

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>Telemedicine is allowed in Ecuador. The Ministry of Public Health in the <i>Lineamientos Implementación del modelo de Atención Integral de Salud (Guideline to Implementing the Integral Health Care Standard)</i> defines telemedicine as ‘the provision of distance medical health services, using information and communication technologies for its implementation.’</p> <p>Also, the Ministry of Telecommunications, in the <i>Agenda de Transformación Digital del Ecuador (Digital Transformation Agenda of Ecuador)</i>, add that telemedicine ‘is performed by professionals using information and communications technology (ICTs) to exchange data, make diagnoses, recommend treatments, prevent diseases and injuries, as well as for the ongoing training of health professionals in research and evaluation activities, to improve the health of each individual and their communities.’</p>
<p>2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.</p> <p>The Organic Law on Health, which is the main authority on medical law in Ecuador, does not expressly address telemedicine and, in general, the activity is not regulated in Ecuador’s legal system in a comprehensive manner. Recent regulations, such as the <i>Guideline to Implementing the Integral Health Care Standard</i>, reference telemedicine only to provide definitions within the context of establishing the administrative model for the Ecuadorian health system, which is largely based on an in-person care scheme.</p>
<p>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</p> <p>The Ministry of Public Health is responsible for the formulation of national health policies and the regulation and control of all health-related activities, including telemedicine and Remote Second Opinion (RSO) services.</p> <p>National Agency for Sanitary Regulation, Control and Vigilance is responsible for the accreditation of public and private health entities.</p>
<p>4. Was telemedicine authorised during the Covid-19 pandemic?</p> <p>Telemedicine was authorised before, during and after the Covid-19 pandemic. Telemedicine started as a national programme in 2009 through a pilot plan aimed at the provision of health</p>

services in rural communities. This programme was guided by the Ministry of Telecommunications and the Ministry of Public Health.

In 2020, with the onset of the Covid-19 pandemic, telemedicine was first introduced as a form of teleworking for healthcare personnel who could not attend health centres in person. Then, it was intended for vulnerable groups, such as people with chronic diseases, hypertension, pregnant women, and diabetes.

In addition, the National Agency for Regulation, Control and Health Surveillance, along with the Ministry of Telecommunications, launched the '171 line', the website **www.citas.med.ec**, and the App SaludEc, where it was possible to make an appointment online with the doctor needed.

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?

The Ministry of Public Health has shown interest in telemedicine-related projects on several occasions. However, it has not publicly proposed the regulation of telemedicine in Ecuador.

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

According to the *Guideline to Implementing the Integral Health Care Standard*, the teleservices allowed are teleconsultation and second opinion. During the Covid-19 pandemic, telediagnosis was also implemented.

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

Anyone who consent to telemedicine consultation can enjoy telemedicine services. In Ecuador, telemedicine has been used in both cases, doctor-doctor and in patient-doctor remote medical services.

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.

In Ecuador, telemedicine is available in both public and private health systems. After the Covid-19 pandemic, the public health sector resumed telemedicine-free projects in rural areas.

In the private sector, telemedicine is under mandatory insurance coverage, according to the coverage agreement of the respective plan since it is considered a valid method of consultation.

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 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).

All health professionals must comply with a list of requirements to be eligible to exercise their profession and only they can provide medical care services, in person or remotely.

According to the Organic Law on Health, a health professional practising medicine within Ecuador must have a medical university degree granted by one of the established and legally recognised universities in the country, or by a university outside of Ecuador provided that the degree is revalidated and endorsed in Ecuador. Registration of the degree with the Secretary of Higher Education, Science, Technology and Innovation is necessary.

The health professional also must have completed one year of paid practice in rural or marginal urban parishes. In the case of health professionals who have obtained their degrees outside of Ecuador, the health authority will verify that they have fulfilled the prerequisites of practice in rural or marginal urban areas in the country where the degree was obtained.

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

There is no additional education or training required for physicians to provide telemedicine services. Medical personnel must comply with the basic standards of the Medical Ethical Code and the Guideline to Implementing the Integral Health Care Standard.

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

Physicians providing telemedicine services do not have any registration requirement but they must have their valid professional licences.

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

In Ecuador, there is no specific authorisation for institutions providing telemedicine services. However, companies that provide health services must comply with the requirements established in the Law that Regulates Prepaid Health and Medical Assistance Companies, such as an operating licence granted by the sanitary health authority.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

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

In Ecuador, there is no specific regulation for telemedicine platforms. Healthcare providers use online platforms such as Zoom or Teams. These platforms must enable the capture, storage, presentation, transmission, and printing of digital and identified health information.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
<p>There are no legal requirements regarding electronic equipment and internet speed for telemedicine services. However, public sector projects providing telemedicine services to rural areas, require a computer station with internet access, a high-definition screen with speakers, a multifunction printer and a scanner.</p> <p>Other healthcare entities that provide telemedicine services do not have any applicable regulation on the specifications of their electronic equipment. However, they must comply with basic standards of connectivity, equipment and good medical attention.</p>
16. Does the legislation provide for specific rules concerning patients' medical records?
In Ecuador, medical records are mandatory and confidential. According to the Article 7 of The Organic Law on Health, every person has the right to 'have a single medical record written in precise, understandable and complete terms; as well as confidentiality for the information contained therein and to be given their epicrisis.'
17. Are there geographic location requirements applicable to the provision of telemedicine services?
There are no geographic location requirements applicable to the provision of telemedicine services in Ecuador.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
Healthcare professionals need to obtain patients' consent for all medical care. According to Article 7 of the Organic Law on Health, the patient has the right to exercise the autonomy of their will through written informed consent and make decisions regarding their health status, diagnostic procedures and treatment. The only exceptions are in cases of urgency, emergency, or risk to the life of people and public health.
19. Is there any other important requirement that should be highlighted?
No.
DATA PRIVACY ASPECTS

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

In Ecuador, there are no specific provisions on data privacy aspects for telemedicine services. However, the patient's data in the medical records must be preserved, obeying the privacy and professional secrecy of the information outlined in the Organic Law on Health, Medical Ethical Code, and the Regulation of Confidential Information in the National Health System.

In addition, all data collected during the provision of medicine services must comply with the rules set forth in the Organic Law for the Protection of Personal Data (OLPPD). According to the OLPPD, health data is a special category of personal data, and any processing of this information must comply with the following minimum standards:

1. Health data generated in public or private health establishments will be treated in compliance with the principles of confidentiality and professional secrecy. The owner of the information must give prior consent as determined by law, except in cases where the treatment is necessary to protect the vital interests of the person concerned.
2. The health data processed must be previously anonymised or pseudonymised, avoiding the possibility of identifying the owners of the data.
3. Any processing of anonymised health data must be previously authorised by the Personal Data Protection Authority. In order to obtain the above-mentioned authorisation, the interested party must submit a technical protocol containing the necessary parameters that guarantee the protection of such data and the prior favourable report issued by the Health Authority.

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. The Regulation on Confidential Information in the National Health System provides the technical norms related to administration, confidentiality, and security in the custody of medical records.

In addition, the Organic Law for the Protection of Personal Data establishes that those responsible for the processing of personal data must comply with the following requirements:

1. They must be in accordance with the principle of personal data security.
2. They must implement a permanent verification, evaluation, and assessment of the efficiency, efficacy, and effectiveness of the security measures implemented to guarantee and improve the security of the processing of personal data.
3. They must demonstrate that the measures adopted mitigate the risks identified.
4. Some of the security measures suggested by OLPPD to protect personal data are:
5. Anonymisation, pseudonymisation, or encryption measures for personal data.
6. Measures aimed at maintaining the permanent confidentiality, integrity, and availability of systems and services for the processing of personal data.

7. Use of international standards for an adequate risk management and information security systems.

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

Yes, the Organic Law for the Protection of Personal Data (OLPPD) allows the transfer of information abroad, 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 Ecuadorian Data Protection Authority, or when the agent responsible for the data processing provides guarantees of compliance with the OLPPD by means of:

1. Ensure compliance with principles, rights, and obligations in the processing of personal data at a standard equal to or greater than the Ecuadorian regulations in force.
2. Effective guarantee of the right to the protection of personal data, through the access to administrative or judicial actions.
3. Ensure the right to compensatory damages, if applicable.

The international transfer of personal data shall be based on a legal instrument that contemplates the standards determined above, as well as those established by the Authority for the Protection of Personal Data. These legal instruments are binding.

The transfer of patient information abroad must follow the standards previously described in questions 20 and 21. In addition, each health entity has a protocol for transferring information.

23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?

There is no registration of databases requirement that companies must observe.

Regarding the recording data, all medical services must be recorded in a physical medical record or in electronic platforms that must have the following security standards:

1. Only healthcare personnel are authorised to use the patient's medical records for medical purposes.
2. Only authorised healthcare personnel shall have access to the electronically archived documents by means of personal access codes.
3. Only healthcare personnel will be able to use the information contained in the medical record, and the results of laboratory and imaging tests.
4. All institutions that handle relevant patient health information must have adequate security and safekeeping systems.
5. Physical documents containing confidential information that does not require archiving must be destroyed to avoid reuse.

The public healthcare system uses the *Plataforma de Registro de Atención en Salud (PRAS)* (Health Care Registration Platform). The private healthcare system does not have a standardised platform for storing patient information. However, they must use an electronic

platform with an adequate database for digitalised files and indexing methods for the information.

LIABILITIES

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

There is no specific liability of healthcare professionals involved in telemedicine practices. However, regarding general health services, Article 202 of the Organic Law on Health establishes that any unjustified act, that generates harm to the patient shall be considered an infraction in the following cases:

- regulatory breach;
- total or partial lack of technical knowledge or experience;
- omission of the required care or diligence; or
- negligence, in the omission or unjustified delay in its professional obligation.

The infringements will be sanctioned with the following penalties:

- fine;
- suspension of the authorisation or licence;
- suspension of the professional practice;
- asset forfeiture; and
- partial, temporary, or definitive closure of the corresponding establishment.

These penalties are imposed without prejudice to the criminal sanctions that may be applied.

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 Telecommunications approximately two million Ecuadorians received health care through various technological tools during the Covid-19 pandemic.

1. The 171 line received 1,415,045 calls, of which more than 572 thousand were directly related to Covid-19. In addition, 51,961 cases were referred to telemedicine and 6,615 to the Ministry of Public Health.
2. The **web cita.med.ec** is another tool that was strengthened to provide medical care. A total of 330,345 medical appointments were booked.
3. The SaludEc App registered 80 thousand of downloads. In total, 66,668 triages were registered, and 6,197 cases were referred to the 171 line for telemedicine.

There is no data registered regarding telemedicine services that were provided by the private health system.

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 regulation;
- increase of adjacent telemedicine industries;
- strengthen security systems to ensure adequate processing of patient data; and
- develop data storage systems that allow the collection of private and public information related to telemedicine services.