HEALTHCARE REGULATION

Mexico

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Getting The Deal Through

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Healthcare Regulation

Consulting editors

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Quick reference guide enabling side-by-side comparison of local insights, including into organisation, financing and structure of the healthcare system; pricing and reimbursement; healthcare organisations and business structures; competition, anti-corruption and transparency; regulation of healthcare services and professionals; data protection, privacy and digital health; and key developments.

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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 comprises public (social security institutions) and private insurers, out-of-pocket payments and informal arrangements.

The major public segments of the Mexican healthcare system are:

- Social security institutions exclusively directed to formal workers, in which the funding comes from contributions by the federal government, the employer and the employee, such as the:
  - Mexican Social Security Institute;
  - Civil Service Social Security and Services Institute;
  - Social Security Institute for the Mexican Armed Forces; and
  - PEMEX Medical Services, for Mexican petroleum workers.

- Public institutions exclusively directed to attend people not covered by social security, in which the funding comes from the federal government, states and patients, such as the:
  - Wellness and Health Institute; and
  - states' health institutions.

In the public sector, social security and public institutions provide medicines. However, if the medicine is not available when required, some public insurers allow private registered drugstores to supply prescribed medicines and to request their refund.

The private sector comprises 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 - 07 September 2023

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 our jurisdiction is the Health Law and its Regulations where it establishes the basis to access to healthcare services, distribute competences, and the concurrence between the federal government and the rest of the federal entities (states) in terms of general health.

Law stated - 07 September 2023

Financing

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

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

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

Law stated - 07 September 2023

Delivery structures

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

According to Health Law and its regulations, depending on the type of healthcare services, these services should be provided by physicians licensed in Mexico and 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, which is a National Formulary issued by the MoH. Public insurers acquire those listed products mostly by public tender processes. The IMSS is the largest public-sector buyer of drugs.

Law stated - 07 September 2023

Access and coverage

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

The rules that govern access to treatment and emergency services are:

- 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.

These are the items and services that are covered:

- medical care;
- mother-child care;
- family planning;
- mental health;
- promotion of human resources training;
- laboral 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 meanwhile new technology and alternatives in health are being developed.

Law stated - 07 September 2023

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 public and private sector. It could be emphasised that healthcare services in private sector is available to population depending on their scheme of self-regulated maximum retail price.

Law stated - 07 September 2023

Gaps in cost coverage

Are there any gaps in cost coverage?

In public-sector there are no gaps in cost coverage due the service is fully provided by the state, they do not make any kind of billing to people. Otherwise, in private sector depends on each scheme of self-regulated maximum retail price.

Law stated - 07 September 2023

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 sectors. However, several mechanisms are in place, enabling 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.

Under that scheme, price reviews and eventual changes are done annually. This new administration is implementing modifications frequently, so it can impact the frequency of price changes. It is anticipated that the austerity measures that have been taken by the government recently will continue and may drive a more frequent price review.

Law stated - 07 September 2023

Reimbursement

How is reimbursement for healthcare services structured?

Public institutions do not have to invest time to structure reimbursement methods for people because they do not make billing of healthcare services to patients or people that made use of that in their instances, the government takes over it.

On the other hand, in the private sector the reimbursement structure depends on each scheme of self-regulated maximum retail price.

Law stated - 07 September 2023

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. Likewise, as commented above, public insurers that acquire healthcare services through direct acquisition or public tender are the ones that decide on the corresponding reimbursement.

Law stated - 07 September 2023

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) are the main laws that govern the provision of health services in Mexico. Prior to opening, hospitals and specialist healthcare centres require a licence granted by the Mexican Healthcare Regulatory Agency (COFEPRIS). The main requirement for getting a licence is to provide a description of the internal organisation and human and financial resources, internal rules of the establishment, a description of healthcare facilities and services and 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 giving only notice of operation to COFEPRIS rather than getting a licence.

The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) is an agency in charge of the control and surveillance in all aspects related to 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 Prevention and Promotion of Health of the

Ministry of Health. COFEPRIS' faculties depend directly on such Undersecretary.

Law stated - 07 September 2023

Legal structures

What types of legal entities can offer healthcare services?

The Health Law regulations do not clearly specify that certain types of healthcare services can only be provided by specified types of entities. Therefore, associations, corporations and limited liability companies can provide healthcare services, if they get a licence, or a notice of operation given to COFEPRIS.

Law stated - 07 September 2023

Foreign companies

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

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

Law stated - 07 September 2023

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 - 07 September 2023

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 powers to pursue any infringement of competition law by healthcare providers.

On 9 August 2017, COFECE published a study concluding there are some competition anomalies in these markets, which are essentially derived from a lack of development in regulations and public policies.

Law stated - 07 September 2023

Private enforcement

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

The Federal Antitrust Law allows for private entities to request investigations, as well as providing numerous examples and evidence related to a given investigation in progress.

COFECE proceedings have three central features: the secrecy of investigations, discretion surrounding dawn raids and the linkage 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 - 07 September 2023

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 Anticorruption 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 Anticorruption Law for Government Procurement. The GAAR sanctions, 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 - 07 September 2023

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 process 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;
- the handling of radiation sources for medical or diagnosis purpose;
- establishments where surgical or obstetrical acts and hemodialysis services are practised; and
- mixing centres for preparation of parenteral, nutritionally medicated mixtures.

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

Law stated - 07 September 2023

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 licensed health professionals across borders in the country, and the requirements that govern the mobility of licensed health professionals across borders are:

- join a programme or an organisation that is focused on bringing health services to other places of the world;
- be a health professional with a professional licence;
- have a passport;
- language domain of the principal language in the place to travel, better if it is certified, generally English domain;
- available to travel; and
- and the personal documents that are requested by each instance.

Law stated - 07 September 2023

Collaboration between healthcare professionals

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

Scientific and educational events

The Integrity, Ethics and Transparency of Health Supplies Companies Code states that congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported, or any other third party must have, as a 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 corresponding 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 the Integrity, Ethics and Transparency of Health Supplies Companies Code, samples are provided directly, in fair amounts and without cost to healthcare professionals, so that they may get to know the products or to initiate treatment.

According to article 49 of the HLR concerning advertising, providing samples of products for free does not require approval, if they meet the requirements of the approved medicinal product. These samples should be contained in a package with fewer units than the approved product.

The Integrity, Ethics and Transparency of Health Supplies Companies Code establishes guidelines for sampling. It prohibits members to offer or supply samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples.

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.

We always recommend our clients have strict control on product samples since there have been cases of the re-sale of said samples.

Gifts and donations

The Integrity, Ethics and Transparency of Health Supplies Companies Code essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value may be offered to healthcare professionals, or incentives of any kind, 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.

The Integrity, Ethics and Transparency of Health Supplies Companies Code delineates 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 - 07 September 2023

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?

The Ethics and Transparency of Health Supplies Companies Code 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, cost, 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 - 07 September 2023

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 our jurisdiction are:

- in public and private college:
  - they must approve the study programme;
  - they must perform a social service;
  - in the case of physicians and nurses, they must perform professional practices and internships; and
  - they must file all the requested documents with their educational institution in order to get the professional licence.

Only for the private college, the students must approve a test regarding the principal areas of their profession according to their finished study programme.

Law stated - 07 September 2023

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 to sanction non-compliance.

Ultimately, these legal proceedings can result in the revocation of the licence. Also, it is entitled to implement measures on behalf of public health, such as the seizure of products, ordering 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 to illegal health services. In addition, COFEPRIS commonly enters into collaboration agreements with the general attorney to investigate and prevent illegal health services.

Law stated - 07 September 2023

Patient complaints

How are patient complaints processed and adjudicated?

In accordance with our Health Law, complaints filed by users regarding the medical care received must be addressed and resolved in a timely and effective manner by the health service providers or by the entities that the health institutions have defined for such purpose, when the solution corresponds to their area of competence.

Law stated - 07 September 2023

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 the 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.

Law stated - 07 September 2023

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 at least the following qualifications:

- data privacy expertise; and

- enough authority and resources to implement measures to protect personal data.

Law stated - 07 September 2023

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 on 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 issued specific guidelines or rules for data protection and privacy in the healthcare sector yet, but they have issued some decisions advising how to protect or disclose information related to the healthcare sector in cases where freedom of information request refusals was contested.

Law stated - 07 September 2023

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 quite recent in comparison with other areas such as healthcare products and services. Thus, there are no enforcement trends that have emerged during the previous 12 months. However, as a result of an investigation process started by INAI in February 2019 related to a data breach at KPMG Mexico, the INAI is calling for the need to modify Mexican data protection law to include an obligation to notify the DPA in case of a data breach.

Law stated - 07 September 2023

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 - 07 September 2023

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?

The initiative to reform various regulations of the General Health Law aims to regulate the use of medical devices. Among what is proposed, it is worth noting that:

- prosthetics, diagnostic agents and dental supplies should be considered as medical devices;
- the term 'essential accessories for health' will be replaced with the term 'medical devices;
- for sale or supply, as well as for importation, the retailers must have a health authorisation from the Ministry of Health; and
- the details of the medical device's use will be detailed in the instructions of the corresponding product, in printed or electronic form.

In addition, on 20 December 2021, the new version of the Mexican Official Standard (NOM) NOM-241-SSA1-2021 on good medical device manufacturing practices was published in the Official Gazette.

In general terms, this new version of the NOM seems clearer than the previous one as it focuses on giving a greater order to the specifications that must be considered in each of the stages of the life cycle of a medical device (eg, in each step of the manufacturing chain until its distribution and marketing). In particular, the chapter on the quality management system was strengthened.

Among the modifications, it is important to highlight that the scope of the definition of a medical device is extended because of technological advances, now including:

any instrument, device, utensil, machine, software, implantable product or material, diagnostic agent, material, substance or similar product to be used, alone or in combination, directly or indirectly in human beings with any of the following purposes of use indicated in the document itself.

The inclusion of the definitions of 'software' as a medical device is of high relevance and solves the old loop in the regulation of software in connection with medical devices. Until now, this category was not included in the current legislation despite the fact that there are various programmes and applications that address health matters.

Likewise, reference is made to the use of digital media, including digital records and the use of electronic signatures. Simultaneously, following the changes and inclusions throughout the new NOM, these are reflected in the inclusion of various terms to be compatible with the new figures.

This standard will leave NOM-241-SSA1-2012 without effect until it enters into force in 2023.

Proposal for a general law on humanities, sciences, technologies and innovation

This proposal promotes the continuous generation of new knowledge, as well as the articulation of basic science and frontier research with activities in the field of humanities, sciences, technologies and innovation. This is aimed at influencing priority issues for national development with the purpose of guaranteeing that public benefits gained from the development of sciences and technologies will result in social welfare and contribute to the care and restoration of the environment. It also aims to promote the strengthening of national sovereignty and the integral development of

Mexico.

New strategy regarding linkage regulation in Mexico

Currently, the regulatory provisions of the linkage system do not take into consideration the patent holder.

Recently, the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) has been issuing a periodic listing of applications for generic and biosimilar medicines, including general information such as the application date, applicant's name, generic name, pharmaceutical form and date of publication; and a format to 'oppose' generic and biosimilar applications based on a patent or patents in force, known as the 'Opposition Format'.

The foregoing is an attempt to partially comply with the obligation provided for in the United States-Mexico-Canada Agreement (USMCA); however, this is not enough to avoid eventual patent violations, since neither of the two publications comply with the administrative, legal and security procedures necessary for it to be considered valid and have legal effects. In addition, the notice requirements referred to in the USMCA are not met, since COFEPRIS at no time notifies the patent holder to alert him of a possible violation; but leaves the burden on the patent holder to review the list to detect it.

In view of the above, it is not a notice by the authorities (COFEPRIS and/or by the Mexican Institute of Industrial Property (IMPI)) of the patent linkage system once the linkage mechanism has been initiated between COFEPRIS and IMPI to prevent possible violations and does not offer enough information or grant adequate time and sufficient opportunity for the patent holder to be properly heard, prior to the commercialisation of an allegedly infringing product, needless to say, there is a specific legal remedy or action for the patent holder.

In view of the above, Olivares is developing a new innovative action that may avoid this lack of due notice to patent owners.

Law stated - 07 September 2023

Jurisdictions

Australia	Clayton Utz
Canada	Stikeman Elliott LLP
India	LexOrbis
Ireland	Matheson LLP
Italy	CMS Italy
Japan	Anderson Mōri & Tomotsune
Mexico	OLIVARES
Sweden	Cirio Advokatbyrå AB
Turkey	Gün + Partners
USA	Norton Rose Fulbright