



**TELEMEDICINE
ANALYSIS OF THE NEW ACT 19.869 AND
CHALLENGES RELATED TO THE COVID-19 PANDEMIC**

CONTEXT

- Telemedicine as the use of technology in the provision of health services, precedes the new regulations on the subject.
- For several months, the possibility of issuing a regulation providing a specific framework to telemedicine has been evaluated.
- The situation triggered as a result of the Covid-19 Coronavirus pandemic, has determined that the Authorities trying to avoid face to face meetings between patients and medical personnel.
- With telemedicine, the aim is to improve demand management, reduce attendance at medical institutions, avoid unnecessary commuting and, mainly, keep a direct contact with the patient, always guaranteeing the confidentiality of the information.

TELEMEDICINE IN THE WORLD

- Although it is an increasingly used tool in the world, many countries currently lack of a specific legal regulation that provides a framework of certainty for users and providers of health services.
- As an example, in the region, Argentina has some recommendations issued by the Ministry of Health and Brazil has a resolution issued by the Federal Council of Medicine.
- The European Union, on the other hand, has a regulation that includes aspects such as the license or authorization of professionals, the confidentiality of information and informed consent.
- In the United States, each state has its own regulations for the practice of medicine, which entails some difficulties to practice this profession through this resource.

NEW ACT ON TELEMEDICINE

- Act 19.869 (“Act”) aims at the implementation and development of telemedicine as a provision of health services, in order to improve its efficiency, quality and increase its coverage, through the use of information and communication technologies.
- The Act makes clear that telemedicine is a form of health service provision.
- It is defined as the provision of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment and prevention of diseases and injuries, research and evaluation of health care providers, all in the interest of improving the health of their individuals and their communities.
- The telemedicine Act was enacted and entered into force on April 2, 2020.

COMPLEMENTARITY AS A PRINCIPLE

- The clinical practice of medicine requires a direct contact with the patient.
- Telemedicine is a complement to the assistance provided by the physician.
- These principles are set forth in section 24 of Act 19.826 and provide grounds for telemedicine manifestations that preexisted the referred Act.
- Telemedicine services must be provided and exercised in compliance with the Code of Medical Ethics.

OTHER GUIDING PRINCIPLES OF THE ACT

- **Universality:** better access for the entire population to health services is guaranteed.
- **Equity:** services are closer to the population in remote places and with scarce resources.
- **Quality of services:** an improvement in the quality and comprehensive care of the patient is promoted, strengthening the capacities of health personnel.
- **Efficiency:** it allows optimizing healthcare resources, improving demand management, reducing hospital stays, reducing the repetition of medical acts and commuting through the communication of professionals.
- **Decentralization:** it is a strategy of use of health resources that optimizes the attention in health services, strengthening the decentralization process Integrated National Health System.
- **Confidentiality:** confidentiality must be preserved in the doctor-patient relationship, guaranteeing security in the exchange of information between professionals or healthcare centers.

TELEMEDICINE SERVICES

- Telemedicine services are considered all those recognized as such by the Ministry of Public Health (“MSP”)
- Those that are recognized in the future and those that are already recognized are included.
- The Act interprets Act 18.335, on patients and users of health services, to include medical benefits carried out by telemedicine.
- The Act empowers MSP so that within 90 days from the date of enactment of the Act, it dictates the protocols of action. By using the term “empowers” this implies that the MSP can, on the one hand, understand that there are services that do not require protocols to operate, and, on the other, the health providers should not wait for these protocols to render services of telemedicine, having to adjust to them in case they are later issued by the MPS.
- It is to be expected, however, that due to the health emergency situation, the regulation by the MSP will be issue shortly.

TELEMEDICINE PROVIDERS

- Telemedicine services can be offered by all the health services that are included in section 3, Act No. 18.335, that are those organizations *“with natural or legal persons as members, such as institutions, entities, companies, public or private agencies - of particular or collective nature - or of a mixed nature, that provide benefits related to health”* .
- In order to offer Telemedicine services, the provider must give detailed information to their users in this regard, and, also, must have the special human resources require in this kind of services and the necessary infrastructure .

PATIENT CONSENT

- Section 7, states that, in order to provide telemedicine services, it is necessary to have the patient express consent (section 11 of Act 18,335).
- The said consent can be revoked by the patient at any time, but it will only take effect as long as the patient communicates his will correctly to the health service.
- There are no formalities to communicate the consent, but it must exist.
- The referred section, also classifies the activities carried out in Telemedicine services as "medical acts", which entails an important definition.

PATIENT'S RIGHTS AND DUTIES

- All patient's rights and duties are applied by the new legislation.
- Just as an example, there are included: the right to receive an equal treatment without any type of discrimination; the right to access to an integral health attention that includes the promotion, protection, recovery, rehabilitation, and palliative care; the right to be treated by professionals trained and empowered by competent authorities; the right to have access to quality medicines, authorized by the MSP; the right to have access to the results of any analysis whenever is requested by the patient; the right to refuse to receive medical attention and to be informed of the consequences; the right to have a respectful and dignified treatment; and the right to be informed of everything related to the patient disease.

PATIENTS AND USERS DUTY TO TAKE PERSONAL CARE OF THEIR HELTH

- Health users and patients must take care of their personal health and ask for guidance in case of illness. Also, they must respect and comply with all medical instructions in order to prevent any danger to others. Patients and users must give secure, accurate and certain information of their disease process and adopted habits to all the medical team; and be responsible for following the indicated treatment, among others.

DATA PRIVACY PROTECTION

- The Act takes seriously on personal data protection of the patient and user that might use this modality of Telemedicine.
- For that reason, the personal data of patients and users is considered as "sensitive data" and, therefore, especially protected under section 18 of Act No. 18,331 (Data Privacy Act)

OTHER OBLIGATIONS

- Every health service (defined by section 3 of Act 18.335) that provides this telemedicine services must give detailed information of its scope and have the appropriate technology to guarantee it (section 6)
- There must be a correct shielding of the software elements that are used in the implementation of this modality and the handling of data, in such a way that unauthorized person cannot have access to sensitive patient data (section 8)
- These are obligations for doctors and officials of health providers. Failure to comply may result in eventual administrative sanctions, as well as potential claims derived from the violation of these provisions.

INCIDENCE OF NON-MEDICAL PERSONNEL

- Non- medical personnel responsible for carrying out search tasks, data transmission may intervene in the telemedicine healthcare process, in order to control that the information is reliable, technical support, etc.
- These officials must have training and competence that ensures the proper use of telemedicine.

TELEMEDICINE PRACTICE BY FOREIGN PROFESSIONALS

- Before the medical appointment, the professional must prove to the user's health service, that he is duly registered and authorized to practice his or her profession in his or her country of residence.
- Naturally, professionals who are registered and authorized to practice the profession in Uruguay are excepted.

IMPORTANT ASPECTS OF TELEMEDICINE IN RELATION TO THE PANDEMIC

- Telemedicine is a way of health service.
- It is a health service used in addition to the assistance provided by the treating doctor, that was used and legal already before the Act, and with it, now it has a specific and proper regulation.
- Telemedicine services has been/will be considered and recognized by the MSP, before or after the Act.
- The Act empowers the MSP to issue action protocols. Anyway, there may be some telemedicine services that do not require protocols to operate. Therefore, health providers must not wait for these protocols to provide telemedicine services, and must only comply with any eventual protocols in case they are later issued by the MSP.
- There are no formalities regarding the way in which the consent of the patient treated by telemedicine must be obtained. Although, it must exist.
- Personal data that is shared in telemedicine is confidential and special protected by the Act.

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