

Legal status of ozone therapy in Brazil - Update

Roberto Quintero, Legal Advisor of AEPROMO, IMEOF and ISCO3

Regulatory characteristics of ozone therapy in Brazil

- It is the country with the most current regulations on ozone therapy and which are specifically directed at different health professionals. Brazil has authorized and regulated the practice of ozone therapy in the following professions: Dentistry (2015); human medicine (2018) but only in the public sector; physiotherapy (2018); pharmacy (2020); nursing (2020); veterinary (2020); and biomedicine (2020).
- It is one of the few countries in the world where the federal councils of the different health professions, such as physicians, dentists, veterinarians, nurses, pharmacists, etc., have the very important and key power to authorize the practice of different therapies and to regulate them. In the vast majority of countries, government authorities are responsible for authorizing and regulating the practice of therapies. In Brazil this power has been delegated to the federal councils. In addition, these as in many professional associations in other countries, have the power to sanction professionals for violations of their deontological codes.
- Brazil has two regulations on ozone therapy in human medicine, fully in force and legal, which are absolutely contradictory to each other.

Given the very important Brazilian normative acquis on ozone therapy, it is convenient to analyze the health professions individually.

Regulation of ozone therapy in dentistry (2015)

In 2015, the Federal Council of Dentistry (CFO) recognized and regulated the use for dental practice of ozone therapy by Resolution 166 of November 24, 2015. ¹

On the basis of this resolution, the Annex to Resolution CFO-166/2015 was approved. It points out that ozone "is a potent antimicrobial and its action occurs through several biochemical pathways and chains with important action on bacteria, viruses and fungi." It specifies the application areas of ozone therapy in dentistry (article 2).

Regulation of ozone therapy in physiotherapy (2018)

Based on Ordinance [portaria] 971 of 2006, the Federal Council of Physiotherapy and Occupational Therapy (COFFITO) authorized "the practice by the Physiotherapist of complementary acts to his regulated professional practice, in the terms of this resolution and of Ordinance No. 971/2006" (article 1). ²

¹ Resolução No 166, 24 novembro 2015. Reconhece e regulamenta o uso pelo cirurgião-dentista da prática da Ozonioterapia. Diário Oficial da União - Seção 1, Nº 234, terça-feira, 8 de dezembro de 2015, p. 95. ISSN 1677-7042 95

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=95&data=08/12/2015>

² Consejo Federal de Fisioterapia y Terapia Ocupacional (COFFITO), Resolución 380/2010, 3 de noviembre de 2010. <https://www.coffito.gov.br/nsite/?p=1437>

However, it would be necessary to wait until 2018 for the physiotherapist to be able to practice ozone therapy, because it was only this year that it was incorporated into the Unified Health Service. For this, the second paragraph of resolution 380/2010 of the COFFITO is interpreted, which states that the "the Physiotherapist will also be considered authorized to practice all complementary acts that are related to the health of the human being and that may be regulated by the Ministry of Health through a specific ordinance."

Regulation of ozone therapy in human medicine but only in the public sector. In the private sector not yet authorized (2018)

Currently ozone therapy is from the legal point of view in a totally contradictory and complex situation that could be synthesized in which a step forward has been taken with the recognition of ozone therapy in the public health service; and a step back has been taken with the prohibition of the practice of ozone therapy in the private health sector.

Ozone therapy authorized in the public medical health service (March 21, 2018)

The Ministry of Health of Brazil integrated the practice of ozone therapy into the public health service on March 21, 2018. ³ The Ministry affirms that "ozone therapy is an inexpensive complementary and integrative practice"; notes that the therapy has a "proven and recognized safety". It adds that "the therapeutic potential of ozone" has gained much attention administered with "precise therapeutic doses." It indicates that this therapy "contributes to the improvement of various diseases, since it can help to recover naturally the functional capacity of the human and animal organism."

Ozone therapy unauthorized in the private medical health service (April 20, 2018)

The Federal Council of Medicine (CFM) is an organization with constitutional powers of inspection and standardization of medical practice, to have and keep the professional registration of physicians and to apply sanctions to them prescribed in the Code of Medical Ethics. ⁴

One day before a month had passed since the approval of ozone therapy in the public sphere, the CFM decided (April 20, 2018) that ozone therapy is "a procedure that can be performed only experimentally. This implies that medical treatments based on this approach must be carried out only within the scope of studies that meet criteria defined by the National Commission of Ethics in Research (Conep)." In other words, if it is not used as an experimental procedure, its practice is prohibited. ⁵

³ Portaria nº 702, de 21 de março de 2018. Diário Oficial da União - seção 1, ISSN 1677-7042, Nº 56, quinta-feira, 22 de março de 2018, pages 74-75.

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=22/03/2018&jornal=515&pagina=74&totalArquivos=190>

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=22/03/2018&jornal=515&pagina=75&totalArquivos=190> Pág. consultada September 7, 2018.

⁴ http://portal.cfm.org.br/index.php?option=com_content&view=article&id=20671&Itemid=23

consultada 23 julio 2018

As a consequence of this resolution, the physician can only use ozone therapy on an "experimental" basis. Failure to comply will lead to investigations and ethical-professional procedures against the offenders.

Two opposing regulations in the area of human medicine

Currently in Brazil are two regulations that are openly contrary to each other. On the one hand, in accordance with the ordinance No. 702 of March 21, 2018 of the Ministry of Health, ⁶ozone therapy can be used in the public health sector of the country and consequently, those who practice it may rely on this ordinance. And on the other hand the Federal Council of Medicine has regulated that its practice is prohibited, unless it is used as "experimental"; and that the physician could face being sanctioned in accordance with the Code of Ethics.

Which of the two provisions have the highest legal hierarchy and which one prevails over the other? Ordinance No. 702 of March 21, 2018 from the government or Resolution CFM No. 2.181 / 2018?

The two regulations (that of the Ministry of Health and that of the CFM) have legal basis and will be in force as long as they are not repealed, modified or declared unconstitutional by a competent court.

At present, the daily contradiction that the physician may be faced with is the following: The physician who works, for example, part time in the mornings in the public health service, can use ozone therapy protected by ordinance No. 702 of March 21, 2018 of the Ministry of Health. That same physician in his private practice, in the afternoon, could no longer use it due to CFM Resolution No.2.181 / 2018 of the Federal Council of Medicine (CFM).

A more detailed analysis of the Brazilian situation can be found in the document Preliminary Legal Assessment - Legal Situation of Ozone Therapy in Brazil. ⁷

Regulation of ozone therapy in pharmacy (January 30, 2020)

The Federal Council of Pharmacy (CFF) in 2020 said that “medicinal oxygen and ozone act mainly by pharmacological, immunological or metabolic means, have properties to prevent, treat and alleviate illnesses or diseases and are used in inhalation/nebulization therapies;” it recognizes “ozone therapy services as a complementary and integrative practice as a pharmacist's attribution” (art.1). ⁸

The “pharmacist's duties in the practice of ozone therapy” are detailed in art. 4.

⁶ Portaria nº 702, de 21 de março de 2018. http://portal.impresanacional.gov.br/web/guest/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/7526450/do1-2018-03-22-portaria-n-702-de-21-de-marco-de-2018-7526446 Pág. Consultada 18 julio 2018.

⁷ Roberto Quintero et al., Evaluación Jurídica Preliminar - Situación Legal de la Ozonoterapia en Brasil. Imeof, 2018. https://aepromo.org/pdf/legal_ozono_Brasil_ago18.pdf

⁸ Consejo Federal de Farmacia (CFF), Resolución 685, 30 enero 2020 <https://www.in.gov.br/web/dou/-/resolucao-n-685-de-30-de-janeiro-de-2020-255613547>

Regulation of ozone therapy in nursing (February 20, 2020)

The Federal Nursing Council (COFEN) in 2020 “approves and grants normative force to Opinion No. 56/2019”, on “Regulation. Ozone therapy as a nursing practice in Brazil.”⁹

It points out that "the nurse, duly trained, can prescribe Ozone Therapy, as a complementary therapy, following national and international protocols, in accordance with the Nursing diagnoses and the corresponding application routes."

It specifies that the "Madrid Declaration on Ozone Therapy" (2010), be adopted "as the main guiding instrument for the prescription of Ozone Therapy by nurses." It should be remembered that said Declaration was approved on its 1st. edition in 2010. Since then, it has had two updated editions (2015 and 2020). ISCO3 (International Scientific Committee of Ozone Therapy), in charge of updating the declaration, is doing so every five years, precisely so that the declaration is a living and up-to-date reference instrument for ozone therapists around the world.¹⁰

Regulation of ozone therapy in biomedicine (June 16, 2020)

The Federal Council of Biomedicine (CFBM) decided in 2020 "the recognition of the biomedical professional in the practice of ozone therapy."¹¹

Decided “that the biomedical doctor can practice ozone therapy as a complementary Integrative practice of their professional activity.”

Regulation of ozone therapy in veterinary medicine (October 22, 2020)

The Federal Council of Veterinary Medicine in 2020 defined the guidelines for ozone therapy in animals, stating that “Ozone therapy in animals, including the indication, prescription and application, is a clinical activity exclusive to the veterinary”.¹²

“The veterinarian must” be expressly authorized by the owner, guardian or guardian of the animal “through informed consent.

Common points of ozone therapy regulations

- Most regulations indicate that professionals who wish to practice ozone therapy must previously take ozone therapy courses, the intensity of which varies in each regulation.
- The regulations specify that the ozone therapy equipment used must be duly authorized by ANVISA (National Health Surveillance Agency).

Bill on ozone therapy (2017)

The then senator Valdir Raupp de Matos of the MDB (Brazilian Democratic Movement) presented in 2017 the Federal Law Project 227/2017 by which the prescription of Ozone

⁹ Consejo Federal de Enfermería (COFEN), Opinión Normativa N° 001/2020/COFEN [20 febrero 2020] http://www.cofen.gov.br/parecer-normativo-no-001-2020_77357.html

¹⁰ <https://isco3.org/madrid-declaration-on-ozone-therapy-3rd-edition-isco3/>

¹¹ Consejo Federal de Biomedicina (CFBM), Resolución 321, 16 junio 2020. <https://cfbm.gov.br/wp-content/uploads/2020/06/RESOLUCAO-CFBM-No-321-DE-16-JUNHO-DE-2020.pdf>

¹² Consejo Federal de Medicina Veterinaria, Resolución CFMV 1364, 22 octubre 2020. <https://www.amvzn.com.br/246-resolucao-cfmv-n-1-364-de-22-de-outubro-de-2020>

Therapy is "authorized throughout the country." ¹³

The bill authorizes ozone therapy "as a complementary medical treatment throughout the national territory" (article 1).

Medical ozone production equipment must be certified by ANVISA (National Health Surveillance Agency) (art. 2, I).

The physician must inform the patient that it is a complementary treatment (art. 2, II).

The ozone therapy treatment "does not exclude the right of access to other therapeutic modalities" (art. 2, sole paragraph).

The ozone therapy procedure is of public relevance (art. 3).

The project was approved by the federal senate in 2017 and the same year on November 1, it was sent to the Chamber of Deputies, being approved by it in 2022; and forwarded to the Federal Senate on May 17, 2022 through official letter 307/2022/PS-GSE.

As the bill was approved in its entirety by the Senate and the Chamber of Deputies, it is expected, except last minute surprises, that it will be sent to the President of the Republic for his signature and subsequent publication in the Official Journal of the Federation for its entry into force.

Despite the very advanced stage of its processing, up to now, it is still a bill. It is not yet a law in force.

¹³ <http://legis.senado.leg.br/sdleg-getter/documento?dm=5393036&disposition=inline>