

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES
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LAWS AND REGULATIONS ON TELEMEDICINE
<p>1. Is telemedicine allowed in your country? If so, how is it defined?</p> <p>Yes, it is allowed. In Colombia, it is defined 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 communication technologies that allow them to exchange data with the purpose of facilitating access and timeliness in the provision of services to the population that has limitations of supply, access to services or both in their geographic area.</p>
<p>2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.</p> <p>Since 2007, through Law 1122 of 2007, Colombia began to implement the concept of telemedicine in the provision of health services by public institutions. Then, with Law 1419 of 2010, the rules for telehealth were established and the concept of telemedicine was defined. Subsequently, Resolution 2654 of 2019 set the parameters for the practice of telemedicine in the country.</p>
<p>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</p> <ol style="list-style-type: none"> 1. Ministry of Health: is the head of the health sector in the country. It is responsible for directing, evaluating, and regulating the health system, through the formulation of policies, plans and programmes. 2. Local Health Authorities: regional and municipal agencies in charge of authorising health service providers' activities. 3. National Health Superintendency: entity in charge of inspection, surveillance and control over the activities related to the provision of Health Services.
<p>4. Was telemedicine authorised during the Covid-19 pandemic?</p> <p>Yes. On 12 April 2020, the Government issued Decree 538 of 2020 and Resolution 2654 of 2019, through which it ordered health care providers to implement technological platforms with audio and video to guarantee health care services.</p>
<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>

One of the effects of the pandemic was the agile implementation of the telemedicine regulation that Colombia had in place since 2019. For this reason, so far, it has not been necessary for any regulatory change in this regard and currently healthcare providers continue to provide telemedicine. Since 2019, the regulation on telemedicine has included a free choice of the modality of care by the users, as well as the autonomy of the health professionals at the time of requesting the patient in person.

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

The services that can be provided through telemedicine are tele-guidance to the user, tele-support between health professionals, tele-diagnosis, tele-treatment, tele-prescription of surgeries.

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

Telemedicine may involve:

- doctor-patient;
- more than one doctor-patient;
- doctor-doctor;
- doctor-doctor-patient medical board;
- tele-counsellor-user; and
- non-professional health personnel (technician, auxiliary, etc).

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.

The Colombian Health System finances the services provided in the telemedicine modality, when:

1. these are provided by registered providers in the Special Registry of Health Providers (REPS); and
2. the service plans, products and technologies are included in the list published by the Ministry of Health which details those financed by the Health System.

In addition, the law establishes that up to five per cent of the investment budget of the Communications Fund of the Ministry of Communications will be allocated to finance the investments required to connectivity of the Public Health Institutions in Colombia.

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

It is not mandatory to have insurance to provide health services through telemedicine.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS
<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, alternative health therapies providers, etc).</p>
<p>Generally, telemedicine in Colombia has no restrictions in the provision of services. All health care services can be provided through the telemedicine modality if the professional does not consider otherwise according to the patient's pathology.</p>
<p>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</p>
<p>As a rule, institutions that provide health services require that people who perform activities in these areas have basic or intermediate knowledge in digital platforms. However, there are no special requirements of formal education to provide services under the telemedicine modality.</p>
<p>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</p>
<p>No. Physicians do not require prior authorisation to provide telemedicine services.</p>
<p>13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</p>
<p>The health care institutions shall be authorised to provide health care services, and they shall also be authorised to provide the services through telemedicine.</p>
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
<p>14. Are there specific requirements applicable to the telemedicine platform?</p>
<p>The technological platforms used to offer telemedicine services may be provided by the same provider or by a third party and will be under the responsibility of the health service provider.</p> <p>The healthcare service providers that provide the telemedicine modality must guarantee the authenticity, integrity, availability and reliability of the data, and must use the necessary techniques to avoid the risk of impersonation, alteration, loss of confidentiality and any undue or fraudulent or unauthorised access to the platform.</p> <p>In accordance with the law, the following must be complied with:</p> <ol style="list-style-type: none"> 1. The platform must comply with the security, privacy and personal data protection guidelines established in the specific regulation. 2. The communication and exchange of data between healthcare providers and patients must be done on the provider's technological platforms that meet the security criteria for

<p>the exchange of information, have security certificates, encryption algorithms and guarantee the security, privacy and confidentiality of the information.</p> <p>3. The platform must comply with the interoperability standards established for content and electronic data interchange, in accordance with the regulations governing the matter.</p>
<p>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</p>
<p>No.</p>
<p>16. Does the legislation provide for specific rules concerning patients' medical records?</p>
<p>No. The same rules established for the provision of in-person services apply. The telemedicine regulations establish that all activities performed in an appointment under this modality must be filed in the patient's medical record.</p>
<p>17. Are there geographic location requirements applicable to the provision of telemedicine services?</p>
<p>Telemedicine can be offered and used by any provider in any geographical area of the country.</p>
<p>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</p>
<p>Yes. The person responsible for a telemedicine activity must obtain the patient's consent or of their representative. Additionally, the patient should be informed about how this process works (the scope, risks, benefits, responsibilities, privacy and confidentiality management, handling of personal data, contact protocols, prescription conditions, procedures to follow in emergency situations, procedures to follow in case of technological failures, including communication failures and risks of confidentiality violations during virtual consultations, among others).</p>
<p>19. Is there any other important requirement that should be highlighted?</p>
<p>No.</p>
<p>DATA PRIVACY ASPECTS</p>
<p>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.</p>
<p>Yes. Since, as part of the performance and execution of telemedicine activities, the handling and collection of personal data and sensitive data will be performed, it is important to note that such handling must be done in accordance with local regulations, thus:</p> <ol style="list-style-type: none"> 1. Institutional health providers that act as controllers or processors must comply with general requirements from the data protection regulation.

2. In spite of the above, the need of a robust and compliant privacy policy would be one of the most important requirements that institutional health providers shall comply with. Such policy must be compliant with local regulation and it shall be drafted in Spanish.
3. Also, institutional health providers must obtain a previous, clear and express authorisation from the patients to handle their personal data. Since the data to be handled would include sensitive data (eg, health information) it is necessary that the consent is more specific than usual.
4. Implementing adequate security and confidentiality measures, that should also be included as part of a cybersecurity policy or incident response policy, are also necessary.
5. Institutional health providers must grant to patients the rights established in the local regulation and have in place adequate communication channels for the exercise of those rights by data subjects.

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

The regulation does not specifically refer to standards or criteria on security requirements for the handling of patient's information. However, it establishes general requirements on security standards to be applied for all databases. The authority would usually advise on the implementation of standards as high or better as ISO27001. Note, that complying with such high standard is not a legal requirement, thus if institutional health providers have adequate standards depending on the type of data that they handle, the size of the institution, among others, different standards that warrant adequate handling and security could be implemented.

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

Yes. Colombian regulation establishes a difference between international data transfers and international data transmissions. The first concept refers to the sharing between two controllers, while transmissions refer to sharing data with a third party that acts a processor of the information. For both cases there are requirements as follows:

1. International data transmissions: express and clear authorisation from the data subject to perform the transmission must be obtained. If the authorisation is not obtained, to perform the international transmission pursuant to a Data Transmission Agreement (similar to the European Union's standard clauses), in which the general obligations for processor are established and also establishing the general terms of the transmission, must be in place. In general terms and from an accountability perspective, the said agreement should always be in place if a transmission of data is performed.
2. International Data transfers: in general terms those should be performed to countries that are recognised by the local authorities as 'Adequate Countries' to which data can be transferred (this includes the EU, United Kingdom, the United States, and all the countries that are considered as adequate by the EU, among others). Authorisation from the data subject to perform a transfer should also be in place. The data subject should also be informed of the policies that would apply, as well as the way in which rights can be exercised. If the country to which the data is going to be transferred is not considered as an 'Adequate Country', and there is no clear authorisation from the data subject to perform the transfer to such country, it is necessary to obtain a declaration of conformity by the authorities. Also, from the perspective of compliance with accountability, it is advised to execute data transfer agreements.

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 Superintendency of Industry and Commerce (SIC) which is the local authority in charge of enforcing the data protection regulation, has in place a registry for databases which data controllers must comply with. The registry is mandatory for data controllers having total assets of more than approximately USD 776,000 (amount applicable for 2022).

From the data protection perspective, there are no specific requirements on recording the data of patient in medical records. Such recording must comply with general medical records requirements.

LIABILITIES

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

Telemedicine practices follow the general rules of medical liability. In Colombia, the medical liability must be proven. In case of damages caused to the patient as a consequence of the service provided by the professional, the institution will be liable, unless the institution proves that the damages are not related to the procedure performed and are not a consequence of the professional's malpractice.

TELEMEDICINE NUMBERS AND TRENDS

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

According to the Ministry of health statistics by November 2021, 127,404,668 events on telemedicine were performed, which is equivalent to 6,066,989 telemedicine events per month.

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 expected trends for telemedicine in Colombia are:

- to increase the flexibility of the ways in which health services are provided through the use of technologies;
- to ensure information security, its security and the quality of health services;
- to increase the provision of health services through telemedicine in rural areas of the country; and
- to increase the technological education of health professionals.