

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Alejandro Luna Arena and Marcela de La Peña Ramos, Santamarina y Steta S.C
Date of completion: 30 November 2022

LAWS AND REGULATIONS ON TELEMEDICINE

1. Is telemedicine allowed in your country? If so, how is it defined?

Telemedicine, or its broad concept, telehealth, is allowed within Mexico. Although there is no specific regulation on this matter, the current regulation does not preclude access to remote medical care through the use of information and communication technology (ICT), considering services such as advisory, patient follow-up and interconsultation, or even for remote consultation or teleconsultation.

Telemedicine and telehealth (as such) are neither legally defined nor specifically regulated under any applicable federal or state legal framework in Mexico. Therefore, the National Center for Technological Excellence in Health (Centro Nacional de Excelencia Tecnológica en Salud or 'CENETEC'), a decentralised body of the Ministry of Health, jointly with higher education institutions from Mexico and abroad (eg, Brazil and Spain) prepared a compilation of the concepts of telemedicine and telehealth (to include such concepts in the study plans of the educational institutions) and obtained a glossary of terms related to telemedicine (a preliminary list was presented to the Internal Committee of CENETEC for an initial review, and then analysed and discussed with the panel of experts that comprised international experts and those from all around Mexico), and consequently adopted the definition provided by the World Health Organization (WHO): 'The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for medical diagnosis, treatment and prevention of disease and injuries, research and evaluation and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities'.

Even though there is no specific regulation for the rendering of telemedicine/telehealth, please note that the General Health Law expressly provides that healthcare providers may rely on electronic means as a tool for the provision of healthcare services, and this would naturally include telehealth in its broadest context, such as the use of telecoms and media to provide healthcare services.

2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

As previously explained, there is no specific legal framework regarding telemedicine in Mexico. Nevertheless, health professionals must comply with the applicable and current regulation for general and specialised medical practice by putting patient safety first, as well as the health professionals safety and the safety of the transmission of information.

According to the Political Constitution of the United Mexican States (the 'Political Constitution'), access to healthcare is a human right that implies the right not only to treat a disease but also to prevent it. Therefore, it is considered as an individual guarantee from which the General Health Law and its regulation is derived, and states that the Federation and states will contribute to National Health System (Sistema Nacional de Salud or SNS) consolidation and operation by the execution of Coordination Agreements with the Ministry of Health.

On 11 June 2013, our Political Constitution was amended regarding telecoms matters, known as the Telecommunications Reform, including that the Federal Executive would be in charge of the universal digital inclusion policy, which would include objectives and goals in terms of infrastructure, accessibility and connectivity, ICT and digital skills, as well as digital

government, government and open data programs; the promotion of public and private investment in telehealth applications; telemedicine and the electronic clinical file or record; and the development of applications, systems and digital content.

Thus, telemedicine and telehealth are regulated by general principles applicable to healthcare in general, mainly foreseen by the General Health Law; the Regulation of the General Health Law concerning the Provision of Health Care Services; and the Mexican Official Standards (Norma Oficial Mexicana or NOM), which are mandatory technical provisions that establish specific requirements for rendering healthcare services.

Besides the protection of the patient and health professional, as mentioned, the security of personal information provided by the patient has been prioritised under our current legislation. Therefore, the General Law for the Protection of Personal Data in Possession of Bound Subjects, and the Federal Law on the Protection of Personal Data in Possession of Individuals and its Regulation provide the basis on which every person may make a decision about the protection of their personal information through the Privacy Notice, and the exercise of their right to access, rectify, cancel or eliminate, or oppose the use of their information (known as Access, Rectification, Cancellation and Opposition (ARCO) rights).

Nevertheless, the law provides that the persons obliged by it are not compelled to obtain patient consent regarding the use of the patient's information for prevention or medical diagnosis, or for providing health assistance, according to a NOM: NOM-004-SSA3-2012 – Of the clinical record and some other Mexican Standards (Normas Mexicanas or 'NMX') regarding security techniques on ICTs.

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

Given that there is no specific regulation on telemedicine matters, no specific license is required; therefore, as mentioned, current applicable laws and regulations should be complied with, and, for example, health professionals shall be certified by the Directorate General of Professionals of the Federal Ministry of Public Education.

According to the Internal Regulations of the Ministry of Health, published on 2 February 2010 in the Federal Official Gazette (Diario Oficial de la Federación or DOF), CENETEC was created to satisfy the management and evaluations of health technologies through the generation, integration and disclosure of information, recommendations and advisory based on the best evidence available, with the intent of supporting decisions that facilitate effective access to health services. However, even though CENETEC has the authority to enact regulations, guidelines and/or ordinances on telehealth, it has only drafted a NOM, which was not officially approved or published and thus, never became mandatory.

4. Was telemedicine authorised during the Covid-19 pandemic?

Telemedicine was not expressly authorised during the Covid-19 pandemic, although its use became common in practice. That said, CENETEC was incorporated in 2010 and the Telecommunication Reform, which considers telemedicine and telehealth, was enacted in 2013. However, the pandemic certainly led to the implementation of emerging plans to contain the pandemic and therefore, health measures for people's health and the treatment of information about patients infected by Covid-19, including the provision of healthcare services via telehealth.

5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?

From a regulatory perspective, there have been no changes, even though, from a practical perspective, the scope of telemedicine and telehealth has increased to enable a better use of resources and for distant populations to have access to medical attention, and at an early stage.

<p>It is important to note that, on December 2015, a draft of PROY-NOM-036-SSA3-2015 – For the ruling of remote medical assistance, was published in the DOF for public consultation, as was then provided by the former Federal Law on Metrology and Standardization (cancelled by the current Quality Infrastructure Law published in the DOF in 2020), but unfortunately, based on a technical study and the opinions provided during the public consultation, the committee entrusted with its review and implementation concluded that the use of ITCs should be seen as a support tool for medicine and not as an additional activity; therefore, it should not be regulated separately from current medical procedures. Furthermore, the development of technology is growing exponentially, and there is a risk that if a new draft is not prepared, Mexico could end up with an obsolete NOM from a technological point of view; therefore, the said NOM not only does not contribute to improving medical practice but also may limit future innovative technology and the further development of telehealth.</p>
<p>6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis and telesurgery)?</p>
<p>So far, the services granted through different telehealth programmes are as follows: (1) medical advice, whereby the health professional provides emotional support, information and education regarding healthcare to patients; (2) health training and academic research on medical matters in a collaborative way; (3) consultation, whereby the health professional provides attention to the patient through different activities, thereby evaluating the health condition, and biological, psychological, social and cultural risk factors in order to detect pathologies that may alter the patient's health or development; (4) coordination of services regarding the human and material resources of the health institution; (5) health education addressed to the community in order to encourage lifestyle changes ; (6) interconsultation through the intervention of more than one health specialist; (7) diagnostic interpretation starting with laboratory or cabinet studies; (8) patient follow-up after the patient's first appointment; (9) medical visits through the daily observation of patients hospitalized by doctors, nurses, students and health professionals or technicians in order to evaluate their progress and provide indications for their recovery and rehabilitation; and (10) second opinion, whereby a patient or his/her legal representative requires a doctor or group of doctors independent from the one that issued the first diagnosis and treatment to analyse the case and provide a second opinion regarding a patient's health condition.</p>
<p>7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.</p>
<p>Given the services provided through telehealth doctors, patients, students, technicians and even the community for health education purposes may use telehealth services.</p> <p>However, if a foreign doctor or physician is to provide the health service and such a professional is not duly qualified locally, that is, has not been certified by the Mexican Ministry of Public Education under the Federal Law on Professions, such telemedicine science can only be provided on a doctor-to-doctor basis and the foreign doctor can only provide consultations or a second opinion to the local Mexican qualified doctor, who, in turn, can provide information on the diagnosis, treatment or prescription directly to the patient in Mexico.</p>
<p>8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.</p>
<p>There are plenty of funding models for telemedicine in Mexico according to need, the size of hospitals and the capacity to pay for every health institution.</p> <p>First, the public health system in Mexico is funded by the Expenditure Budget from the federation, as well as local governments, who have the obligation to assign resources for funding health services and for the purchase of products related to digital health. Therefore, on the grounds of the Acquisitions Law, public hospitals may purchase equipment, software</p>

<p>and digital devices to provide healthcare through a competitive bidding process and/or direct purchase when bidding does not comply with the requirements of health institutions.</p> <p>On the other hand, public health institutions may have access to resources to renew their medical equipment or acquire new technology through funds granted by a private–public partnership (PPP), whereby an agreement between the public and private sector is executed and part of the services that should be responsible for the public sector are carried out by the private sector. Such a funding model is ruled by the PPP Law and its regulation, in addition to complying with other laws, such as the General Law on National Property, and the Federal Budget and Tax Liability Law. Additionally, the private sector provides funding and the state is in charge of managing the funds. Other forms of funding are long-term credits or different forms of leasing.</p> <p>To the best of our knowledge, telemedicine is not under mandatory insurance coverage. Nevertheless, insurance companies may include telemedicine in their coverage, as long as the medical care complies with the current applicable law, regulation and NOMs.</p>
<p>9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.</p>
<p>As mentioned, insurance companies may include telemedicine in their coverage, as long as the medical care complies with the current applicable law, regulation and NOMs.</p>
<p>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</p>
<p>10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists and alternative health therapy providers).</p>
<p>Everyone authorised to practise medicine in México may provide telemedicine services, as long as they have the corresponding authorisation to provide such health services, for example, students who have obtained authorisation to provide services restricted to healthcare within the scope of their respective speciality on health, and those obliged and restricted to act in accordance with applicable laws, regulation and ordinances, that is, physicians, homeopaths, dental surgeons, veterinarians and nursing graduates, who may only prescribe when the services of an authorised physician are not available.</p>
<p>11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?</p>
<p>No, there are no specific education requirements or training that healthcare professionals should meet besides their authorisation to practise their profession, and if a specialisation is exercised, then authorisation for such a specialisation would be needed.</p>
<p>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</p>
<p>No, there is no special registration needed for physicians that provide telemedicine services.</p> <p>However, physicians and/or any other healthcare providers that provide medical services, whether in a traditional way or through telehealth, must be duly and previously authorised through the certification of the Mexican Ministry of Public Education as health professionals.</p>
<p>13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</p>
<p>No special license or authorisation is required for providing telemedicine services by institutional healthcare providers, besides the normal authorisations, such as certification for</p>

<p>establishments that provide in-person healthcare. Human resources need to be certified to provide medical services, and equipment and medical devices used for telemedicine are recognised and certified by the Mexican Federal Commission for the Protection Against Health Risks (Comisión Federal para la Protección contra Riesgos Sanitarios or 'COFEPRIS', which is an Food and Drug Administration (FDA) equivalent in Mexico regarding its scope of regulatory authority). All medical attention provided to patients must be recorded, if possible, electronically, according to the applicable NOM 035-SSA3 regarding health information. There should be at least a medical information system for the management of the sensitive information of patients according to NOM 024-SSA3 and the informed consent of patients should be provided for the procedure that will be carried out.</p>
<p>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</p>
<p>14. Are there specific requirements applicable to the telemedicine platform?</p>
<p>Although there is no Mexican legislation and/or regulation currently foreseeing the provision of telehealth in general, CENETEC, in its efforts and actions that seek to achieve the legal recognition of this matter, has issued guidelines and/or best practices on telehealth. Such guidelines are not mandatory, but may serve as a basis to other regulatory agencies, such as COFEPRIS, in evaluating, inspecting and/or assessing the provision of telemedicine services.</p> <p>These guidelines provide, among other requirements, the following for the telemedicine platform: (1) consulting physician and nurse; (2) interconsulting physician; (3) consulting unit either fixed or mobile; (4) interconsulting unit; (5) telecoms network; (6) medical equipment; (7) informatic equipment; (8) videoconferencing equipment; and (9) technical support staff.</p>
<p>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</p>
<p>The requirements regarding electronic equipment for telemedicine services are as follows: (1) telecoms networks; (2) bandwidth requirements; (3) existing protocols and topologies; (4) videoconferencing system; (5) standards (HL7, DICOM and SNOMED); (6) biomedical equipment; (7) routing of medical signals: data, voice, video, and static and dynamic images (real-time and deferred); (8) clinical information sending system; and (9) information storage and processing site.</p> <p>Therefore, it is important to take into consideration the following: (1) telecoms infrastructure based on international standards; (2) ease of installation of hardware; (3) ease of system management; and (4) consider medical equipment that meets international standards. These requirements were foreseen under the CENETEC guidelines.</p>
<p>16. Does legislation provide for specific rules concerning patients' medical records?</p>
<p>Yes, under the general health regulations and standards, there are some specific rules regarding patients' medical records, especially if the healthcare provider applies any Electronic Health Registration Information System (Sistema de Información para la Regulación de Establecimientos de Salud or 'SIRES'), among others, electronic health records, such as the access and authentication of the patient and the health provider to the system, for which a specific access key shall be provided in order to guarantee that the system can only be accessed by the authorised persons. The aforementioned rules, as provided under NOM-024-SSA3-2012, provide standards upon which information should be generated, processed, conserved, interpreted and secured during the exchange of information between information systems, as well as technical specifications for possible scenarios for the exchange of information. SIRES shall be certified by the General Directorate for Health Information through a conformity assessment process.</p>

17. Are there geographic location requirements applicable to the provision of telemedicine services?
It is not a requirement, but it is recommended that for a telemedicine programme to have a greater impact, it should be in a geographical zone that is difficult to access.
18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?
The healthcare professional needs to obtain a letter of informed consent from the patient according to NOM 004 SSA3-2012 – of the clinical file, which provides that informed consent should be written, executed by the patient, his/her legal representative or the closest relative. Through this document, the patient accepts a medical or surgical procedure or treatment for diagnostic, therapeutic, rehabilitation, palliative or research (clinical) purposes, and has been properly and previously informed about the risks and benefits that may be expected due to such treatment.
19. Is there any other important requirement that should be highlighted?
Even though it is not a requirement, telemedicine is recommended for patients that may require a subsequent medical follow-up visit, given that the clinical file has been created, which leads to a more controlled situation, with more elements of information.
DATA PRIVACY ASPECTS
20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description.
<p>In Mexico, the processing of personal data in the possession of private entities is regulated by the Federal Law for the Protection of Personal Data in Possession of Private Entities (Ley Federal de Protección de Datos Personales en Posesión de los Particulares), its Regulations and the Guidelines on the Privacy Notice (the 'Data Protection Law').</p> <p>Under the Data Protection Law, 'processing' is defined as 'the collection, use, disclosure or storage of personal data by any means, and the use of the data includes the action of accessing, handling, benefiting from, transferring or disposing of personal data'.</p> <p>Furthermore, a 'transfer' is understood to be 'any kind of communication of personal data made to a person other than the controller, processor or data subject'; and a 'remittance' is 'any kind of communication of personal data between the controller and the processor, within or outside Mexican territory'.</p> <p>The general rule regarding data privacy is that sensitive personal data may not be used, unless the express consent of the data subject was previously obtained. However, there is an express exception that provides that when personal data is needed for preventive treatment, medical diagnosis and/or the provision of medical healthcare treatment under emergency circumstances, express consent may not be needed.</p>
21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?
<p>According to the response to item 20, the express consent of the patient to use personal data will not be necessary, as long as the data subject is not in a position to grant his/her consent, according to the General Health Law, and the use of data was by someone subject to professional secrecy or similar.</p> <p>Likewise, the party responsible for safeguarding personal data will not be compelled to</p>

<p>cancel the personal data of the patient when he/she is subject to treatment for prevention or medical diagnosis, as long as the treatment is made by someone subject to professional secrecy.</p> <p>This was also foreseen under CENETEC's guidelines, as well as applicable law on data privacy and the NOMs.</p>
<p>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</p>
<p>The international communication of personal data may be deemed either a 'transfer' or 'remittance', depending on the purpose for communicating the personal data and the recipient of the data. Each of these communications must meet specific requirements, which are described below.</p> <p>Transfer of personal data</p> <p>Any transfer of personal data must be: (1) consented to by the data subject, except where exempted pursuant to the Data Protection Law; (2) notified to the data subject by means of a privacy notice; and (3) limited to those purposes that justify the transfer.</p> <p>A data controller would be able to transfer personal data without the consent of a data subject only if the transfer is, among others, needed for the prevention of an illness, or medical diagnosis, healthcare assistance, medical treatment or the management of health services.</p> <p>Remittance of personal data</p> <p>A remittance does not need to be notified to a data subject by means of a privacy notice nor does it require the consent of the data subject. However, to carry out the remittance, the data controller and data processor shall establish a relationship through either contractual clauses or any other legal instrument (eg a deferred prosecution agreement (DPA)) with the purpose of evidencing the existence, scope and content of the relationship, which should be consistent with the privacy notice delivered by the data controller to the relevant data subject. Additionally, certain specific obligations must be specifically included for the processors.</p> <p>Any international data transfer may be evidenced by either an agreement or any other document, whereby the third party assumes the same data protection obligations undertaken by the data controller, and the conditions for processing such personal data as consented to by the data subject and as detailed in the corresponding privacy notice. International data transfers do not require the approval of the National Institute of Access to Information (Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales or 'INAI') (which is the competent authority) or any other Mexican regulatory agency to be completed and there is no need to submit standard contractual clauses or comparable instruments to any of them.</p>
<p>23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?</p>
<p>NOM 024-SSA3-2012 – Electronic Health Registration Information Systems provides the criteria under which the exchange of information between electronic health record information systems, among which are electronic health records, must be generated, processed and retained, as well as the mechanisms under which the Health Service Providers of the National Health System shall register, exchange and consolidate the information.</p>
<p>LIABILITIES</p>

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

There is no express regulation on the liability of healthcare professionals regarding telemedicine practice; however, any healthcare provider is subject to the same liability as any other professional providing services, pursuant to standard duties of care and/or omissions under our civil law systems.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

According to a study by the Centre for Public Opinion at the Universidad Tecnológica de México ('UNITEC') in September 2021, which was presented to the Director of Telehealth of CENETEC, 74 per cent of people who answered the survey considered that Mexico should encourage telemedicine practice and 63 per cent agreed that this kind of service could be quite useful for solving problems regarding health coverage in the country.

26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

The pandemic has certainly demonstrated how useful telemedicine could be in solving problems, such as a better use of resources, having access to medical care in faraway areas of the country and early medical care. Mexico must keep up with this trend, and update its legislation and regulations in the sector, taking into account that its investment in the healthcare service sector is being reduced at a time when more quality healthcare services are required.