

<b>TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES</b>
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<b>LAWS AND REGULATIONS ON TELEMEDICINE</b>
<b>1. Is telemedicine allowed in your country? If so, how is it defined?</b>
<p>Yes, telemedicine is considered as a service that basic level health establishments and services offer. It is defined by the Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017, as 'the contactless external medical support or assistance, in a direct non-face-to-face manner, between the health professional and the person requesting the service, including inter-consultation between professionals, carried out through any system included in information and communication technology, to provide assistance or support doctor, regardless of the distance that separates those involved in the service.' It also involves medical teaching activities.</p>
<b>2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.</b>
<p>In the Dominican Republic, telemedicine's framework is relatively limited. However, since telemedicine's introduction into medical practice, this framework has been the key piece for the operation of this new medical service.</p> <p>First, there is the Dominican Constitution and binding international treaties, where the citizen's right of health is established and the state's responsibility for propitiate it by any means and circumstances.</p> <p>Based on the above, Article 1 of the General Law of Health, No 42-01, regulates all actions that let the Dominican State make the right of health effective to all the population.</p> <p>Next, follows the Technical Guidelines for the Enabling of Surgical and Clinical Services of 2017. We particularly highlight this regulation because is the only one which recognises and defines what telemedicine is and describes what it entails.</p> <p>The Guidelines of Enabling of Healthcare Establishments and Medical Services No 1,183-03, establishes the rules for healthcare establishments and medical service providers, ensuring that it is compliant, and issues all permits and authorisations for their operations.</p> <p>Other binding laws are the Civil Code, General Law of Telecommunications, No 153-98, and Personal Data Protection Law, No 173-13.</p>
<b>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</b>
<p>The Health and Social Assistance Ministry's responsibilities regarding telemedicine are to:</p> <ul style="list-style-type: none"><li>• guarantee the right of health and access to a high-quality, adequate, and timely healthcare services (General Law of Health, No 42-01);</li><li>• enable all the policies, guidelines, rules, and proceedings in accordance with the law, binding to the Dominican health system and observe its compliance (General Law of Health, No 42-01);</li><li>• enable healthcare providers to operate in the Dominican Republic, and consequently regulate and supervise their activities (Law No 87-07 of 9 May 2001, which created the Dominican System of Social Security, and General Law of Health, No 42-01).</li></ul>
<b>4. Was telemedicine authorized during the Covid-19 pandemic?</b>

<p>Yes, it had already been authorised before the pandemic. As consequence of the Strategy and Course of Action 2012-2017 promoted by the OPS and approved by the Board of Directors in 2011. This introduced the concept of telemedicine into the Dominican Republic and some aspects and requirements in the Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017.</p> <p>By 2020, with Covid-19's arrival, the practice of telemedicine was needed, and necessary and healthcare providers start to apply it.</p>
<p><b>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?</b></p>
<p>We have not identified any changes or the possibility of changes in the regulatory landscape post-pandemic.</p>
<p><b>6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, teliagnosis, telesurgery, among others)</b></p>
<p>According to the Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017, telemedicine involves any external and contactless consultation between a healthcare provider and the person who needs the consultation through Information and Communications Technology (ICT). In that order, and without any specified limitation, telemedicine could entail teleconsultation, second opinions, teliagnosis, telesurgery, among any other health services which can be executed in that way.</p>
<p><b>7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.</b></p>
<p>The Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017 establishes that telemedicine can only be provided by healthcare professionals who comply with what is established in the Guidelines and binding rules. In can be used by doctor-doctor, as expressively authorised in the Guidelines, and by doctor-patient.</p> <p>It can also be used for medical education purposes, but only if it is approved by the medical institution.</p>
<p><b>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.</b></p>
<p>Telemedicine is considered as a service offered by basic level health establishments, and is therefore available in the public health system. However, there is no official information or specific regulation as to whether it is under mandatory insurance coverage.</p>
<p><b>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</b></p>
<p>To date, there is no official information or specific regulation concerning this matter, but it is currently under consultation with the Dominican Republic's Health authorities.</p>
<p><b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b></p>
<p><b>10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)</b></p>
<p>The Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017, does not limited the healthcare professionals able to practice telemedicine.</p>
<p><b>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</b></p>
<p>No. According to the Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017, the only education requirement is to be accredited to practice medicine in the Dominican Republic, by the official permits and/or authorisations.</p>

<b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b>
<p>Yes. It does not apply only to physicians, but to all healthcare providers. Telemedicine services must be enabled by the competent sanitary authority under the conditions of the General Law of Health, No 42-01, the Guidelines of Enabling of Healthcare Establishments and Medical Services No 1,183-03 and the Law of Medications No 246-06.</p> <p>Telemedicine services must also have management agreements with specific local health establishments, so they act as reference institutions for services, diagnosis given in telemedicine consultation, and liability. (<i>Technical Guidelines for the Enabling of Surgical and Clinical Services</i>, 2017, point 8.14.3).</p>
<b>13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
Yes, health care providers must have an Enabled Certificate issued by the competent sanitary authority, and management agreements with specific local health establishments.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>
The Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017, point 8.14.1, indicates that telemedicine services must have the required ICT for requests and offer the assistance.
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>
No. There are no requirements other than those indicated above.
<b>16. Does the legislation provide for specific rules concerning patients' medical records?</b>
<p>According to point 8.14.2 of the Technical Guidelines for the Enabling of Surgical and Clinical Services, 2017, telemedicine services must have a wellbeing management of: informed consent, confidentiality, respect, professional secrecy of patient medical history and other controlled information, in accordance with strict rules.</p> <p>The General Law of Health, No 42-01, Article 28, also indicates that people have the right of respect to their personality, human dignity and intimacy and not be discriminated against by means of ethnicity, age, religion, social condition, politics, sex, legal status, economic situation, physical, intellectual, sensorial or any other limitation.</p> <p>The Personal Data Protection Law, No 173-13, applies to all Dominican territory, and has as purpose the 'wholesome protection of all personal data settles in files, publics registry, data banks or any other technical means of data treatment destined to issue informs, private or public [...]'. This Law this includes patient medical records in any form.</p>
<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>
It is not specified in legislation or guidelines related to this matter.
<b>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</b>
Yes, the healthcare professional needs to obtain patient consent to engage in telemedicine. According to the General Law of Health, No 42-01, Article 28, patients have the right (among others) to:

<ul style="list-style-type: none"> <li>adequate and constant information about processes, including diagnosis, prognostics, and treatment alternatives;</li> <li>decide, have access to previous information and comprehension, accept or reject medical treatment;</li> <li>registry or written reliability of all their processes of health/illness;</li> <li>not to be subjected to medical or surgical treatment which involves significant risk to their physical integrity, health, and life, without written consent or their guardian's written consent, (in cases of incapacity of expressing written consent) always to their benefit.</li> </ul>
This disposition is applicable to all medical services.
<b>19. Is there any other important requirement that should be highlighted?</b>
To date, no, it is not.
<b>DATA PRIVACY ASPECTS</b>
<b>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.</b>
<p>Yes, managing personal data of others is a very sensitive responsibility, and it should be considered alongside all issues involved, especially when referring to health data.</p> <p>In the Dominican Republic, the Personal Data Protection Law, No 173-13 applies to personal data protection in all circumstances, but the scope of this law does not reach many technical aspects of personal data versus ICT, which has a direct impact on the telemedicine market.</p>
<b>21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?</b>
<p>The Personal Data Protection Law, No 173-13, is based on many principles, among them, security, which states that technical, organisational and security measures must be adopted to protect personal data and avoid its alteration, lost or non-authorized consultation or access (Personal Data Protection Law, No 173-13, Art 5, point 5).</p> <p>The General Law of Telecommunications, No 153-98, Article 5 indicates that communications and all data issued through ICT services is private and inviolable with the exceptions established by law.</p>
<b>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</b>
Yes, it does.
<b>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?</b>
<p>Yes. According to Article 42 of the Personal Data Protection Law, No 173-13, any file, registry, database or data bank, private or public must have adequate data policies that grant the security and control measures, to avoid the improper management of personal data.</p> <p>Regarding the second question, Article 76 of the law in reference, establishes that only written and the express consent of the data owner enable access to their personal data treatment revealing political opinion, religious, philosophical and union convictions, health and sex life information.</p>
<b>LIABILITIES</b>
<b>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</b>
The General Law of Health, No 42-01 establishes in Article 164 that 'the professional or any other person authorised to practice medical actions will be responsible ethically, penally and

civily in cases involving proceedings compliance, technical rules and any other means according to ethical, diligence and prudence, [...]. As long as there is no approved guidelines that establishes medical practice in all its levels, occupations in health science and health actions, the established obligation in this article will be ruled by the common law.'

In that order, Article 1,382 of the Dominican Civil Code states that any harm caused by a person's action, enforces the responsibility to put it right. Inevitably, this applies to healthcare professionals and medical institutions which, through their practice, can cause harm to others, engaging their liability.

According to the doctrine, medical practice is considered as a risky activity capable of generating liability, and with the introduction of telemedicine into the equation, brings many challenges. When we talk about a service given through ICT which is not always optimal, s a situation arises as to whether responsibility lies with the healthcare professional practice or the ICT services providers.

The Dominican legal frame of civil liability is limited, being essentially based on the principle of harm established in the Civil Code, and as explained above, telemedicine is also lightly regulated in the Dominican Republic. However, based on the above, we can specify that medical practice by a healthcare professional or institution involved in healthcare, in person or through telemedicine (which is the market interest), will engage medical liability of the professionals or entities related, according to the bidding laws.

#### **TELEMEDICINE NUMBERS AND TRENDS**

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

To date, there is no official information or specific regulation concerning this matter.

##### **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.**

We have not been able to identify the perspective and trends relating to this matter in the near future.