LIFE SCIENCES & HEALTHCARE

CLIENT ALERT

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RESOLUTION NO. 2.227/18, ENACTED BY THE FEDERAL BOARD OF MEDICINE (CFM) REGULATES TELEMEDICINE IN BRAZIL

The Federal Board of Medicine (CFM) Resolution No. 2.227/18, published today, regulates in further detail long-distance medical consultations and procedures through technological means.

The new Resolution drastically changes CFM's views on the matter. CFM's Resolution No. 1,643/2002 (now revoked) was quite laconic, and the interpretation adopted so far has been predominantly conservative, in that telemedicine was deemed legal only as second medical opinion and provided that the patient was accompanied by a local doctor when enjoying telemedicine services, among other few exceptions.

Telemedicine — now authorized more broadly and defined as the "practice of medicine, mediated by technology, for the purposes of assistance, education, research, prevention of illnesses and injuries, and the promotion of health" — can encompass, among others, the following activities:

- **Teleconsultation —** although defined as a *"remote medical consultation, mediated by technologies, with physician and patient located in different geographical locations*", teleconsultations demand, as a rule, the prior establishment of a presential relationship between physician and patient. Moreover, in long-term treatments, presential appointments are recommended to take place at least every 120 days. Physicians must keep certain records of such sessions, as well as of the patient's case, and prepare a report containing *"all the relevant clinical data*" — a copy of which shall be forwarded to the patient;

- **Telediagnosis —** is defined as the *"medical act performed at distance, geographical or temporal, with the transmission of graphics, images and data for the emission of a medical opinion or report, by a physician with a Register of Qualified Specialist in the medical expertise connected to such proceeding*". The diagnosis will obey, as a rule, scientific guidelines established by the expert association connected to such method — which must be forwarded to the Federal Board of Medicine for examination and approval.

PRACTICE AREA
Life Sciences & Healthcare

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For further information, please send a message to **news@veirano.com.br**

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- **Telesurgery —** is the "execution of a remote surgical procedure, mediated by safe invasive technologies, with robotic equipment and executing physician in different physical spaces." Telesurgeries may only be carried out with "adequate and safe infrastructure, with guarantees of proper technical functioning, efficient and redundant bandwidth, stable energy supply and efficient protection against virus or hacker breaches" — and demand, at least, a physician to remotely operate the robotic equipment in addition to a local physician with proper expertise to locally take over, if necessary, the surgical procedure.

In the exercise of such activities, the following guidelines and restrictions shall be observed:

- **Confidentiality and preservation of information —** the Resolution requires that the rules set forth by the Federal Board of Medicine on *"preservation, manipulation, integrity, truthfulness, confidentiality, privacy and guarantee of professional secrecy of data*" be observed. All data exchanged by images, text and/or audio (I.) between physicians, (II.) between a physician and a patient, and/or (III.) between a physician and a healthcare professional shall be preserved by the physician responsible for treating the patient. In addition to these standards, the Brazilian General Data Protection Statute (Federal Law n. 13.709/2018) — although not directly mentioned by the Resolution —, will also regulate the use and preservation of such information. Under the Brazilian Data Protection Law, personal information connected to "*health, genetic or biometric*" data is considered "*sensitive personal data*" — and, thus, accorded a higher degree of protection.

- **Geographical limitations —** only legal entities with *"head offices in Brazil and registered before the Regional Boards of Medicine*", with a registered responsible physician, shall be allowed to practice telemedicine in the Brazilian territory. Their branch offices must also be duly registered at the appropriate Regional Boards of Medicine.

The enactment of the new Resolution is based on the potential of telemedicine for providing specialized medical treatment to patients who live on distant locations. It also aims at solving the problem of great demand for health services in Brazil — which is compounded by the migration of patients in search of treatment. In addition to direct benefits to patients who will enjoy long-distance medical services, the new regulation also opens up a new market for providers of IT and telecommunications services and solutions.

The new Resolution shall become effective within 90 (ninety) days of its publication.

We are at your attention if you have any questions or need additional information.

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