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| 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 in Peru. Law No 30421 (the 'Telehealth Framework Law') defines telemedicine as the 'provision of remote health services in the components of promotion, prevention, diagnosis, treatment, recovery, rehabilitation and palliative care, provided by health personnel who use ICTs, with the purpose of facilitating access to health services for all the population'.</p> |
| 2. Please provide a high-level overview of the legal framework regarding telemedicine in your country. |
| <p>Telemedicine is specifically regulated by the Telehealth Framework Law, the Supreme Decree No 005-2021-SA ('Regulation of the Telehealth Framework Law'); Legislative Decree No 1303 that optimises processes related to Telehealth; and Legislative Decree No 1490 that strengthens the scope of Telehealth; as well as by Ministerial Resolution No 365-2008-MINSA that approves the Telehealth Technical Standard; Ministerial Resolution No 117-2020-MINSA that approves the Directive for the implementation and development of synchronous and asynchronous Telemedicine services; Ministerial Resolution No 1010-2020-MINSA that approves the Technical Document: National Telehealth Plan Perú 2020-2023; Ministerial Resolution No 1045-2020-MINSA that approves the Administrative Directive for the scheduling of health personnel shifts and assignment of health users for their attention in Telemedicine services; and Ministerial Resolution No 968-2021-MINSA that approves the Administrative Directive that establishes the information security mechanisms in the electronic prescription for Telemedicine, among others.</p> |
| 3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities. |
| <p>The Ministry of Health formulates, plans, directs, coordinates, supervises, and evaluates the national and sectoral telehealth policy. It elaborates the National Telehealth Plan and defines the quality standards for the provision of telehealth services. The National Health Superintendence supervises compliance with the obligations of the Health Service Provider Institutions, Health Insurance Fund Administrators Institutions and IPRESS Management Units, which are generated in the provision of the telehealth service. The National Institute for the Defense of Competition and the Protection of Intellectual Property supervises and monitors compliance with the rights recognised for consumers.</p> |
| 4. Was telemedicine authorised during the Covid-19 pandemic? |
| <p>During the Covid-19 pandemic, telemedicine was authorised in Peru.</p> |
| 5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario? |
| <p>There has already been a change in regulation in the post-pandemic scenario. Examples of that are the Regulation of the Telehealth Framework Law and the National Telehealth Plan Perú 2020–2023.</p> |
| 6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis and telesurgery)? |
| <p>The Regulation of the Telehealth Framework Law expressly allows for: (1) teleconsultation; (2)</p> |

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| teleinterconsultation; (3) teleorientation; (4) telemonitoring; and (5) others established by the Ministry of Health through a Ministerial Resolution. |
| 7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed. |
| Anyone can use telemedicine services. Both doctor-doctor and patient-doctor telemedicine services are allowed. |
| 8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies. |
| The Telehealth Framework Law states that the health insurance fund administrators (<i>instituciones administradoras de fondos de aseguramiento en salud</i> or IAFAS) and other insurance modalities guarantee the financing of telehealth services. In that sense, Regulation of the Telehealth Framework Law states that public, private and mixed IAFAS must include in their coverage plans, the financing of benefits through telehealth services, as appropriate. It clarifies this matter by indicating that the public, private and mixed IAFAS ensure the financing for the contracting of telehealth services, which include the provision of medicines, other pharmaceutical products, and medical devices, necessary to guarantee the care, recovery, and rehabilitation of the telehealth user, according to the service that is provided. In Peru, telehealth (including telemedicine) is available within the public health system and is under mandatory insurance coverage. |
| 9. Please indicate whether any insurance requirements are applicable to telemedicine service providers. |
| There are currently no insurance requirements applicable to telemedicine service 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 and alternative health therapies providers). |
| Any physician licensed in Peru and who is a member of the National College of Physicians can practise telemedicine. |
| 11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services? |
| No, not required by law. |
| 12. Is there any registration requirement applicable to physicians that provide telemedicine services? |
| No, not required by law. |
| 13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services. |
| No special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services. |
| REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES |
| 14. Are there specific requirements applicable to the telemedicine platform? |
| There are no specific requirements applicable to the telemedicine platform. |

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| 15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services? |
| The Telehealth Technical Standard states the requirements regarding electronic equipment, such as: (1) permanent power supply; (2) technology (hardware, software, medical terminals, data networks and telecoms) that has technical-scientific support, (3) technology that does not interfere with the environment; (4) information and communication equipment maintenance; (5) information that is transmitted accurately, reliably and in a timely manner; and (6) procedures for the capture, storage and transmission of the information. It does not mention requirements for internet speed. |
| 16. Does the legislation provide for specific rules concerning patients' medical records? |
| According to the Telehealth Technical Standard, all patients treated under the telemedicine modality must have a medical record (electronic or physical), in compliance with the Technical Health Standard for the Management of Medical Records. This implies that all findings, recommendations and services used under the telemedicine modality must be properly registered. |
| 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. |
| 18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth? |
| The Regulation of the Telehealth Framework Law states that the doctor or professional health researcher who performs telemedicine requires informed consent from the telehealth user in the mandatory situations established by the Regulation of Law No 29414, the law that establishes the Rights of Users of Health Services. It also indicates that in the case of teleinterconsultation, prior to carrying out this act, the informed consent of the patient must be obtained. However, in the cases of telemonitoring and teleguidance, informed consent is not required prior to the provision of the service; it is only necessary to inform the patient or health user about the conditions, nature and restrictions of the telemedicine service. |
| 19. Is there any other important requirement that should be highlighted? |
| No. |
| DATA PRIVACY ASPECTS |
| 20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description. |
| The Personal Data Protection Law, enacted by Law No 29733, and its regulations, approved by Supreme Decree No 003-2013-JUS, apply to personal data (information concerning an individual, which identifies or could be used to identify the individual) contained or destined to be contained in a public or private personal database to be processed in Peru. Sensitive data (eg, data related to health, and, in general, physical, mental and emotional characteristics, facts or circumstances of emotional or family life, and personal habits corresponding to the most intimate sphere of private life) must be specially protected and requires that the consent of the data subject be expressed in writing. |
| 21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information? |

Data controllers and those responsible for processing must adopt technical, organisational and legal measures necessary to guarantee the security of the personal data they hold. The measures taken must ensure a level of security appropriate to the nature and purpose of the personal data involved.

The Data Protection Authority has passed a directive enacted by Directorial Resolution No 019-2013-JUS/DGPDP establishing the security standards for the processing of personal data. This directive establishes different standards depending on the features of the database.

The relevant criteria are: (1) the number of data subjects whose data is contained in the database; (2) number of fields in the database (eg, name, address and phone number); (3) existence of sensitive data; and (4) data controller of the database (an individual or entity).

The law that created the National Registry of Electronic Medical Records, enacted by Law No 30024, and its regulations, approved by Supreme Decree No 009-2017-SA, set forth additional security measures applicable to electronic medical records.

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

Special rules apply to cross-border transfers. Exporters of personal data must refrain from making cross-border transfers of personal data if the destination country does not provide adequate protection levels.

If the destination country fails to provide adequate protection levels, the data exporter must guarantee that the treatment of personal data meets adequate protection levels (eg, contractual clauses and Code of Conduct for business groups). This does not apply when, among other cases: (1) the data subject has given his/her prior, informed, express and unequivocal consent to the transfer of data under such circumstances; or (2) the cross-border transfer of personal data is needed for the performance of a contractual relationship in which the data subject is a party and those activities that the management of the contractual relationship requires.

Likewise, in cases of cross-border transfers, the data importer must assume the same obligations that correspond to the data exporter as a data controller. For such purposes, the data exporter may employ contractual clauses or other legal instruments to establish such obligations, and the conditions in which the data subject consented to the processing of his/her personal data.

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?

Data controllers must register their databases containing personal data (this process is carried out before the Data Protection Authority) and report the transfer of personal data abroad with the Data Protection Authority.

No specific requirements for the recording of data in the patient's medical records are contained in the Personal Data Protection Law or in the Law that created the National Registry of Electronic Medical Records.

LIABILITIES

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

No specific type of liability is created for telehealth services. Civil liability operates on a case-by-case basis.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of

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| telemedicine in your country? |
| No. |
| 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. |
| <p>Since the pandemic, telehealth services have intensified in Peru. Before the pandemic, medicine was understood to be almost 100 per cent face-to-face; however, recent years have taught us that this is not always the case. The implementation of various technological advances has opened up a field of application of medicine that is more efficient than what we knew before. It is precisely in this new conception of the profession that telemedicine plays a fundamental role.</p> <p>There are many opportunities to be exploited in relation to telemedicine services. This allows for more effective time management, which in turn helps with planning, diagnosis and prognosis of patients through faster and more efficient care. This not only reduces costs but also allows for a better distribution of healthcare services.</p> <p>Telemedicine has brought important changes in the way medicine is practised by making it more efficient. However, it is necessary to have greater investment in infrastructure and information and communication technology (ICT) to be able to implement these changes. This investment must go hand in hand with specialised companies that guarantee quality and trustworthy results.</p> <p>Indeed, in Peru, one of the main factors for the success and further expansion of telemedicine is to have adequate infrastructure. For this, it is necessary to make investments with specialised companies to ensure the quality and compatibility of systems. It is also important for all medical staff to be trained in how to use ICTs, in addition to being trained in communicating with patients through electronic means. The same should happen in rural areas, where staff should be trained to use and maintain this equipment. Training in relation to patients is crucial, as there are certain cultural and generational barriers that must be overcome in order to make more efficient use of these tools.</p> <p>Finally, it is important to point out that the protection of personal data is essential to obtain adequate medical care and is fundamental due to the growing risks associated with digital care. It is necessary to generate greater investment in the platforms that manage this data to improve its use and trust in the systems. It is also crucial that the government works hand in hand with private enterprise to design and implement reliable, secure platforms that support healthcare administration through artificial intelligence (AI)-controlled systems.</p> |