PANORAMIC

HEALTHCARE REGULATION

Mexico

LEXOLOGY

Healthcare Regulation

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ORGANISATION, FINANCING AND STRUCTURE OF THE HEALTHCARE SYSTEM

Organisation

How is healthcare in your jurisdiction organised? What is the role of government?

The Mexican healthcare system is financed by public (social security institutions) and private insurers, out-of-pocket payments and informal arrangements.

The major public segments of the Mexican healthcare system are as follows:

- Social security institutions for employees exclusively, the funding of which comes from contributions by the federal government, the employer and the employee. These institutions include the Mexican Social Security Institute, the Civil Service Social Security and Services Institute, the Social Security Institute for the Mexican Armed Forces and PEMEX Medical Services (for Mexican petroleum workers); and
- Public institutions exclusively directed to attend to people not covered by social security, the funding of which comes from the federal government, states and patients. They include the Wellness and Health Institute and state health institutions.

In the public sector, social security and public institutions provide medicines. If the medicine is not available when required, some public insurers allow privately registered pharmacies to supply it and request their refund.

The private sector is made up of private institutions, insurers and independent professionals, the users of which are not restricted. Individuals and private insurers fund this sector. Private health insurance generally covers professional, executive and higher levels of the private sector. Enrolment in private health insurance has increased considerably over the years. According to official figures, up to 50 per cent of annual health spending in Mexico comes from out-of-pocket payments related to private doctors, insurance and drug acquisitions.

The role of government is to guarantee, bring and facilitate healthcare services to the Mexican population based on article 4 of the Mexican Federal Constitution.

Law stated - 23 octubre 2024

Key legislation

What key legislation governs the provision of healthcare services in your jurisdiction?

The key legislation that governs the provision of healthcare services in Mexico is the Health Law and its Regulations for Health Services. They establish the basis of access to healthcare services and assign competences, in particular between the federal government and the rest of the federal entities (states), in terms of general health.

Law stated - 23 octubre 2024

Financing

How is the healthcare system financed in the various patient care sectors?

The manner in which healthcare institutions are financed depends on whether they belong to the public or private sector rather than on whether they belong to the outpatient or inpatient sector.

Public sector

Public-sector healthcare institutions are mostly financed through contributions from public and private-sector workers. Employers and employees both pay a tax solely for the purpose of providing healthcare services. There are special rules for those who are unable to pay but are still eligible to benefit from the healthcare system.

Private sector

According to official figures, up to 50 per cent of annual health spending in Mexico comes from out-of-pocket expenses, related to private doctors, insurance and drug acquisitions.

Law stated - 23 octubre 2024

Delivery structures

What are the basic structures for the delivery of care to patients in your jurisdiction?

The Health Law and its Regulations establish which healthcare services should be provided by physicians licensed in Mexico and which should be provided through licensed healthcare centres. Enrolment of patients in social security healthcare centres derives from their social security rights. The enrolment of patients in public healthcare centres derives from national policies to provide healthcare to citizens. The enrolment of patients in private healthcare centres is an individual decision.

In the public sector (social security and public institutions), healthcare centres dispense medicinal products prescribed by their healthcare professionals from a medicinal products' list issued by the Ministry of Health. Public insurers acquire those listed products mostly by public tender processes. The Mexican Social Security Institute is the largest public-sector buyer of drugs.

Law stated - 23 octubre 2024

Access and coverage

What rules govern access to treatment and emergency services? Which items and services are covered and which are not covered?

The legal framework for access to treatment and emergency services is made up of:

- the Mexican Federal Constitution;
- the Health Law and its Regulations;

- the Social Security Law; and
- the Security and Social Services of Federal Workers Institute Law.

The items and services covered are:

- medical care;
- mother-child care;
- family planning;
- mental health;
- promotion of human resources training;
- occupational health; and
- prevention and control of non-transmissible diseases, syndemics, pandemics and accidents.

Currently, there are no items or services that are not covered, at least while new technology and alternatives in health are being developed.

Law stated - 23 octubre 2024

Exclusions from statutory coverage

Are any groups excluded from statutory coverage? Are any groups covered under alternative schemes?

There are no groups excluded from statutory coverage in the public and private sectors. It should be noted however that the availability of healthcare services in the private sector depends on the scheme of self-regulated maximum retail price to which each individual subscribes.

Law stated - 23 octubre 2024

Gaps in cost coverage

Are there any gaps in cost coverage?

In the public sector there are no gaps in cost coverage as services are fully provided by the state – individuals are not requested to pay. In the private sector, the gap in cost coverage depends on each scheme of self-regulated maximum retail price.

Law stated - 23 octubre 2024

HEALTHCARE PRICING AND REIMBURSEMENT

Pricing

How are prices for healthcare services set and paid for in your jurisdiction? To what extent is the cost of healthcare services governed by law or regulation?

Mexican laws do not establish specific provisions concerning healthcare services pricing for either the outpatient or inpatient sector. However, several mechanisms are in place to enable a certain degree of control of such prices in practice.

Private-sector price control is based on a scheme of self-regulated maximum retail price (MRP) covering services and is overseen by the Ministry of Economy. Private-sector company participation is voluntary. Under the price control, each service MRP must not exceed an international reference price, estimated as the average price in six major markets and a market factor. There are no established sanctions for MRP violations.

Price reviews and eventual changes are conducted and implemented annually. The new government frequently implements changes that have an impact on the frequency of price changes. For instance, it is expected that the austerity measures recently taken by the government will remain in place for the foreseeable future, which may drive more frequent price reviews.

Law stated - 23 octubre 2024

Reimbursement

How is reimbursement for healthcare services structured?

The reimbursement structure for public institutions is simple because healthcare services are free to patients at the point of access. The government takes responsibility for managing these services. The Commission for Drug Price Negotiations, which is made up of several public offices (including the Ministries of Economy and Health) negotiates with the patent holder or licensee to establish a single price of a patented drug for all sales to the public sector.

By contrast, in the private sector the reimbursement structure depends on each scheme of self-regulated maximum retail price.

Law stated - 23 octubre 2024

Adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursement of healthcare services?

The Ministry of Economy is empowered to raise observations in the scheme of self-regulated maximum retail price. The Commission for Drug Price Negotiations, which is made up of several public offices, including the Ministries of Economy and Health, negotiates with the patent holder or licensee to establish the single price of a patented drug for all sales to the public sector.

Likewise, public insurers that acquire healthcare services through direct acquisition or public tender decide on the corresponding reimbursement.

Law stated - 23 octubre 2024

HEALTHCARE ORGANISATIONS AND BUSINESS STRUCTURES

Legal authorisation
What steps are necessary to authorise the provision of healthcare services, and what laws govern this?

The Health Law and its Regulations for Health Services, and the Mexican Official Norm for Hospitals (NOM-016-SSA3-2012) make up the legal framework governing the provision of health services in Mexico. Prior to opening, hospitals and specialist healthcare centres require a licence granted by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) – the Mexican healthcare regulatory agency. The main requirement for obtaining a licence is to provide a description of the internal organisation and human and financial resources, the internal rules of the establishment, a description of healthcare facilities and services, and the name of a designated qualified person. For high-risk healthcare services, such as radiotherapy and hemodialysis, an additional licence is required. Conversely, low-risk healthcare services that do not involve surgeries or obstetric services may require only a notice of operation to COFEPRIS rather than a licence.

COFEPRIS is the agency in charge of the control and surveillance in all aspects of sanitary regulation (in connection to drugs, medical devices, health services, food supplements, food and beverages, cosmetics, pesticides, clinical studies, etc).

In August 2020, COFEPRIS was incorporated into the Undersecretary for the Prevention and Promotion of Health of the Ministry of Health. COFEPRIS' powers depend directly on such Undersecretary.

Law stated - 23 octubre 2024

Legal structures
What types of legal entities can offer healthcare services?

The Health Law Regulations do not explicitly state that certain types of healthcare services can be provided by specified types of entities only. Therefore, associations, corporations and limited liability companies can provide healthcare services if they either obtain a licence from, or provide notice of operation to, COFEPRIS.

Law stated - 23 octubre 2024

Foreign companies
What further steps are necessary for foreign companies to offer healthcare services?

Pursuant to current COFEPRIS criteria, companies constituted in Mexico must hold a licence. Thus, foreign companies might either constitute a company in Mexico or have a holding agreement with a local partner.

Law stated - 23 octubre 2024

Healthcare arrangements

What regulatory and legal issues commonly arise in relation to healthcare arrangements? What are the main rules and principles that apply to extraterritorial participation in these arrangements?

The regulatory and legal issues commonly raised in relation to healthcare arrangements concern the time that those in charge take to answer the applications requesting inquiries, the licensing process and verification visits to the establishments.

Law stated - 23 octubre 2024

COMPETITION, ANTI-CORRUPTION AND TRANSPARENCY RULES

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

The Federal Economic Competition Commission (COFECE) has the power to pursue any infringement of competition law by healthcare providers. In 2016, COFECE launched an antitrust analysis of the pharmaceutical market in Mexico for the first time, which was justified by the market's numerous flaws and the confusion surrounding its multiple rules.

On 9 August 2017, COFECE published its analysis, concluding that there are some competition anomalies in this market that essentially derive from a lack of clear regulations and public policies. COFECE considers that these anomalies mainly stem from the following facts:

- the linkage system between patents and the approval of generics is non-transparent;
- data for approved healthcare products is not up-to-date and remains incomplete;
- the incomplete use of the Bolar exemption delays the approval of generics;
- several patents are granted for the same active substance; and
- patent infringement is commonplace.

COFECE recommends that public policies be issued to both remove obstacles to generics entry and promote demand for generics. The authors of this chapter feel that some of COFECE's recommendations are justified, such as seeking to improve the quality, access to and transparency of public data of approved healthcare products, but others are worrying, in particular restrictions on granting some types of patents.

COFECE's recommendations are not binding and can be considered as 'a first approximation'.

Law stated - 23 octubre 2024

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

The Federal Antitrust Law allows for private entities to request investigations by COFECE, and provides numerous examples and evidence related to a given investigation in progress.

COFECE's proceedings have three central features: the secrecy of investigations, discretion surrounding dawn raids and the link that has come about between dawn raids and its own immunity programme.

Further, once the preliminary determination of antitrust practices is declared and published in the Mexican government's Official Gazette, anyone related or affected by the decision has the opportunity to appeal and submit evidence.

Follow-on private litigation against manufacturers is possible but has not been as widespread as in other jurisdictions, such as the United States.

Law stated - 23 octubre 2024

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

The main mandatory anti-corruption rules and provisions currently in place that are applicable to private parties, whether individuals or corporations (including healthcare providers), are contained in:

- the Mexican Federal Constitution;
- the Federal Anti-corruption Law for Government Procurement;
- the Federal Criminal Code; and
- the international anti-corruption conventions to which Mexico is a party – namely:
    - the United Nations Convention against Corruption;
    - the Inter-American Convention Against Corruption; and
    - the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Since 19 July 2017, the General Act of Administrative Responsibilities (GAAR) entered into force in Mexico, repealing the Federal Anti-corruption Law for Government Procurement. The GAAR punishes, among other corrupt activities, the actions of private parties related to administrative liabilities when interacting with public officials, such as bribery,

illegal participation in administrative procedures, influence peddling, collusion and undue contracting of former public officials. Some of the main administrative liabilities considered under the GAAR include the disqualification from public acquisitions for no less than three months and no more than 10 years, and the suspension of activities for no less than three months and no more than three years.

Law stated - 23 octubre 2024

REGULATION OF HEALTHCARE SERVICES

Licensing authority and process

Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

The authority in charge of licensing and regulating patient care facilities is the Federal Commission for the Protection against Sanitary Risks (COFEPRIS). The licensing processes apply to:

- the manufacture of drugs that contains narcotics, psychotropics, vaccines, toxoids, serums, animal-based antitoxins and blood products;
- the elaboration, manufacture or preparation of drugs, pesticides, vegetal nutrients or toxic or dangerous substances;
- the application of pesticides; and
- the handling of radiation sources for medical or diagnosis purpose.

They also apply more generally to:

- establishments where surgical or obstetrical acts and hemodialysis services are practised; and
- mixing centres for the preparation of parenteral, nutritionally medicated mixtures.

Also, the authority in charge of licensing and regulating healthcare professionals is the Minister of Education.

Law stated - 23 octubre 2024

Cross-border regulation

What requirements and restrictions govern the mobility of licensed health professionals across borders?

There are no restrictions that govern the mobility of foreign licensed health professionals across borders. However, a foreign medical degree is not automatically recognised as equivalent to a Mexican medical degree. The foreign degree must be validated by the Mexican educational authorities – namely, the Ministry of Education – and the foreign professional may be requested to take a knowledge exam called the 'National examination of aspirants to medical residencies' to obtain a licence authorising the practice of medicine in Mexico.

Law stated - 23 octubre 2024

Collaboration between healthcare professionals

What authorisations are required for collaboration between healthcare professionals? How is this regulated?

Scientific and educational events

The Code of Integrity, Ethics and Transparency of Healthcare SupplyCompanies (CIETEMIS), issued by the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA), states that congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by any other third party (eg, pharmaceutical companies or healthcare organisations) must have, as their main purpose, scientific exchange and medical education.

Whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily, to improve their knowledge of patient care. In each case, programmes must comply with the guidelines of the applicable laws; they must have a strict scientific content sustained, if required, on clinical evidence; and, most importantly, they must be accredited and certified by the relevant academic authorities.

Support in general will not be offered, under any circumstance, to have any kind of influence on the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

Samples

According to CIETEMIS, samples are provided directly, in fair amounts and without cost to healthcare professionals so that they may get to know the products or initiate treatment.

According to article 49 of the Health Law and its Regulations, providing samples of products for free does not require approval if the samples meet the requirements of the approved medicinal product. These samples should be contained in a package with fewer units than the approved product.

CIETEMIS establishes guidelines for sampling. It prohibits CETIFARMA members from offering or supplying samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples.

CETIFARMA members are required to have full and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians.

The authors of this chapter recommend that manufacturers keep strict control of their product samples as there have been cases of sample ressale.

Gifts and donations

CIETEMIS essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value or incentives of any kind may be offered to healthcare professionals as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study.

No gifts, bonuses, pecuniary advantages, benefits in kind or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional aids related to the practice of medicine or pharmaceutical activities. CIETEMIS defines an 'inexpensive promotional aid' as one that does not exceed the equivalent of 10 units of measure (around US$50).

Regarding healthcare professionals in government institutions, article 52 of the Federal Law of Responsibilities for Government Officers expressly forbids such officers from requesting, accepting or receiving any gifts or donations from persons whose commercial or industrial activities are directly linked, regulated or supervised by government officers.

Law stated - 23 octubre 2024

Collaboration between patient care facilities and healthcare professionals

What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?

CIETEMIS establishes that collaboration between patient care facilities and healthcare professionals must have a written agreement in place that will include, at least:

- the activities to be undertaken and their cost, and the source and destination of funding; and
- direct and indirect support and any other relevant non-financial aid.

Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded.

Law stated - 23 octubre 2024

Training of healthcare professionals

What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?

The educational and training requirements that physicians and healthcare professionals must satisfy to obtain the right to practise in Mexico are:

- to complete an approved study programme in a private or public college;
- to work for one year in social services;

- in the case of physicians and nurses, to complete professional practices and internships; and
- to file all the requested documents with their educational institution in order to obtain their professional licence.

Students enrolled in private colleges must take as specific test (called 'Examination for graduation from a bachelor's degree') to determine whether they possess the key knowledge and skills upon completing their degree. .

Law stated - 23 octubre 2024

Discipline and enforcement

What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?

COFEPRIS can request reports from licensed holders, make on-site inspection visits to the facilities and initiate ex officio legal proceedings for non-compliance.

Ultimately, these legal proceedings can result in the revocation of the licence. Also, COFEPRIS is also entitled to implement measures on behalf of public health, such as seizing products or ordering the partial or total suspension of activities, services or advertisements.

Under certain conditions, COFEPRIS has the statutory authority to revoke any health service approval or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage or unit of measure for sanctions, to the closure of the corresponding establishment or facility.

The imposition of administrative sanctions does not exclude civil and criminal liability. Administrative infringers can incur penalties ranging from a fine up to 50,000 times the minimum wage to final closure of the establishment. Repeated infringement is also considered to be a criminal offence.

COFEPRIS has broad jurisdiction over illegal health services. In addition, COFEPRIS commonly enters into collaboration agreements with the general attorney to investigate and prevent illegal health services.

Law stated - 23 octubre 2024

Patient complaints

How are patient complaints processed and adjudicated?

Under the Mexico Health Law, complaints filed by users regarding medical care they received must be addressed and resolved in a timely and effective manner by the health service providers or by the entities designated by the health institutions for such purpose, when the solution also falls within their remit.

Law stated - 23 octubre 2024

DATA PROTECTION, PRIVACY AND DIGITAL HEALTH

Responsible authorities and applicable legislation

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation?

The applicable legislation is the Federal Law on Transparency and Access to Public Government Information and the responsible authority for its compliance is the National Institute for Transparency, Access to Information and Personal Data Protection (INAI). This authority is responsible for overseeing the Regulations for the Protection of Personal Data. Its main purpose is the disclosure of governmental activities, budgets and overall public information, as well as the protection of personal data and individuals' right to privacy. The INAI has the authority to:

- conduct investigations;
- review and sanction data protection controllers; and
- authorise, oversee and revoke certifying entities.

The Ministry of Economy is responsible for informing and educating on the obligations regarding the protection of personal data between national and international corporations with commercial activities in the Mexican territory. Among other responsibilities, it must issue the relevant guidelines for the content and scope of the privacy notice in cooperation with the INAI.

The INAI has not published specific guidelines or rules for data protection and privacy in the healthcare sector yet. However, it has issued decisions that provide advice on how to protect or disclose information related to the healthcare sector in cases where freedom of information request refusals was contested.

Law stated - 23 octubre 2024

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

The main and mandatory requirement is the appointment of a data protection officer (person or department) as a controller by the healthcare provider. There are no statutory requirements for the qualifications of such an officer, but it is advisable to appoint a person or department with data privacy expertise, and enough authority and resources to implement measures to protect personal data.

Law stated - 23 octubre 2024

Regulatory guidance

Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The Ministry of Economy is responsible for informing and educating on the obligations regarding the protection of personal data between national and international corporations with commercial activities in the Mexican territory. Among other responsibilities, it must issue the relevant guidelines for the content and scope of the privacy notice in cooperation with the INAI.

The INAI has not published specific guidelines or rules for data protection and privacy in the healthcare sector yet. However, it has issued decisions that provide advice on how to protect or disclose information related to the healthcare sector in cases where freedom of information request refusals was contested.

Law stated - 23 octubre 2024

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

The establishment and development of the legal framework for data protection in Mexico is recent compared with other areas such as healthcare products and services. Thus, no enforcement trends have emerged during the past 12 months. However, as a result of an investigation process started by the INAI in February 2019 related to a data breach at KPMG Mexico, the INAI is calling for an amendment of Mexican data protection law to include an obligation to notify it of any data breach.

Law stated - 23 octubre 2024

Digital health services

Which authorities regulate the provision of digital health services and what is the applicable legislation? What basic requirements are placed on healthcare providers when it comes to digital health services?

The General Health Law regulates the provision of health services by physicians licensed in Mexico. This law does not yet specifically establish digital health services, which is why new types of services such as telemedicine remain unusual in Mexico.

Law stated - 23 octubre 2024

UPDATE AND TRENDS

Key developments

Are there any current or foreseeable legislative initiatives, court cases, laws or other rules that affect the regulation of healthcare? What has recently changed (or will likely change), and what steps need to be taken in preparation?

Quality of manufacturing practices for medical devices

Draft regulation NOM PROY-NOM-241-SSA1-2024 establishes minimum requirements for the design, development, good manufacturing practices, storage and distribution of medical devices. It aims to provide a clear framework to ensure that the manufacturing of medical devices is safe, meets quality standards and effectively protects consumer health.

Healthcare-associated infections

Draft regulation PROY-NOM-045-SSA-2024 includes the organisational and operational mechanisms, along with the coordination actions required to implement measures for epidemiological surveillance, prevention and control of healthcare-associated infections. The objective is to enhance the capacity of health services to identify and mitigate the risk of acquiring and transmitting infections among patients, staff, visitors and students, among other groups.

The objectives and application of this standard include establishing the specifications that must be adhered to for the epidemiological surveillance, prevention and control of healthcare-associated infections, with the aim of enhancing safety and quality of care and reducing the risk of infection, complications and mortality among health service users. Additionally, it is intended to be enforced nationwide, in both public and private medical care facilities.

Life sciences regulation

The Regulation of the General Health Law on Health Research and the NOM for Health Research in Human Beings set out the guidelines and standards for the clinical trial protocol, including rules concerning documents, compilation, confidentiality and reports.

Essentially, any clinical trial must be conducted following ethical guidelines and must always respect the dignity, rights and welfare of human beings (NOM for Health Research in Human Beings).

When clinical trials last longer than one year, annual technical reports must be compiled for the health authorities.

General Health Law amendments

It is proposed that a regulatory framework be established for the application of artificial intelligence in medical settings, aimed at advancing public health interests.

This framework will involve the introduction of a new chapter in the General Health Law concerning the regulation of artificial intelligence in healthcare. The framework must be implemented in an ethical and responsible manner, ensuring the protection of personal data and the privacy rights of patients, while also fostering equity and inclusiveness in its deployment.

Only artificial intelligence systems that have received authorisation from the Ministry of Health shall be permitted for use, to guarantee their reliability, accuracy, privacy, security, quality and therapeutic efficacy.

Importation of health products

On 11 September 2024, a decree was published in the Official Gazette that removes the legal possibility of importing into Mexico of health products without a marketing authorisation. Such importation of medicines and medical devices had been possible under the provisions of the Equivalence Decree of 28 January 2020 and its modification decree of 22 June 2021.

The 2020 and 2021 decrees had provided for the possibility of obtaining a marketing authorisation for the imported product through a similar process to the one stated in the Health Law Regulations, but in a much shorter period than the one provided in the regulations, on the basis that the requirements had been met through equivalence. In this sense and regarding the procedures initiated prior to thee decree of 11 September 2024, the prosecution of the applications will continue their course based on the corresponding provisions.

Likewise, the 2020 decree and its modification opened the way for the participation of companies in public tenders to offer products without a marketing authorisation that covered a certain need in the sector. Now that the effects of these provisions have ceased, however, it will no longer be possible to participate in public tenders without a marketing authorisation, which should have a positive impact on the development of the procurement process for health products.

Law stated - 23 octubre 2024