

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 Panama. Law No 203 of 13 May 2021 sets forth guidelines for the development of telehealth in Panama and establishes other provisions ('Law No 203').</p> <p>Law No 203 defines telemedicine as the '[p]rovision of remote health services, in the components of promotion, prevention, recovery or rehabilitation, by qualified health professionals who use information and communication technologies (ICT) designed and endorsed for this purpose, and that allows them to exchange real data automatically, synchronously or asynchronously, with the purpose of facilitating the population's access to high-quality remote health services'.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>Telemedicine is regulated by Law No 203. The purpose of Law No 203 is to develop telehealth in Panama, under the doctor-patient modality, as a method of supporting the Ministry of Health (Ministerio de Salud) and the Social Security Office (Caja de Seguro Social) in health matters, with the purpose of contributing to the decongestion of hospitals, carrying out preventive and/or initial diagnoses more quickly and remote monitoring of patients.</p> <p>Notwithstanding the foregoing, with regards to the exercise of the medical profession by an authorised physician, telemedicine is subject to compliance with Law No 66 of 10 November 1947 that approved the Panamanian Health Code (Código Sanitario de la República de Panamá) ('Law No 66') and Law No 88 of 1 July 1941 by which the National Hygiene Board was created, which is the body that dictates measures related to the practice of medicine (as amended and regulated) ('Law No 88').</p> <p>Please note that the National Hygiene Board was later replaced by the Technical Council of Public Health (Consejo Técnico de Salud Pública).</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>Pursuant to Article 21 of Law No 203, the key licensing bodies for telemedicine are the Ministry of Health and the Social Security Office. These entities are in charge of the implementation of the Telemedicine System in the Republic of Panama.</p> <p>Nonetheless, the law provides for the possible consultation or engagement of other entities, both public and private, including the Authority of Governmental Innovation (Autoridad de Innovación Gubernamental or AIG).</p> <p>Furthermore, all institutional healthcare providers and physicians must obtain and maintain a licence granted by the Technical Council of Public Health functioning within the Ministry of Health.</p> <p>Pursuant to Law No 203, the individual responsible for the telemedicine service must be a</p>

licensed physician. The said doctor must ensure that his/her diagnosis and recommendations adhere to the information received from patients, and that the training and competence of said personnel are adequate to guarantee the patient's safety.

**4. Was Telemedicine authorised during the Covid-19 pandemic?**

Law No 203, which sets forth guidelines for telemedicine, was enacted on 18 March 2021, which was indeed during the Covid-19 pandemic.

**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?**

As of today, no changes to Law No 203 nor any regulation implementing such a law have been enacted.

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

Even though Law No 203 is not specific as to all the services that could be provided through telemedicine, it sets forth the different categories, activities and responsibilities that healthcare providers must comply with. As such, it is safe to assume that said categories, activities and responsibilities outline the different services that are allowed under telemedicine.

For example, second opinions, teleconsultation, telesurgery and telediagnosis are within the aforementioned categories, activities or responsibilities.

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

Pursuant to Law No 203, telemedicine can be provided under the following modalities: (1) doctor-patient; (2) doctor-doctor; (3) doctor-medical board; and (4) patient face-to-face with a non-professional healthcare provider (ie, technician, technologist and assistant)-doctor.

**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.**

In Panama, both public and private health systems are allowed to implement telemedicine. As previously mentioned, the Ministry of Health and the Social Security Office are in charge of the implementation of the Telemedicine System in the Republic of Panama. Law No 203 provides that any private entity that wishes to implement telehealth measures may do so, as long as it complies with the guidelines established in Law No 203.

As of today, there has been no development with regards to 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 therapy providers).**

<p>In Panama, the regulation regarding licensing healthcare professionals is applicable to doctors, nurses, dentists, physiotherapists, psychologists and pharmacists. They all must comply with the requirements established by the Technical Council of Public Health or their governing authority to be eligible to exercise their profession.</p> <p>Article 16 of Law No 203 provides that medical services provided by telehealth or telemedicine are subject to the same limitations that are established for the practice of face-to-face medicine in Panama.</p>
<p><b>11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?</b></p>
<p>Law No 203 provides that the Central Government, through the entities it deems appropriate, will train all health personnel in the use of the necessary technology to implement the provisions of said law.</p> <p>The training prescribed in Article 18 of Law No 203 is mandatory for all public servants who work in the health sector. Those who do not comply will be administratively sanctioned by the respective institutions in which they work.</p>
<p><b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b></p>
<p>As of today, there are no registration requirements.</p>
<p><b>13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</b></p>
<p>No, there are no special licenses or authorisations that are mandatory for institutional healthcare providers engaged in telemedicine services, besides their regulatory licences issued by the Technical Council of Public Health and the need to comply with Law No 66 and Law No 88 described above.</p>
<p><b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b></p>
<p><b>14. Are there specific requirements applicable to the telemedicine platform?</b></p>
<p>Pursuant to Article 17 of Law No 203, technological platforms for telehealth are defined as ‘[a]ll information technology elements that support the operation of the system of a medical institution, including hardware, communications platforms and specialized software, which can be provided by an operator, technology of the providers or by a third party. These platforms will be under the responsibility of whoever provides the health service.’</p> <p>Furthermore, all the components of the technological platforms used in telemedicine must comply with the HL7 standard for the transfer of clinical data, as well as with the procedural terminology codes and international classification of diseases, and must also allow intercommunication with current technological systems.</p>
<p><b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b></p>
<p>Law No 203 establishes that health establishments and medical services that practise telehealth must have the necessary human and technological resources to carry it out in safe conditions. Therefore, they must implement strategies for such purposes, including the following:</p>

- guarantee the permanent supply of electrical energy and communication systems, according to the needs of the service provided, and technological availability, according to the installed service;
- use technology (hardware, software, medical terminals, data networks and telecoms) that have technical conditions of sufficient quality and standards, with support and technical-scientific support available;
- guarantee that the elements of the technology used do not interfere with the environment and the safe use of the equipment, considering environmental conditions;
- ensure that the information and communication equipment is maintained to guarantee the quality of information, the monitoring of protocols and the continuity of the service; maintenance must be carried out by the technological provider or the government, in accordance with a preventive plan that includes the revision and calibration of equipment, in accordance with the requirements and indications of the manufacturers, which is stated in the resume of each team;
- ensure that any medical capture terminal that has contact with the patient complies with the necessary technical conditions to guarantee safe care;
- ensure that the technology used provides the minimum requirements to ensure that the information transmitted is accurate, reliable and timely;
- guarantee that the procedures for the capture, storage and transmission of information are known by the personnel in charge and responsible for its application; and
- guarantee that the digitisation and compression parameters selected in the equipment, during data or image capture, have the necessary resolution to allow a correct diagnosis.

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

Law No 203 provides that telemedicine activities must be registered in the digital patient's medical record.

In addition, they need to comply with Law No 68 of 20 November 2003, which regulates the rights and obligations of patients in matters concerning information, and informed and free decision-making. Law No 68 sets forth the basic guidelines applicable to medical records.

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

Pursuant to Article 9 of Law No 203, telemedicine can only be offered and used within the geographical zone of the Republic of Panama.

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

Pursuant to Law No 203, it is necessary to obtain the patient's consent to engage in telehealth.

The person responsible for a telehealth or telemedicine activity must obtain the informed consent of the patient, user or their representative, where applicable, and inform him/her of how the care works through the use of ICT, the scope, risks, benefits, responsibilities, management of privacy and confidentiality, management of personal data, contact protocols according to the category of telemedicine that is used, the conditions for the prescription of health technology, the procedures to follow in emergency situations, the procedures to follow due to technological failures, including communication failures, and the risks of breaches of confidentiality during

virtual consultations, among others.

Consent will be recorded in the clinical history of the person, who, with his/her digital, electronic or handwritten signature, as the case may be, will declare that he/she understood the information provided and agreed to be treated in this modality.

Furthermore, Law No 81 of 2019 regulated by Executive Decree No 285 of 2021 ('ED 285' and collectively with Law No 81, the 'Data Protection Regulations'), regulate personal data protection in Panama. The Data Protection Regulations provide that the consent regarding sensitive health personal data must be previous, unequivocal and express.

In addition, Law No 68 sets forth specific provisions applicable to patient's consent, as well as the obligations of healthcare providers and rights of patients, in general.

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

Pursuant to Law No 203, as part of telemedicine services, the authorised physician responsible for the diagnosis, opinion and treatment recommended to the patient may use the following tools, as required by the case:

- Digital System of Medical Prescriptions: consists of a digital platform through which all medical prescriptions that are issued in the framework of care under the telemedicine modality will be issued;
- Digital System of Disability Certificates: consists of a digital platform through which certificates can be issued that the user is incapacitated to carry out his/her usual tasks for a certain period of time; and
- Digital Medical Record System: consists of a digital platform through which certificates can be issued that the user was treated under the telemedicine modality, indicating the place, date and time of care.

The electronic signature used in any of the aforementioned documents will be fully valid when they comply with the requirements established in the regulations that regulate such matters.

#### **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 Data Protection Regulations provide the legal framework applicable to data protection in Panama.

Health professionals must comply with the Data Protection Regulations.

The Data Protection Regulations define 'personal information' as the personal information of an individual that identifies him/her or makes him/her identifiable. It also classifies 'sensitive data' as data that refers to the intimate sphere of its owner, or whose improper use could give rise to discrimination or entail a serious risk for the individual, such as information about their racial or ethnic origin, beliefs or religious, philosophical and moral convictions; union membership; political opinions; data related to health, life, sexual preference or orientation; and genetic data or biometric data, subject to regulation and aimed at identifying a natural person univocally. The requirements to treat sensitive data are more stringent than those for other personal data.

In addition, Law No 68 regulated the rights and obligations of patients in matters concerning information, and informed and free decision-making.

#### **21. Does the applicable regulation provide for criteria and requirements for security**

**systems to protect the patient's information?**

The Data Protection Regulations established the basic technical and organisational measures sufficient to guarantee the confidentiality, integrity, availability and resilience of the processing of personal data systems and services. For that matter, national and international regulations and standards are to be considered as well.

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

Yes, the Data Protection Regulations provide that cross-border transfers are permitted, as long as the data controller or processor ensures compliance with Law No 81's standards or with standards equal to or higher than those set out in the law. Furthermore, ED 285 provides that personal data may be transferred to other countries, as long as one of the following conditions are met: (1) the country or organisation provides an equivalent or higher level of data protection than Law No 81 and ED 285; (2) when the data controller offers and guarantees the adequate compliance with principles, data subjects rights and the data protection regime provided in Law No 81 and ED 285; (3) the data subject's consent is granted; (4) the transfer is necessary for medical prevention or diagnosis, provision of healthcare, medical treatment or management of health services; (5) the transfer is necessary to safeguard public interest, the legal representation of the data subject or justice; (6) the transfer is necessary for the recognition, exercise or defence of a right in a judicial process or in cases of international judicial collaboration; (7) the transfer is necessary for maintenance of and compliance with the data controller and data subject's relationship; (8) the transfer is necessary to complete wire or stock transfers; and (9) the objective of the transfer is international cooperation between intelligence organisations fighting against organised crime, terrorism, money laundering, cybercrimes, child pornography and narcotrafficking.

Furthermore, Law No 81 provides that records of all transfers must be kept, specifically information on the controller; the nature of the data transferred; the legal foundation of its existence; how the data was transferred; information on the importer, and individuals and entities to whom the data may be transferred; security measures, protocols and a technical description of the database; the form and conditions in which people can receive or access the data transferred to them; the procedures to be carried out for rectification; the updating of the data; and the time of conservation of the data and any change to the indicated elements, as well as the identities of all the people who accessed the personal data within 15 days working from the beginning of this activity and the duration for which they had access.

**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?**

Even though there is not an obligation to register databases with the supervisory authority, the controller has the obligation to maintain records of databases transferred to third parties, which must contain the information described in Article 35 of ED 285. Such records must be provided to the supervisory authority or any other competent authority, if required.

**LIABILITIES**

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

Pursuant to Law No 203, Law No 66 and Law No 88, healthcare professionals must obtain the required regulatory licences to practise medicine in their particular field of expertise.

The Panamanian Health Code sets forth the procedure, penalties and sanctions that can be applicable in the event that a violation of the duties set forth therein occurs. The penalties for sanitary infractions (which are of an administrative nature) are independent of those that those constituting a crime and regulated by the Criminal Code (including those covered by Articles 131 et al punishing crimes against human life) or those that could be treated as civil liability and therefore covered by the provisions of the Panamanian Civil Code.

No penalty or sanction may be applied without prior judgment having been established by the existence of the infringement.

Furthermore, Article 381 of the Panamanian Criminal Code provides that 'Whoever exercises a profession for which suitability or special qualification is required, without having obtained it, will be punished with imprisonment from two to five years'.

## **TELEMEDICINE NUMBERS AND TRENDS**

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

There isn't any official public disclosure of information concerning the use and acceptance of telemedicine in Panama. However, different media outlets have published information regarding the implementation of telemedicine by the Ministry of Health and their regional offices, not only for the doctor-patient modality but also for general doctors to specialists, but such information is not official and is very vague.

### **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.**

Given that Law No 203 has not been further regulated and the government has yet to establish the Telemedicine System described in Law No 203 with the collaboration of the Ministry of Health and the Social Security Office, it is not feasible to provide information concerning the perspectives and trends in relation to the matter at this point.