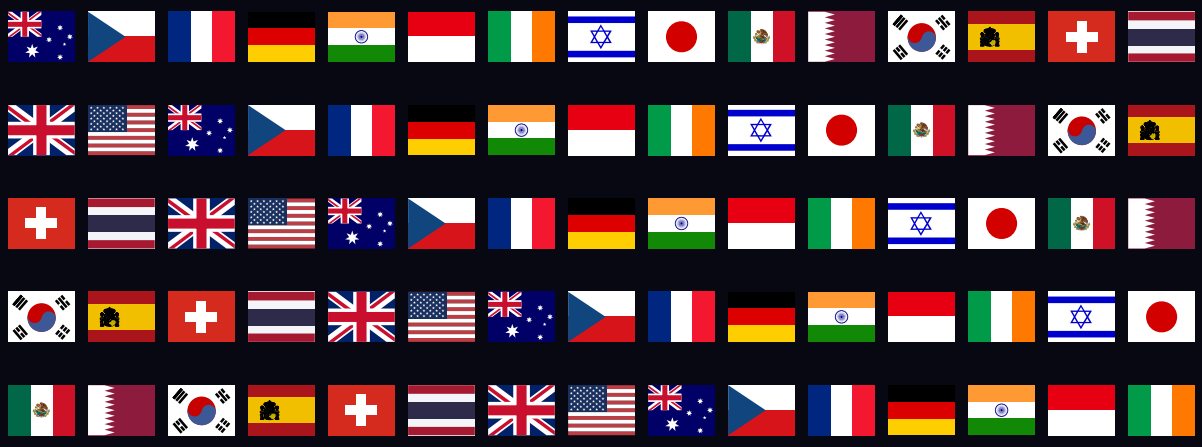
DIGITAL HEALTH

Mexico



LEXOLOGY
Getting The Deal Through

Consulting editor
Latham & Watkins LLP

Digital Health

Consulting editors

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Latham & Watkins LLP

Quick reference guide enabling side-by-side comparison of local insights, including market overview; legal and regulatory framework; data protection and management; intellectual property rights, licensing and enforcement; advertising, marketing and e-commerce; payment and reimbursement; and recent trends.

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MARKET OVERVIEW AND TRANSACTIONAL ISSUES

Key market players and innovations

Who are the key players active in your local digital health market and what are the most prominent areas of innovation?

The key players active in the development of digital health technologies in Mexico are start-ups (mainly tech companies), healthcare providers such as hospitals, academic institutions and investors. The principal areas of innovation are:

- medical software;
- healthcare apps;
- artificial intelligence analysing clinical lab tests and research;
- telemedicine; and
- electronic health records.

Law stated - 13 January 2023

Investment climate

How would you describe the investment climate for digital health technologies in your jurisdiction, including any noteworthy challenges?

The digital health market has been growing steadily in Mexico in the past couple of years. It has been positively affected by the intense growth of the information technologies market in the country, which (with an output of US$15.5 billion) grew at a rate of 9 per cent during the first quarter of 2020 . One challenge is the lack of regulation for several digital health technologies; however, a regulation proposal is currently being discussed in Mexico's Congress.

Law stated - 13 January 2023

Recent deals

What are the most notable recent deals in the digital health sector in your jurisdiction?

Despite a lack of enthusiasm from the federal government when it comes to digital health matters, local state authorities have been open to digital health technologies. This has allowed the implementation of digital health systems in various states through public–private partnerships and other schemes where the private investor is responsible for the development and management of the infrastructure and the state is responsible for bringing patients into the hospital. For example, some financial institutions have created a healthcare services provider for the beneficiaries of insurance companies in selected hospitals and for supplying medicine prescribed by doctors through pharmacies. In such a system, the healthcare services provider, hospitals, insurance companies and pharmacies are all linked, allowing the patient to have a remote appointment with their doctor, who can prescribe medicine digitally. The prescription can be obtained online from a pharmacy or by using a QR code, and the payment by insurance companies is done remotely.

Another example is the implementation of digital technology in operation rooms, where private investors develop the technology – including software and health inputs (such as surgical medical instruments and medicine) – to help with various operations in government facilities. The government enters into a contract for the services with the provider for

a certain number of years, and at the contract's expiration the government has the option to buy the technology.

Law stated - 13 January 2023

Due diligence

What due diligence issues should investors address before acquiring a stake in digital health ventures?

The first and most important matter is understanding how the products or services of a digital health venture are classified in Mexico. This will determine the requirements (eg, labelling, advertising) and authorisations (eg, marketing authorisations, operation notice) required for the business to operate legally. Another step is verifying that the services or products comply with the Official Mexican Standards or NOMs specified for that kind of service or product (ie, the fulfilment of the Mexican regulation regarding operation rooms and hospital equipment, among others).

Furthermore, it must be determined whether the digital health product or service is intended for public or private markets, as specific requirements may apply to a public-market product.

Law stated - 13 January 2023

Financing and government support

What financing structures are commonly used by digital health ventures in your jurisdiction? Are there any notable government financing or other support initiatives to promote development of the digital health space?

It is uncommon to receive government financing for digital health ventures; however, some local governments have been open to the implementation of digital health services through public–private partnerships and other schemes, where the private investor is responsible for the development and management of the infrastructure and technology, and the state is responsible for bringing patients into the hospital. The most common financing structure used in digital health ventures is private investment. A large venture capital market in Mexico is focused on technology investments , including digital health (in 2021, technology investments were above US$1 billion). These venture capital investments are often minority equity positions (from 20 per cent to 30 per cent) and funded through a mix of equity and debt (by local commercial banks and other financial institutions).

Law stated - 13 January 2023

LEGAL AND REGULATORY FRAMEWORK

Legislation

What principal legislation governs the digital health sector in your jurisdiction?

Currently, there is no principal legislation concerning digital health products or services. Such products or services tend to be indirectly regulated under various legislations and standards. For example, the General Health Law contains provisions regarding the use of information and communication technologies in health matters and electronic medical records. The Healthcare Services Regulation likewise contains a provision on digital prescriptions with a focus on the requirements for them to be issued, but it is silent on the issuance of such prescription through digital channels.

In principle, digital products and services must comply with the general regulation applicable to similar products and services that are marketed or offered in the traditional way. These are governed by the General Health Law, the Health

Input Regulations, the Healthcare Services Regulation and several Official Mexican Standards, depending on the service or product.

A case worth mentioning is the software as a medical device. The 'Official Mexican Standard NOM-241-SSA1-2021, Good practices for the manufacturing of medical devices' , published on 20 December 2021 and coming into force on 21 June 2023, is the first legal provision in Mexico that regulates software as a medical device. Accordingly, software is considered a medical device so long as it:

- is used for one or more medical purposes;
- does not need to be part of a hardware to fulfil its intended purpose;
- can run on general computing platforms; and
- can be used alone or in combination with other products (eg, as a module or other medical devices).

If software (including a mobile application) meets the above criteria it will be considered a medical device, while software that only runs on a specific physical medical device is excluded from such classification and will not require registration to be marketed within the Mexican territory.

There are several initiatives underway to amend the legal framework and regulate digital health. Some are focused on electronic clinical records and digital prescriptions; others place a broader focus on digital health as an ecosystem – these are still pending approval by Congress.

Law stated - 13 January 2023

Regulatory and enforcement bodies

Which notable regulatory and enforcement bodies have jurisdiction over the digital health sector?

The Ministry of Health is the regulatory and enforcement body for the digital health sector through the Federal Commission for the Protection against Sanitary Risks. The latter entity is in charge of protecting the population against health risks caused by the use and consumption of goods, services and other health-related products.

Additionally, in terms of prices and commercial matters, the Ministry of Economy has jurisdiction over the digital health sector through the Federal Consumer Protection Agency, a body in charge of protecting and promoting consumer rights.

Law stated - 13 January 2023

Licensing and authorisation

What licensing and authorisation requirements and procedures apply to the provision of digital health products and services in your jurisdiction?

In general, digital health products are mostly classified as medical devices, in which case they must secure a marketing authorisation to become commercialised in Mexico. If a product is manufactured domestically, the facility where the manufacturing takes place must secure a sanitary licence and appoint a sanitary responsible person. However, if the product is manufactured abroad, the warehouse within the Mexican territory where the products are stored must have an operation notice and a sanitary responsible person. In addition to a marketing authorisation, an imported product requires an import permit to enter the country.

In relation to services to be rendered through digital technologies, for the time being there is no specific regulation other than the usual laws applicable to medical services (whenever such a service is performed digitally).

Medical software is not currently classified as a device and, therefore, does not require a marketing authorisation nor an import permit for its commercialisation in Mexico. Software that is necessary in the operation of a medical equipment is considered a part of the device; although the software itself does not require a marketing authorisation, it is included in the marketing authorisation of the medical equipment it runs on. As of July 2023, however, software may be classified as a medical device if it:

- is used for one or more medical purposes;
- does not need to be part of medical hardware to fulfil its intended purpose;
- is capable of running on general computing platforms; and
- can be used alone or in combination with other products (eg, as a module or other medical devices).

Software as a medical device will need to function accurately, completely and according to its design. Therefore, marketing authorisation for software will be needed, though the requirements have not yet been published.

Law stated - 13 January 2023

Soft law and guidance

Is there any notable 'soft' law or guidance governing digital health?

In 2014, the National Center for Health Technology Excellence (CENETEC) issued guidelines on telehealth, telemedicine and the long-distance training of healthcare professionals. These guidelines are not compulsory, are quite broad and have not been properly publicised, so they are barely known and have not been updated since their publication in 2014. The National Health System (the Mexican Social Security Institute for private employees) published its own guidelines on telehealth and telemedicine that are applicable in 12 hospitals in the states of Baja California, Baja California Sur, Sonora, Sinaloa, Nayarit, Jalisco, Colima and Michoacán.

In the context of interoperability, some NGOs have been active in the adoption of international standards for the transfer of clinical data Health Level Seven (HL7).

Law stated - 13 January 2023

Liability regimes

What are the key liability regimes applicable to digital health products and services in your jurisdiction? How do these apply to the cross-border provision of digital health products and services?

The key liability regimes applicable to health products are civil and administrative. Civil liability is based on damages caused to someone or something by the use of technology or services (malpractice). Conversely, administrative liability does not seek to compensate the damage to the victim but to sanction improper conduct.

In the case of civil liability, any injured or harmed consumer has the right to be compensated for damages caused by the goods or services sold, either as a consequence of:

- contract liability, based on the lack of conformity of the goods or services;
- extra-contractual (tort) liability; and
- strict liability, where there is no need for a wrongful or illicit action or omission to have occurred.

Besides, under Mexican procedural law, a group of at least 30 persons can file a class action to claim damages.

Administrative liability can be determined by the Federal Commission for the Protection against Sanitary Risks (based on a violation of the General Health Law by any act, service or product that jeopardises public health in any sense), and by the Federal Consumer Protection Agency in charge of protecting and promoting consumer rights. In both cases, the sanctions are remarkably similar and include fines, product seizure, service ban and facility closure.

Cross-border digital health products and services need to comply with similar requirements as those applicable to local products and services; however, there is a practical problem when trying to enforce these rights against a company or a person that does not have an address or a legal representative in Mexico. In both civil and administrative liability, the person responsible for the product or service will be notified and must appear before the Mexican authorities to be held responsible.

Law stated - 13 January 2023

DATA PROTECTION AND MANAGEMENT

Definition of 'health data'

What constitutes 'health data'? Is there a definition of 'anonymised' health data?

Under the Official Mexican Standard NOM-004-SSA3-2012 , health data is defined as the patient's unique set of information and personal data held by a medical care establishment, whether public or private, which consists of written, graphic, imaging, electronic, magnetic, electromagnetic, optical, magneto-optical and any other type of document based on which healthcare professionals create records, annotations and certifications corresponding to their intervention in the patient's medical care, in compliance with the applicable legal provisions. Mexican law is silent on anonymised health data.

Law stated - 13 January 2023

Data protection law

What legal protection is afforded to health data in your jurisdiction? Is the level of protection greater than that afforded to other personal data?

Yes, the level of protection afforded to health-related data in Mexico is greater than any other personal data, as it is regarded as sensitive personal data under the Federal Law for the Protection of Personal Data Held by Private Parties. Sensitive personal data is any personal data that, if misused, could lead to discrimination or cause grave danger to the data owner. As a general rule, all processing of personal data is subject to the owner's consent, expressed in writing.

Besides, databases containing sensitive personal data are only allowed to exist when their legitimate and specific purposes are justified by the responsible party, according to the latter's activities or purposes, and reasonable efforts must be made to limit the processing period to the minimum necessary.

A breach of data protection laws can result in significant fines that range from approximately US$450 to US$1.4 million, depending on:

- the nature of the data;
- the intentional nature of the action or omission constituting the violation; and
- the financial position of the data controller.

Moreover, a violation of provisions concerning sensitive personal data (eg, health data) results in sanctions and penalties. Compromising the security of databases, premises, computer programs and equipment, when attributable to the data controller, is considered a criminal offence that may result in imprisonment for up to three or five years, or twice as much if the offence involves unlawful treatment of sensitive personal data.

Law stated - 13 January 2023

Anonymised health data

Is anonymised health data subject to specific regulations or guidelines?

No, anonymised health data is excluded from the scope of data protection laws and regulations in Mexico, as such data cannot lead to the identification of a person.

Law stated - 13 January 2023

Enforcement

How are the data protection laws in your jurisdiction enforced in relation to health data? Have there been any notable regulatory or private enforcement actions in relation to digital healthcare technologies?

The National Institute for Transparency, Access to Information and Protection of Personal Data (INAI) is the authority in charge of granting access to public information and protecting personal data. INAI is constantly monitoring the operation of the responsible parties and that the collection and treatment of personal data are conducted according to legal provisions, especially those related to sensitive personal data that tend to have stricter requirements.

We are aware that INAI has been reviewing closely those parties in charge of handling sensitive personal health data, and has imposed elevated fines on parties responsible for lack of compliance with data protection legislation. However, from the available information, it is not possible to determine if any of these sanctions were imposed because of the use of digital health technologies.

Law stated - 13 January 2023

Cybersecurity

What cybersecurity laws and best practices are relevant for digital health offerings?

There are no specific laws on cybersecurity. However, the personal data protection legal framework requires data controllers and processors to put in place adequate technological security measures taking into consideration:

- the nature of the personal data subject to processing;
- the vulnerability of the processing system; and
- the technological developments in the market.

Such security measures must be reviewed and updated regularly. Cyberattacks, hacking, virus infection and other cybercrimes constitute punishable criminal offences pursuant to the Federal Criminal Code, punishable by imprisonment for up to 12 years.

Law stated - 13 January 2023

Best practices and practical tips

What best practices and practical tips would you recommend to effectively manage the ownership, use and sharing of users' raw and anonymised data, as well as the output of digital health solutions?

Under the data protection laws, data controllers are accountable for complying with legal principles and obligations, including implementing appropriate security measures to protect data against loss, theft and unauthorised use or access. Therefore, it is advisable that any processing of raw health data is preceded by a privacy notice in Spanish that is compliant with data protection legislation and that comprehensively describes the purpose of the process and is updated regularly. The express consent of the owners of the health data must be obtained and kept safe for the duration the data is handled, as the authority may request such information.

In the case of anonymised data, as the owner cannot be identified, it does not fall within the scope of data protection provisions. Therefore, its use, share and any other relevant activity constitutes a commercial decision.

Law stated - 13 January 2023

INTELLECTUAL PROPERTY

Patentability and inventorship

What are the most noteworthy rules and considerations relating to the patentability and inventorship of digital health-related inventions?

Inventions in all technology fields can be patented if they are:

- new and not in the state of the art – that is, technical knowledge made accessible to the public by any means of dissemination in the country or abroad;
- the result of an inventive activity – a creative process whose results are not deduced from the state of the art in a way that is obvious or evident to a technician in the field; and
- are susceptible of industrial application – the possibility that an invention can be produced or used in any branch of economic activity, for the purposes described in the application.

In Mexico, databases, algorithms, software and any other written technology cannot be protected by a patent. These works are protected under the Federal Copyright Law, according to which protection is not required for registration before the competent authority and is not subject to any formality whatsoever; therefore, once the work is fixed on a material support (regardless of its merit, purpose or mode of expression) it will be protected. However, for the copyright to be exercised before a third party, it must be registered with the National Institute of Copyright.

In terms of the Federal Labor Law, employees are entitled to appear as authors of the inventions made for their employer, but the employer owns the inventions and has the right to exploit the patents. Further, employees have the right to receive complementary compensation when the relevance of the invention and the benefits gained by the employer are disproportionate to their salary. Such compensation can be regulated by an agreement between the employer and the employee, which is customary practice in Mexico.

Law stated - 13 January 2023

Patent prosecution

What is the patent application and registration procedure for digital health technologies in your jurisdiction?

The patent application procedure does not distinguish a digital health technology from any other invention, so they follow the same procedure. The inventor, their successor or legal representatives may apply for a patent, which must comply with all required information and documentation. The application can be filed for a specific invention or a set of related inventions that conform to a unique inventive concept. The Mexican Patent and Trademark Office will first verify that all the requirements are met and, if the recognition of a priority is claimed by the applicant, an 18-month term must pass for its prior publication, which will make the patent application public. Afterwards, the authority will conduct a final verification to determine if the requirements are met, and if the information submitted is not enough to allow compliance with the legal and technical requirements, additional information will be requested from the applicant to be filed within a two-month period. Once all the legal and technical requirements are met, the authority issues a patent title, granting the holder a 20-year term for exclusive exploitation. The patent title will be published in the official gazette and become enforceable to third parties.

Law stated - 13 January 2023

Other IP rights

Are any other IP rights relevant in the context of digital health offerings? How are these rights secured?

In Mexico, the code of software, databases, algorithms and any other written invention is considered among ‘works’ and protected through copyright. These kinds of inventions do not require registration or recognition by the copyright authority, as they will be protected once they are fixed on material support. Nonetheless, to enforce copyright before a third party, a certificate from the copyright authority must be secured to increase chances of success.

Law stated - 13 January 2023

Licensing

What practical considerations are relevant when licensing IP rights in digital health technologies?

If a digital health technology is patented, the following considerations must be respected when licensing IP rights:

- the licence must be granted in a written agreement including information on the parties;
- the IP right to be licensed (commercialisation, prosecution, infringement action, etc);
- the term of the agreement and whether it is exclusive or not; and
- the amount to be paid for the licence (or reference that it is a free licence).

Such agreement must be submitted before the Mexican Patent and Trademark Office through a free writ by any of the parties involved in the licensing of the IP right to become effective vis-á-vis third parties.

Concerning software, algorithms, databases and any work protected by copyright, licensing must be compensated and subject to a specific time. The licence can be exclusive or not, and it must be recorded at the National Institute of Copyright to be enforceable on third parties.

Law stated - 13 January 2023

Enforcement

What procedures govern the enforcement of IP rights in digital health technologies? Have there been any notable enforcement actions involving digital health technologies in your jurisdiction?

IP provisions in Mexico do not include a specific procedure for the enforcement of digital health technologies IP rights. The regular enforcement procedures are observed when enforcing IP rights in digital health technologies. First, an infringement procedure must be initiated before the Mexican Patent and Trademark Office, in which the reimbursement of the royalties earned from the exploitation of an IP right may be imposed on the offending party. The interested party must present all relevant evidence to support the action. The final resolution issued by the Mexican Patent and Trademark Office can be challenged through a nullity claim that must be filed before the Federal Court of Administrative Justice. The court's ruling can likewise be reviewed through an amparo action, which must be filed before the circuit courts whose ruling is final and binding.

Regarding software, algorithms, databases and any work protected by a copyright, an infringement in commerce-related matters can be initiated before the Mexican Patent and Trademark Office. The plaintiff must offer all available evidence that will support its claim, and the final resolution of this procedure can be challenged as referred to above and will follow the same path.

No relevant enforcement action involving digital health technologies has come to our attention so far.

Law stated - 13 January 2023

ADVERTISING, MARKETING AND E-COMMERCE

Advertising and marketing

What rules and restrictions govern the advertising and marketing of digital health products and services in your jurisdiction?

Digital health products classified as medical devices are subject to strict advertising and marketing regulations. The marketing of a digital medical device requires authorisation; however, there is no regulation on the availability of the product to patients, which means that in principle anyone can access it without restriction.

The advertising of a medical device strictly follows the characteristics provided under the marketing authorisation, and the latter determines if advertising can be aimed at the public or healthcare professionals only. If advertising is aimed at the public, it must:

- be clear, concise and easily understandable by its target audience;
- contribute (using claims) to hygiene education; and
- include precautionary messages (when the use or consumption of the product may present a health risk).

Before advertising a medical device, a permit must be secured from the Federal Commission for the Protection against Sanitary Risks if it is aimed at the public, or an advertising notice must be submitted before the same sanitary authority if advertising is aimed at healthcare professionals.

On the other hand, the rendering of a medical service is subject to submitting an operation notice that provides the location of the facility and the appointment of the sanitary responsible person, who verifies that the services are rendered in line with applicable technical and legal provisions.

The advertising of medical services (regardless of whether they are offered through digital health technology) must inform the public about the type, characteristics and purpose of the services, including the modalities of access. All medical services to be advertised must have a permit issued by the Federal Commission for the Protection against Sanitary Risks.

Additionally, according to the Federal Consumer Protection Law , the advertising or offering of information about a product or service related to digital health technology and disseminated by any means or media must be truthful, verifiable, clear and free of texts, dialogues, sounds, images, brands, denominations of origin and other descriptions that are misleading or abusive. Misleading or abusive information or advertising is understood as that which is inaccurate, false, exaggerated, partial, contrived or biased.

Law stated - 13 January 2023

e-Commerce

What rules governing e-commerce are relevant for digital health offerings in your jurisdictions?

There are no specific e-commerce rules for digital health offerings, but the general e-commerce rules apply (ie, all information on the offering must be truthful, verifiable, not misleading or abusive, and must not confuse the consumer). The terms and conditions of the use of the e-commerce technology must be presented to the consumer or patient in clear and understandable language and must be accepted by them before they use the technology. Moreover, if the e-commerce offering requires the user to include health data (ie, sensitive personal data), a privacy notice must be displayed explaining how the information will be used and treated, allowing the user to grant written and express consent through their electronic signature or any other authentication mechanism.

Law stated - 13 January 2023

PAYMENT AND REIMBURSEMENT

Coverage

Are digital health products and services covered or reimbursed by the national healthcare system and private insurers?

Telehealth and telemedicine are covered by some members of the National Health System, such as the Mexican Social Security Institute (IMSS), the Institute for Social Security and Services for State Workers and other local public health providers. For example, IMSS has a telemedicine programme in 12 hospitals across Baja California, Baja California Sur, Sonora, Sinaloa, Nayarit, Jalisco, Colima and Michoacán. Long-distance learning programmes have also been implemented at the national level by IMSS.

Some private insurers have developed their own telemedicine and telehealth systems to support their beneficiaries; this has been done in collaboration with hospitals, doctors and pharmacy chains.

With respect to hospitals, The National Healthcare System does not work as a reimbursement system of out-of-pocket expenses, but rather as a system where the hospital is obligated to supply medicines or perform services. Patients who receive medical services through private hospitals or doctors may be reimbursed for their out-of-pocket expenses through private insurers.

Law stated - 13 January 2023

UPDATES AND TRENDS

Recent developments

What have been the most significant recent developments affecting the digital health sector in your jurisdiction, including any notable regulatory actions or legislative changes?

The most relevant recent development is the 'Official Mexican Standard NOM-241-SSA1-2021, Good practices for the manufacturing of medical devices', published on 20 December 2021 and coming into force on 21 June 2023, which regulates software as a medical device. Prior to the enforcement of this standard, software is not classified as a medical device because of its nature, features and use, and such products do not require any additional authorisations for commercialisation (ie, marketing authorisation).

It is worth noting, as a significant development impacting digital health technologies, the fact that Congress is discussing several initiatives to regulate digital health with the aim of bringing more certainty to the market of products and services related to digital health technologies, as well as the legal and technical requirements these should meet.

Law stated - 13 January 2023

Jurisdictions

Australia	Gilbert + Tobin
Czech Republic	dubanska & co
France	Intuity
Germany	Ehlers Ehlers & Partner
India	Chadha & Chadha Intellectual Property Law Firm
Indonesia	ABNR
Ireland	Mason Hayes & Curran LLP
Israel	Naschitz Brandes Amir
Japan	Anderson Mōri & Tomotsune
Mexico	Galicia Abogados SC
Qatar	Al Marri & El Hage Law Office
South Korea	Bae, Kim & Lee LLC
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