine services. According to Resolution CFM No 2,311/2022, the surgeon performing robotic surgery must hold a Specialist Qualification Record (in Portuguese, *Registro de Qualificação de Especialista* (RQE)) and a specific training in robotic surgery.

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

Physicians providing telemedicine services must be duly registered before the CRM of their jurisdiction and inform the entity of their option to serve patients using telemedicine. The Telehealth Law exempts physicians of a secondary registration in cases they only render services in States different from their original registration states remotely, (ie, in telehealth form).

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

Companies that provide telemedicine services must have their headquarters in Brazil and be registered with the CRM of the state where they are based, with annotation of technical responsibility of a physician registered with the same council.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

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

Legal entities offering telecommunication platform and data filing services must be headquartered in Brazil, registered with the CRM of the location of their respective headquarters, with annotation of technical responsibility of a physician registered with the same council.

In case of use of a Digital Medical Record (called SRES) to record the telemedicine service, the platform must meet the standards of representation, terminology and interoperability. The SRES used must enable the capture, storage, presentation, transmission and printing of digital and identified health information, and fully comply with the requirements of Security Assurance Level 2 (NGS2), the Brazilian Public Key Infrastructure Standard ('ICP-Brazil') or another legally accepted standard.

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

The Telehealth Law recognises 'digital responsibility' as one of the principles to which telehealth is subject to. However, the law does not provide for specific legal requirements regarding electronic equipment and internet speed for telemedicine services, except with respect to robotic surgery. Robotic surgery may only be performed with adequate and safe infrastructure for equipment operation, efficient communication bandwidth, stability in the supply of electrical energy and efficient security against computer viruses or hacker invasion.

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

Telemedicine consultation services must be recorded in physical medical records or other information systems, such as the patient's Digital Medical Record in compliance with rules applicable to medical records in general and with the Electronic Patient Records Law No 13,787/2018, that provides for the digitalisation and use of computerised systems for the safekeeping, storage and handling of patient records. Also, the data and images of the patients, contained in the medical records, must be preserved, complying with the legal and CFM rules regarding custody, handling, integrity, veracity, confidentiality, privacy, irrefutability and guarantee of professional secrecy of the information, including the Brazilian General Data Protection Law No 13,709/2018 (LGPD), that provides for specific rules and guarantees to be complied with regarding the processing of personal and sensitive personal data (eg, medical and health-related data).

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

Telemedicine services may only be provided by Brazilian organised legal entities, registered with the CRM of their respective state of incorporation. Acts by health professionals, when practised

through telehealth, will be valid throughout the Brazilian territory and the Telehealth Law expressly exempts physicians from secondary registrations.

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

Telemedicine services require the patient's or the patient's legal representative free, informed consent with respect to telemedicine consultation and transmission of their images and data, submitted by electronic means or reading recorded of the agreement text, and must be part of the patient's electronic health recording system (SRES). Patients may refuse at distance medical treatment through telehealth and are guaranteed in-person treatment when required.

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

The remote issuance of medical reports, sickness certificates or medical prescriptions require, in addition to other the usually mandatory information, that the professional's electronic signature follows specific requirements concerning electronic signatures ('ICP Brazil standards') and a disclaimer that they have been issued in the telemedicine modality.

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 within the telemedicine market. The patient's personal data in the medical records must be preserved, obeying privacy and professional secrecy of the information, as well as processed in accordance with the rules set forth in the applicable legal framework (particularly, the LGPD, and the Electronic Patient Records Law and the CFM Medical Code of Ethics).

The Telemedicine Resolution sets forth that the specialised legislation shall govern the processing of personal data and handling of patient records. Notwithstanding, there are specific provisions in the Telemedicine Resolution concerning data privacy aspects, which shall also be complied with, including the following obligations:

- all data resulting from telemonitoring, including test results, clinical and prescription assessment, and professionals involved must be properly recorded in the patient's medical record; and
- the patients or their representatives must authorise the telemedicine services and the transmission of their data through a term of agreement and authorisation, sent by electronic means or text reading recording with the agreement, and it must be part of the patient's Electronic Health Record System (EHR).

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. CFM's Resolution No 1,821/2007 provides for the technical norms concerning the digitalisation and the use of computerised systems for storing and

handling the documents of patients' records, as well as for the standards for the elimination of paper and the exchange of identified health information.

Telemedicine services must be recorded in a physical medical record or, when computerised systems are used, in an EHR system. The EHR shall have, at least, the following characteristics:

- capacity to use an adequate database for the storage of the digitalised files;
- indexing method that allows the creation of an organised archive, making it possible to search in a simple and efficient manner; and
- compliance with the requirements of the 'Security Assurance Level 2' (NGS2), established in the Certification Manual for Electronic Health Record Systems¹, in the standard of the Brazilian Public Key Infrastructure (ICP-Brazil) or another legally accepted standard.

In addition, personal and sensitive data collected during the provision of telemedicine services must comply with the rules set forth in the LGPD for the protection of personal data.

In general terms, the LGPD only allows for the processing of health data in case there is a valid legal hypothesis attributed for the processing (Article 11 LGPD). Also, the LGPD establishes principles (Article 6 LGPD), which must be observed in all data processing operations (eg, transparency, necessity, adequacy, among others) and the obligation of guaranteeing all data subjects' rights set forth by the LGPD.

Particularly regarding the security of systems, the LGPD is not specific about the criteria and requirements to be adopted to ensure the protection of personal information, providing solely that the agent responsible to process personal data (either the 'Controller' or the 'Processor') shall adopt security, technical and administrative measures to protect the personal data from non-authorized access and accidental or unlawful events of destruction, loss, modification, communication or any other type of improper or unlawful data processing (Article 46, LGPD).

Beyond that, guidance from the Brazilian Data Protection Authority (ANPD) is still expected in this regard, mainly as to the processing of biometric data and the security measures to be adopted, according to Ordinance No 35/2022, which establishes the ANPD Regulatory Agenda for the 2023–2024 biennium. The referred guidance will take into consideration:

- the nature of the information being processed;
- the specific characteristics of the processing;
- the current state of technology, especially in the case of health data; and
- the principles provided for in Article. 6 of the LGPD.

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

Yes, the LGPD authorises international transfers of data whenever the country or international body to which the personal data will be transferred provides a level of data protection that is deemed adequate by the ANPD, or when the agent responsible for the data processing provides guarantees of compliance with the LGPD by means of:

- specific contractual provisions for a given transfer, to be approved by the ANPD;
- standard contractual provisions;
- global corporate standards approved by the ANPD; and

¹ Available at www.portalmedico.org.br and <https://sbis.org.br>.

- regularly issued stamps, certificates and codes of conduct.

However, the ANPD is yet to further regulate the matter of international transfers of personal data according to Ordinance No 35/2022. Thus, Brazil still lacks an official and approved format for standard contractual clauses or an official contact channel to submit specific contractual clauses for approval, as well as a definitive list of countries that are considered adequate under the LGPD regime.

Accordingly, while specific guideline is not provided by the ANPD, in view of the similarity of the Brazilian Law to the GDPR (the European law being even stricter than the Brazilian law), it is safe to make solid assumptions that:

- EU countries will be considered adequate as to data privacy and protection;
- GDPR standard contractual clauses (SCCs) will likely inspire the text of the Brazilian Standard Contractual Clauses; and
- even if neither of the above-mentioned occur, using the GDPR's SCCs in the absence of specific regulation for Brazil can be argued as good faith by the Controller.

This means that the new SCCs issued, pursuant to the European Commission Implementing Decision on standard contractual clauses for the transfer of personal data to third countries and to the EDPB Recommendation No 01/2021, would not affect our findings regarding their applicability and validity in Brazil, since the LGPD was inspired in the GDPR, both regarding the grounds for international transfer of data and the need to adopt safety measures.

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?

The LGPD does not provide for any specific requirements regarding where the company shall store the personal data, nor on specific rules applicable to databases. The LGPD solely imposes requirements that shall be complied with in case of international transfer of data.

Notwithstanding, the ANPD intends to regulate the aspects related to international transfer of personal data, as mentioned, what may affect the existence of data localisation requirements.

On the other hand, CFM Resolution No 1,821/2007 specifically requires that companies providing data storage for telemedicine services must have their headquarters established in Brazil. In addition, pursuant to the Telemedicine Regulation, such companies must be registered in the Regional Council of Medicine of the state where they are headquartered, with the respective technical responsibility of a physician regularly registered in the same Council.

Regarding the recording of data in the patient's medical records, CFM Resolution No 1,638/2002 provides for the following obligations:

- health institutions should ensure permanent supervision of the medical records in their custody, aiming at maintaining the quality and preservation of the information contained therein; and
- the storage and disposal of medical record documents, medical-scientific, historical, and social criteria of relevance to teaching, research, and medical practice should prevail.

In relation to electronic records, the technical norms set forth in Resolution No 1,821/2007 of the CFM, mentioned in question 21 above, shall apply.

Finally, it is worth mentioning that while Article 7 of the Law No 13,787/2018 establishes a permanent storage, considering technological evolution, for patient records patient records filed electronically in optical media, microfilmed or microfilmed or digitised, Article 8 of the same law, establishes a minimum term of 20 years, as of the last record, for the preservation of patient records in paper format, which have not been filed electronically, microfilmed or digitalised.

LIABILITIES

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

Article 14 of CDC sets forth the strict liability of hospitals and other healthcare institutions (ie, regardless of fault). In case of damages to the patient as a result of the service rendered by the professional, the hospital or institution will be liable, unless the institution proves: (a) there was no damage caused to the patient; and (b) the damage results from the acts of the patient himself or of a third party.

On the other hand, paragraph 4 of Article 14 states that the personal liability of the healthcare professionals, will be determined only after the verification of fault, that is, if there was negligence, imprudence or malpractice in the conduct of that professional.

The Telemedicine Resolution reinforces that medical professionals remain liable for any damages arising from the decision to opt for telemedicine over in-person care.

Article 42 of the LGPD states that the controller or the processor who cause material, moral, individual or collective damage to others, as a result of carrying out their activity of processing personal data, in violation of legislation for the protection of personal data, are obligated to redress it. Further, Article 52 of the LGPD foresee that data processing agents that commit infractions of the rules provided in the LGPD are subject to an escalated system of penalties, starting with a warning and ending with a fine.

In that sense, failure to comply with the LGPD by data processing agents may result in several penalties, including: warnings; disclosure of the violation; blocking or deletion of the personal data to which the violation relates; daily fines, or simple fines of up to two percent of the sales of the corporate group in Brazil – limited to BRL 50m – per violation; partial suspension of the functioning of the database for six months; suspension of the exercise of personal data processing activity for up to six months; and a partial or total prohibition of the exercise of data processing activities.

It should be noted, however, that the sanctions indicated above will be applied only in the administrative sphere, pursuant to ANPD Resolution No 4/2023, which approves the Regulation on Dosimetry and Application of Administrative Penalties, and do not hinder the liability for violation of the LGPD or data security in courts. Thus, in addition to the administrative sanctions provided for in the LGPD and applicable by the ANPD, in the cases of violations or incidents related to non-compliance or failures in the protection of personal data, the following may also apply:

1. indemnifications, both moral and pecuniary, which are judicially applied and shall be in accordance with the guidelines and parameters created by the ANPD; and
2. the fines and penalties applied by specific public administration bodies, as applicable to the specific case, as is the case of State Department for Consumer Protection and Defence (PROCON) in the scope of consumer relations, which will apply penalties based on general rules provided by the CDC (prior to the operationalisation of the ANPD).

TELEMEDICINE NUMBERS AND TRENDS

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

According to data from ABRAMGE (Brazilian Association of Health Plans), from the beginning of the Covid-19 pandemic until the end of April 2022, about 5 million virtual consultations have been carried out by the association's operators, which count with roughly 9 million beneficiaries.

Research performed by *Conexa Saúde plataforma* indicates that 73 per cent of patients who have already made an online consultation would adopt the modality habitually.

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.

The most important trends expected for the market are:

- telemedicine market growth and segmentation of the market;
- increase of adjacent telemedicine industries;
- search for more reliable and secure solutions considering the need to ensure data security in health;
- growth in the use of robotics and artificial intelligence; and
- use of wearables for tracking information on real time basis.