Galicia

Life Sciences Update

# Decree that Amends, Adds and Repeals Various Provisions of the General Health Law

Mexico City, January 28, 2026

On January 15, 2026, the decree that amends, adds and repeals various provisions of the General Health Law (the "Decree") was published in the Federal Official Gazette.

Regarding **public procurement of health supplies**, the Ministry of Health shall be responsible for coordinating the diagnosis of needs for medicines and health supplies, as well as for planning and integrating the demand for medicines and high-tech medical equipment within consolidated procurement procedures. Likewise, the Decree provides the promotion of preferential participation of companies that demonstrate investment in the national production chain of medicines, medical devices and health supplies, or that have begun to set up factories, laboratories or warehouses, or that carry out scientific research or develop innovative health products. The federal entities will participate in these consolidated procurement procedures.

**Digital health** is added as a matter of general health and is defined as the use of information and communication technologies in health services, including telehealth, telemedicine, mobile health, electronic medical or health records, and portable devices.

The purposes of digital health are to facilitate remote medical care without the need for travel, optimize human and technological resources, expand coverage, especially in communities with limited access, provide support through consultations with specialists, implement digital education programs, digitalize medical information to facilitate its secure exchange, and analyze data to improve diagnoses and hospital management.

The Ministry of Health will issue provisions for the implementation and supervision of these services, considering aspects such as advice on technological infrastructure, continuing professional development, the development of care guidelines and security protocols for data protection, as well as evaluation mechanisms.

In terms of **health service coverage**, the Decree provides that individuals (whether or not affiliated with social security institutions) may access public institutions in the country, with compensation mechanisms between institutions.

Projects for the creation, replacement, or expansion of medical units, as well as the acquisition of high-tech medical equipment (note: does not include medicines) must be registered in the **National Master Plan for Health Infrastructure and High-Tech Equipment**, which will certify their necessity, justification, and allow for monitoring from inception to implementation, regardless of the source of funding.

**Alternative dispute resolution mechanisms** are incorporated through the National Medical Arbitration Commission ("CONAMED"), which will have full technical, operational, administrative and management autonomy, with powers to issue opinions, recommendations, agreements, rulings and arbitration awards within its sphere of competence. Alternative dispute resolution mechanisms (immediate management, conciliation, mediation and arbitration) shall be regulated by the General Law on Alternative Dispute Resolution Mechanisms and other applicable regulations.

Regarding the **disposal of organs, tissues, blood and blood derivatives**, substantial changes are introduced with a focus on modernizing and expanding the regulatory framework for the disposal of organs, tissues, blood and blood derivatives, comprehensively incorporating the regulation of stem cells and blood products. The powers of the Ministry of Health are expanded to expressly include policy on stem cells and blood products, as well as the obligation to carry out awareness campaigns on the donation of stem cells for transplants and blood for transfusions.

In addition, new essential technical definitions are incorporated, such as "blood products", "stem cell bank", "stem cell collection center", "regenerative medicine facility", "residual plasma", and "transfusion", the definitions of "disposal", "preservation", "traceability", and also "blood derivatives" are updated to include blood products and stem cells within their scope.

In terms of control and supervision, the Decree significantly strengthens the structure of specialized committees in health establishments, establishing the obligation to have Transfusion Medicine Committees with quarterly regular meetings in those that perform transfusions or dispose of blood, blood derivatives and stem cells, as well as Stem Cell Transplant Committees in establishments that perform transplants, infusion and disposal of such cells.

Furthermore, the ethical framework for donation is reinforced by the express incorporation of the principles of altruism, non-profit, feasibility and confidentiality, categorically prohibiting trade

in organs, tissues, stem cells, blood and blood products, and establishing that all donations must be strictly free of charge. Specific requirements for informed consent are established for the donation of stem cells obtained from placental and umbilical cord blood, as well as exceptions to allow the transplantation of stem cells and bone marrow in minors with the express consent of their legal representatives.

The **Federal Health System** is established, comprising the Federal Commission for Protection against Health Risks ("COFEPRIS") and the health protection authorities of the federal entities with which a coordination agreement has been signed for the exercise of powers in health regulation, control, surveillance and promotion, as well as the laboratories of the federal entities in their health regulation component. COFEPRIS will be responsible for coordinating and supervising health control units in the federal entities, as well as pharmacovigilance and technovigilance activities to ensure the safety of authorized products.

COFEPRIS is granted **new powers** relating to narcotics and psychotropic substances, regulation in health emergencies, temporary authorizations, coordination of the Federal Health System, and pharmacovigilance and technovigilance.

**Marketing authorizations** shall be granted for a period of five (5) years and extensions may be requested for ten (10) years, in accordance with health regulations. The following are grounds for cancellation of marketing authorizations: (i) failure to request an extension within the established period; (ii) changing or modifying the product without prior authorization; or (iii) changing or modifying the manufacturer of raw materials without prior authorization from the health authority.

Establishments conducting **health research** must have an Ethics and Research Committee (combining previously separate committees) responsible for registering, evaluating, and ruling on health research protocols with respect to their scientific-methodological, ethical, and regulatory content, as well as biosafety and environmental impact.

A total ban is established on activities related to **electronic cigarettes, vaporizers and similar devices**, including their acquisition, production, manufacture, import, export, marketing, distribution, sale, supply and any form of advertising or promotion, with the exception of consumption and possession when not intended for commercial purposes. Penalties and fines are also provided for violations of this prohibition, as well as the revocation of previously granted authorizations.

Various **psychotropic substances** are reclassified, such as pseudoephedrine, norpseudoephedrine, cathine, nicergoline, bupropion and tramadol, among others. In addition,

various substances are added to the list of **controlled narcotics**, including precursors for the manufacture of fentanyl.

The Decree shall enter into force in accordance with the following:

- In general, the Decree entered into force on January 16, 2026.
- The provisions relating to the inclusion as psychotropic substances of the following substances: cathine, dihydroergocristine, nicergoline, norpseudoephedrine, pseudoephedrine, anfebutamone (bupropion), tramadol, gamma hydroxybutyric acid (GHB), benzquinamide, and gamma butyrolactone (GBL) will enter into force 180 calendar days after the publication of the Decree.
- The "Regulations of the General Health Law on Social Protection in Health", published in the Federal Official Gazette on April 5, 2004, are repealed.
- The Ministry of Health shall integrate the information from the National Master Plan for Health Infrastructure and High-Tech Equipment within a period not exceeding 180 calendar days.
- CONAMED shall issue and update the necessary regulations for the implementation of alternative dispute resolution mechanisms within a period not exceeding 180 calendar days.
- The provisions on preferential participation of companies with national investment in consolidated contracts shall be applicable to contracting procedures carried out as of fiscal year 2026 and whose medicines, medical devices, and other health supplies are scheduled for delivery as of 2027.

* * *