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Amendment to the General Health Law — Decree published on January 15, 2026

I. Context of the Reform

On January 15, 2026, the "Decree Reforming, Adding, and Repealing Various Provisions of the General Health Law" was published in the Official Gazette of the Federation (the "**DOF**"), published by President Claudia Sheinbaum Pardo, and entered into force on January 16, 2026.

This reform constitutes a comprehensive transformation of the Mexican health regulatory framework. More than 100 articles have been amended through reforms, additions, and repeals covering virtually all aspects of the health system. The central objectives of the reform include: (i) strengthening hospital infrastructure through strategic planning; (ii) digitizing health services; (iii) expanding universal access through the exchange of services between public institutions; (iv) incorporating a gender perspective into health policies; (v) imposing an absolute ban on the commercialization of electronic cigarettes and vaping devices, with criminal penalties; and (vi) strengthening mechanisms for protection against health risks.

II. Key Aspects of the Reform

The reform modifies key articles such as Articles 3, 6, 7, 10, 13, 17 Bis, 77 Bis (various sections), 245, 314, 316, 341, and 342 Bis, among others; adds new chapters (IV Bis on the National Medical Arbitration Commission, IV Ter on investment in infrastructure, VI Bis on Digital Health, and XII Ter on the provision of blood and stem cells); and repeals obsolete provisions such as Article 108.

- **Digital Health:** Digital health is now formally included as a matter of general health, defined as the application of information and communication technologies to health services, including telehealth, telemedicine, mobile health, electronic medical records, and wearable devices.

- **Exchange of Services:** Universal access to medical care will be promoted through the exchange of services among public health institutions, with the purpose of ensuring timely and quality care.

- **Infrastructure Planning:** The planning for the creation, replacement, and expansion of health services infrastructure has been established as a matter of general health, to be coordinated through the National Master Plan for Health Infrastructure and High-Tech Medical Equipment.

- **Gender Perspective:** The incorporation of a gender perspective into health strategies, campaigns, and programs has been promoted in order to contribute to equality between women and men in access to the right to health protection.

- **Nutrition and Pain Management:** Comprehensive pain management, as well as the design of public policies aimed at promoting nutritious, sufficient, and quality nutrition, are now included as matters of general health.

III. Institutions and Sectors Affected

The reform directly impacts the following institutions and sectors: the Ministry of Health (endowed with new coordination and planning powers), COFEPRIS (with a strengthened role as the backbone of the Federal Health System), the National Medical Arbitration Commission (with full technical and operational autonomy), public institutions of the National Health System (now required to register their projects in the National Master Plan), IMSS-Bienestar, state governments, suppliers of medicines and medical supplies, and public and private healthcare facilities.

IV. Main Reforms

a. National Master Plan for Health Infrastructure and High-Tech Medical Equipment

Any project to create, replace, or expand medical units of the National Health System's public institutions, as well as to acquire high-tech medical equipment, must have a registration folio in the National Master Plan for Health Infrastructure and High-Tech Medical Equipment. The Ministry of Health will decide on registration requests within two business days, granting a maximum validity of six years, and they can be renewed.

b. Digital Health and Telemedicine

Digital health is formally included as a matter of general health, and defined as the application of information and communication technologies in health services, including telehealth, telemedicine, mobile health, electronic medical records, and portable devices. The Ministry of Health will issue provisions for the implementation, supervision, and continuous improvement of such services, taking into account security protocols for the confidentiality of information and the protection of personal data.

c. Exchange of Health Services

All persons, whether or not they are affiliated with social security institutions, may access health services provided by any public sector institution, depending on the condition, geographical accessibility, or medical urgency, through exchange agreements whereby the institution of origin will reimburse the institution providing the service for the expenses incurred.

d. Consolidated Procurement

The Ministry of Health will plan and integrate the demand for medicines, high-tech medical equipment, and other supplies, promoting the participation of natural persons or legal entities that demonstrate investment in the national territory within the production chain, the installation of factories or laboratories, the development of scientific research, or the acquisition of innovative products.

e. Federal Health System and Strengthening of COFEPRIS

The Federal Health System has been formally established, comprising COFEPRIS and the states' health protection authorities. COFEPRIS expands its powers to propose regulations for protection against health risks in emergency situations, issue temporary authorizations for health supplies during such emergencies, and coordinate pharmacovigilance and technovigilance activities.

f. Prohibition of Electronic Cigarettes

The marketing, production, manufacture, import, export, distribution, sale, and supply of electronic cigarettes, vaping devices, and analogous devices is prohibited throughout the national territory. Violations

of this prohibition will be punishable by one to eight years' imprisonment and a fine equivalent to 100 to 2,000 times the value of the UMA. Health authorizations related to these products will be rendered null and void, and COFEPRIS will notify the relevant holders to immediately cease all activities related thereto.

g. National Health Information Database

The Ministry of Health will create and administer a national health information database containing data on service provision, infrastructure, and medical equipment. This database will enable performance evaluations for the members of the National Health System, facilitate the exchange of services, and strengthen strategic planning.

h. National Medical Arbitration Commission (CONAMED)

CONAMED has been consolidated as a decentralized administrative body with full technical, operational, administrative, and management autonomy, with powers to issue opinions, recommendations, agreements, rulings, and arbitration awards to resolve disputes arising between users and health service providers.

i. Bioethics and Research Ethics Committees

Healthcare establishments must have Bioethics Committees for Healthcare and Research Ethics Committees, both multidisciplinary and interdisciplinary, include non-scientific representatives, and maintain a balance of gender and age.

j. Availability of Blood and Stem Cells

The donation of blood, blood products, and stem cells constitutes a free, voluntary, and altruistic act, intended for repetition, without any commercial or profit-making purpose. The Ministry of Health will determine the availability of residual plasma existing in the national territory for industrialization purposes in order to obtain blood derivatives for the benefit of the population.

V. Recommendations

For the public health sector, the following is recommended:

1) Immediate Registration of Projects: Initiate the corresponding procedures to register infrastructure projects and acquisitions of high-tech medical equipment in the National Master Plan (integration period: 180 calendar days).

2) Preparation for Digital Health: Evaluate the current technological infrastructure, train personnel on telemedicine matters, and establish information security and personal data protection protocols.

3) Exchange Agreements: Execute service exchange agreements with other public health institutions and establish the corresponding financial compensation mechanisms.

4) Update Information Systems: Adapt systems to feed the National Health Information Database with the required statistical and nominal data.

5) Establish Committees: Integrate or update Bioethics Committees for Healthcare and Ethics in Research Committees in accordance with the multidisciplinarity, gender balance, and accreditation requirements established in the reform.

For the private health sector, the following recommendations are provided:

1) Digital Health Compliance: In the event that telemedicine services are offered, ensure compliance with the security, confidentiality, and informed consent protocols to be issued by the Ministry of Health.

2) Institutional Committees: Private establishments must establish Bioethics and Ethics and Research Committees according to their degree of complexity.

3) Alternative Dispute Resolution Mechanisms: Become familiar with the procedures of the National Medical Arbitration Commission and consider the execution of instruments whereby its jurisdiction is recognized.

For suppliers of medicines, medical devices, and supplies:

1) Competitive Advantages: Accredit investment in the national territory (factories, laboratories, warehouses, or scientific research) to participate in consolidated procurement processes commencing in 2027.

2) Pharmacovigilance and Technovigilance: Comply with reporting obligations to COFEPRIS regarding the safety of medicines and medical devices.

3) Cease Activities Related to Electronic Cigarettes: Immediately suspend any activity related to electronic cigarettes, vaping devices, and similar devices to avoid criminal penalties.

For the Medical Technology Industry:

1) Registration of High-Tech Equipment: Ensure that client institutions register acquisitions of high-tech medical equipment in the National Master Plan for Health Infrastructure and High-Tech Medical Equipment.

2) Development of Digital Health Solutions: There is an opportunity to develop telemedicine platforms, electronic records, and portable devices that comply with applicable security and data protection standards.

VI. Conclusion

This reform represents a paradigmatic transformation in Mexican healthcare regulation, placing particular emphasis on strategic planning, digitization, universal access, and institutional strengthening. Timely compliance with the new obligations is essential to avoid penalties and take advantage of the opportunities offered by the new regulatory framework.

We remain at your service to analyze the specific impact of these reforms on your operations and provide you with the legal advice necessary to ensure compliance with the new regulations.

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