

## Telemedicine, legal certainty, and COVID-19: where are we?

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In Brazil, telemedicine activities were exceptionally authorized due to the recent coronavirus disease 2019 (COVID-19), being valid only while the pandemic lasts.(1) The necessary regulation of telemedicine is still being discussed and was subjected to a presidential veto, on the grounds that the regulation of medical activities by means of telemedicine after the end of the current pandemic is a matter that should be regulated by law.(2)

Telemedicine has been a successful tool and was the major international technological innovation implemented during the pandemic(3); however, legal uncertainty on the topic is still common among health care professionals and institutions.(4)

COVID-19 spread across all continents in weeks, overcoming the ability of health care systems to test individuals, as well as to track and contain the disease. (5) Telemedicine activities prevent close contact, decreasing the chance of infection with the COVID-19 virus, accelerate the dissemination of accurate information by making teaching platforms available, and promote access to the opinions of experts in remote locations.(3)

Various countries severely affected by the pandemic have developed and implemented telemedicine platforms. The government of the Chinese province of Shandong, one of the most affected regions, established a comprehensive telemedicine program in March of 2020. The program has provided guidance on prevention and treatment directly to the patients, training for health care professionals, and remote consultation with specialists for medical staff in different locations. This platform has been a great success and a model for other Chinese cities. (6)

Italy, however, encountered various barriers to telemedicine amidst a large number of critical patients and low availability of ICU beds. The limited availability of large-scale telemedicine solutions, the heterogeneity of the tools available, the poor interconnection among telemedicine services operating in different locations, the lack of a multidisciplinary approach to the management of patients, and the absence of clear legal guidelines were factors that limited the wide use of telemedicine. (7)

Telemedicine is not a novelty in the world. The World Medical Association statement, also known as the Tel Aviv Statement, one of the most important telemedicine documents worldwide, was created in 1999. (8) This phenomenon soon arrived in Brazil. In 2002, the Brazilian Conselho Federal de Medicina (CFM, Federal Council of Medicine)(9) formulated a resolution that defined what telemedicine service is, established the minimal infrastructure required, and addressed medical responsibilities and the registration of telemedicine service providers.

This resolution remained dormant for 15 long years, but made sure that "telemedicine, even in a timid way, already existed and worked."(10) Incredibly, CFM new attempt to regulate the topic resulted in the alleged ban on telemedicine nationally. Between the end of 2018 and the beginning of 2019, CFM prepared Resolution no. 2,227,(11) which introduced several innovations applicable to telemedicine and finally provided a robust legal framework for the provision of telemedicine services in Brazil. According to the resolution, these would be the modalities of telemedicine: teleconsultation, teleinterconsultation, telediagnosis, telesurgery, telescreening, telemonitoring (or telesurveillance), teleorientation, and teleconsulting. The legal wording reinforced that each of the eight different modalities of telemedicine would deserve a different approach instead of establishing general rules for telemedicine as a whole. It is important to note that this resolution formally revoked the previous CFM resolution of 2002, and it would only come into force 90 days after its publication.

Resolution no. 2,227(11) had a very short life because it was revoked even before it came into force. Because of the immediate reaction of the medical community, CFM rushed to publish Resolution no. 2,228,(12) which completely revoked Resolution no. 2,227,(11) but expressly reestablished Resolution no. 1,643.(9) Therefore, an unusual legal confusion was created. If Resolution no. 2,228(12) had only revoked Resolution no. 2,227,(11) with nothing else to add, the understanding would be that telemedicine was no longer authorized in Brazil. However, by expressly reestablishing the validity of the 2002 Resolution(9) on telemedicine, Resolution no. 2,228(12) did not effectively prohibit the practice of telemedicine in Brazil.

This resulted in a legal imbroglio. Technically, Resolution no. 1,643<sup>(9)</sup> remains in effect today. This fact still generates doubts and uncertainties in the medical community and in the media; however, it is understood that CFM regulations have never prohibited telemedicine in Brazil. This position is clear considering that the law of telemedicine and the subsequent Brazilian Ministry of Health Ordinance no. 467(13) made it clear that telemedicine would be authorized in Brazil. However, the Code of Medical Ethics, (14) published in 2019, maintains the prohibition of prescribing treatment and procedures without the direct examination of the patient or by any other means of communication or mass media. Therefore, even the greatest enthusiast of telemedicine would be reluctant to rely on the outdated and incomplete Resolution no. 1,643.<sup>(9)</sup>

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It is evident that telemedicine needs to be properly regulated in order to become available after the end of the COVID-19 pandemic. To this end, all interested parties in its approval should be convened to create an adequate legal framework for telemedicine activities.

Given the very favorable results of telemedicine obtained in a very short time in Brazil and worldwide, it is natural to expect that there will be no setbacks, such as the prohibition of telemedicine services in Brazil. Telemedicine has become a critical component during the pandemic and improved the efficacy of health care services, multiplying the capacity of the health

care system to cope with COVID-19. We believe that telemedicine plays a fundamental role in defeating the pandemic and should not be considered just an option or a complement to react against a crisis. Therefore, the dissemination of telemedicine is a path of no return. The regulation of telemedicine will be remembered as a historic landmark for the Brazilian Unified Health Care System in the future.

## **AUTHOR CONTRIBUTIONS**

MVFG and MAFG were responsible for preparing the text, revising the references, and writing the final text.

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