

<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>
Yes, telemedicine is allowed in Uruguay. Uruguayan laws lay down the general guidelines and framework for its implementation and development. Telemedicine is defined as the provision of healthcare services to improve their efficiency and quality and increase medical services across the whole country by using information and communication technologies.
<b>2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.</b>
<p>A specific telemedicine legal framework was established by Act No 19,869 of 2 April 2020 (the Telemedicine Act). The Act mandates the Executive Branch to implement its provisions. However, the Executive Branch is still working on implementing such regulations (the Decree).</p> <p>In the absence of a more detailed regulation, the general regulatory regime of medical practice is fully applicable for telemedicine practice:</p> <ol style="list-style-type: none"><li>1. Act No. 18,211 of 5 December 2007 and its Regulatory Decree No 2/008 of 8 January 2008, which created the National Integrated Health System.</li><li>2. Act No 18,335 of 15 August 2008 and its Regulatory Decree No 274/010 of 8 September 2010, which approved the rights and obligations of users of the health system.</li><li>3. Act No 19,286 of 25 September 2014, which approved the Code of Medical Ethics.</li></ol> <p>There are also certain regulations which, although they do not strictly refer to telemedicine, are applicable to telemedicine services. These are (1) Law No 18,331 of 11 August 2008, which governs the protection of personal data; and (2) Article 194 of Law No 19,670 of 15 October 2018 and Regulatory Decree No 122/019 of May 2019, which refer to the national electronic medical record.</p>
<b>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</b>
To date, there is no special licence required for telemedicine services. The Uruguayan Ministry of Public Health (MoH) is the highest sanitary authority and the responsible for regulating health-related services. All health institutions must gain the approval for their health services from the MoH.
<b>4. Was telemedicine authorized during the Covid-19 pandemic?</b>
Yes. During the Covid-19 pandemic telemedicine was specifically authorised by the Telemedicine Act (2 April 2020), mentioned above.
<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>
Yes. Post-pandemic, it is expected that the Decree will be issued to implement the Telemedicine Act, and therefore more precise rules will govern telemedicine services in Uruguay.
<b>6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)</b>

<p>The Telemedicine Act specifies that the authorisation of teleservices is under the regulation of the Executive Branch. That said, in the pandemic, health institutions used teleconsultation to avoid the massive in-person attendance at hospitals. Also, private health institutions are working with foreign institutions in second opinion services.</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>Anyone who has expressly consented to telemedicine consultation can benefit from telemedicine services, as long as the responsible physician does not refuse to provide telemedicine and expressly indicates that the in-person medical consultation is still required. The Telemedicine Act is meant to give the physician the authority/liberty to decide on the best consultation method. Both doctor-doctor and patient-doctor telemedicine services are permitted.</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>Yes. Telemedicine services are reimbursed through the public reimbursement system. Uruguay has an integrated health system (with public and private institutions) where there is a National Health Fund administered by the Social Security Office, financed with tripartite contributions from the government, employers and workers.</p> <p>The National Health Fund pays each medical institution (integrating the system) a capita per user (ie, a certain 'subsidy' or 'aid' calculated per user), which will vary depending on the characteristics of each user (eg, gender, age, etc).</p> <p>Telemedicine services are included in the capitas paid by the Social Security Office to each health institution.</p>
<p><b>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</b></p>
<p>To date, there are no insurance requirements applicable to telemedicine service providers.</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 Telemedicine Act does not specifically contemplate its application to other healthcare licensed professionals, such as nurses, dentists, physiotherapists, psychologists, pharmacists and nutritionists.</p> <p>The possibility of having such healthcare professionals rendering telemedicine services is not particularly addressed in the Telemedicine Act. In principle, it would be reasonable to infer that any healthcare professional can provide telemedicine services without an additional licence.</p> <p>It is expected that the Decree will impose the obligation on health institutions of training their healthcare employees (medical and non-medical employees) in providing services through 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. There are no further education or training requirements for physicians to provide telemedicine services.</p>
<p><b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b></p>

No. Any physician facing a medical need or inquiry can render their services via telemedicine without the need for any other procedure. Telemedicine is considered as another form of health service provision.
<b>13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
No. To date, there are no special licences or authorisations required by institutional healthcare providers to render telemedicine services. It is expected that the Decree will address this matter. More specifically, it is anticipated that the Decree will dictate to healthcare institutions the obligation of informing the Ministry of Public Health every time such institutions render healthcare services through telemedicine.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>
No. There are no specific requirements regarding telemedicine platforms.
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>
No. There are no legal requirements regarding electronic equipment and internet speed for telemedicine services.
<b>16. Does the legislation provide for specific rules concerning patients' medical records?</b>
Yes. There are specific rules regarding patients' medical records that are fully applicable to the provision of telemedicine services. Such rules (contemplated for in-person services) provide that every medical act (even if performed remotely), must be included in the patient's medical records. We believe that such a provision also applies to telemedicine services.
<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>
No, there are no specific geographic location requirements applicable to the provision of telemedicine services.
<b>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</b>
Yes. Telemedicine services require the patient's (or the patient's legal representative) freely informed consent with respect to the provision of telemedicine services.
<b>19. Is there any other important requirement that should be highlighted?</b>
We have not identified any other relevant issues which are necessary to highlight.
<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>
Yes. Certain data privacy issues which should be considered at the time of rendering telemedicine. In Uruguay, processing of personal data (including health data) is regulated by Act No 18,331 (Data Protection Act), which establishes the general rules that govern data protections. We believe that this body of law is fully applicable to telemedicine services.  Health data is deemed sensitive information by the Data Protection Act, and consequently merits a special protection. More specifically, health data can only be collected with the prior written consent of the patient. The processor of such information is subject to higher levels of security in accordance with the standards established by the Data Protection Office.
<b>21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?</b>

<p>No, there are no specific criteria/requirements for the security systems to be adopted to protect patient information. It is expected that the Decree will address this issue.</p> <p>That said, it is generally accepted that, when dealing with patient personal data, healthcare institutions must adopt the following security measures:</p> <ol style="list-style-type: none"> <li>1. special procedures to obtain access to such information (including special access-codes);</li> <li>2. mechanisms for authentication; and</li> <li>3. mechanisms to secure the privacy and integrity of patient health data information, so that such information cannot be manipulated by third parties.</li> </ol>
<p><b>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</b></p>
<p>Yes. Cross-border transfer of personal data is subject to special requirements, which must be also met where telemedicine services are given.</p> <p>The Data Protection Act states that transfer of personal data is forbidden for those countries that do not have adequate levels of compliance of personal data international standards. This ban does not apply where, in the course of medical treatment, the cross-border transfer of medical data is dictated for medical reasons.</p>
<p><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>
<p>Yes. The registration of databases under the Regulatory with Control Agency of Personal Data (<i>Unidad Reguladora y de Control de Datos Personales</i>) is mandatory.</p> <p>As medical services through telemedicine are considered medical acts, physicians are required to include the information collected on a patient's medical records. There are no special requirements on how physicians must record the patient data, so the general rules for in-person medical attention are fully applicable.</p>
<p><b>LIABILITIES</b></p>
<p><b>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</b></p>
<p>The patient is entitled to compensation for the damage they may have suffered in the course of telemedicine services received.</p> <p>In the case of healthcare professionals and institutions, telemedicine is subject to the same liability regime applicable to in-person medical services. There is no special liability regime for telemedicine practices.</p> <p>That said, under Uruguayan law, physicians are not bound to achieve a certain result but to honour the best practices and standard of care of their profession. Where the physician's adequate care is evidenced, no liability should arise. Consequently, where the physician consults about a patient's diagnosis with another specialist or asks for a second opinion with a specialist abroad, that should certainly mitigate (if not exclude) their professional liability.</p>
<p><b>TELEMEDICINE NUMBERS AND TRENDS</b></p>
<p><b>25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?</b></p>
<p>The Ministry of Public Health has not published any report about the experience of telemedicine during the Covid-19 pandemic. That said, today tele-consultation services are a standard practice in healthcare institutions and have received considerable acceptance from patients.</p>

**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.**

As mentioned, the Executive Branch is still working on the Decree, which is scheduled to set down the basis for future telemedicine practice.

The Decree is part of the Uruguayan government's digital health politics, which among others, has promoted instruments such as the electronic health records and the electronic prescriptions.