

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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LAWS AND REGULATIONS ON TELEMEDICINE

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

Telemedicine services are permitted in Spain, however, neither telemedicine nor teleconsultation services are specifically regulated or defined in Spain by legal or regulatory texts. Only Royal Decree 81/2014, establishing rules on cross-border healthcare (Royal Decree 81/2014) mentions the concept of 'telemedicine services' but does not define it.

Consequently, there is no legal definition of telemedicine, but there are some relevant references which help understand the concept and limits of telemedicine.

For example, the Spanish Code of Medical Ethics (the Ethics Code) does provide some guidance on what is permitted in the field of telemedicine/teleconsultation services. Article 26.3 of the Ethics Code sets out that 'the clinical practice carried out exclusively through telematic means is contrary to the medical ethical standards. The correct medical practice implies a direct contact between the Healthcare Provider (HCP) and patients'. However, the Ethics Code also states in Article 26 that:

'It is ethically acceptable to use email and other non-physical communication means and telemedicine, for second opinions (*segundas opiniones*) and medical check-ups (*revisiones médicas*), as long as the mutual identification is clear, and the right of privacy is guaranteed"; and

'Orientation systems for patients through phone consultation or telemedicine are consistent with medical ethics when such systems are used exclusively as a support tool for the decision-making process'.

The Spanish General Council of Official Medical Colleges has recently approved a new Code of Ethics which still needs to be presented to the official colleges and has not yet entered into force. It introduces a new chapter on information and communication technologies in the field of medical assistance. Article 103 of this new Code of Ethics states that:

'The use of telematic means or other remote communication systems aimed at assisting HCP within the decision-making process is in accordance with medical deontology provided that the identification of those involved and the confidentiality is ensured and provided that the communication methods implemented guarantee the maximum available security.'

In addition, a number of recommendations and guidance documents on the use of such services have been issued by competent health authorities and medical and scientific associations.

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

As mentioned in the response to Question 1 above, telemedicine services are not regulated by Spanish law. However, the following legal references help understand and legally design the provision of telemedicine services:

- Royal Decree 81/2014 mentions the concept of telemedicine services, but does not develop it. The reference is made with the purpose of defining the 'Member State of treatment' (defined as the Member State on whose territory the healthcare is actually

provided to the patient, being, in the case of telemedicine, the Member State where the healthcare provider is established).

- Law 34/2002, on information society services and electronic commerce (Law 34/2002). This Law sets out the information to which recipients of these services and the competent authorities must have access when services are provided by electronic means (ie, detailed contact information, identification of the competent authority to supervise the services, identification number of the service provider, together with codes of conduct to which it has adhered or professional qualifications).
- Royal Decree 1277/2003, which establishes the general basis for the authorisation of healthcare centres, services and premises (Royal Decree 1277/2003). This Royal Decree sets out that medical centres/medical units located in Spain that provide medical services (regardless of whether these services are provided on-site or online) need to be authorised by the relevant authorities.
- Royal Decree 1718/2010, on medical prescriptions and dispensing orders (Royal decree 1718/2010). This Royal Decree establishes a system for electronic prescriptions both made in the context of the healthcare services of the National Health System and in private medical practice.
- Law 3/2018, on the protection of personal data and guarantee of digital rights, together with the European Regulation 2016/769, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (Law 3/2018 and GDPR, respectively). These regulations do not foresee specific requirements for the processing, collection and hosting of personal health data arising out of the telemedicine services. However, the provision of these services is subject to the compliance of such regulations on data protection.
- Spanish Code of Medical Ethics referred to in the response to Question 1.
- Law 44/2003, on the organisation of the health professions (Law 44/2003). According to Law 44/2003, the exercise of the health professions shall be carried out in full technical and scientific autonomy, subject only to the limitations set out by law and subject to the principles and values set out in the applicable regulatory and deontological framework. Therefore, there is a consensus that HCPs can perform telemedicine services if they consider it appropriate from a scientific and technical point of view and in the light of ethical regulations.

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

Telemedicine services are not subject to a specific licence as such. However, medical centres/medical units providing healthcare (both face-to-face and electronically) are subject to prior authorisation which must be granted by the health authorities of the Spanish autonomous region in which the service provider is located, by virtue of Royal Decree 1277/2003. Please note that additional requirements to those set out in the aforementioned Royal Decree may apply in light of the regulations of the corresponding region (eg, licences granted by the Catalan authorities are governed by Decree 151/2017, on common technical-sanitary requirements and guarantees for healthcare centres and services, and licences granted by the Madrid authorities are governed by Decree 51/2006, on the legal regime and procedure for the authorisation and registration of healthcare centres, services and establishments).

These regional health authorities are competent to verify the service provider's compliance with the technical requirements established in the regional regulations.

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

Yes, telemedicine services were already in use before the Covid-19 pandemic. However, during this period, their use became widespread.

Because of the pandemic, the Spanish Ministry of Health issued information notes providing guidance to health centres on how to manage Covid cases telematically (Technical document 'Management and home care of Covid-19', dated June 2020). Among these recommendations,

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| <p>the Spanish Ministry of Health encourages medical centres to 'promote telephone and telematic consultations, leaving the need for a face-to-face assessment to the discretion of the professional after an initial telephone assessment'.</p> <p>Likewise, the official Medical Association of Catalonia published a document in 2020 entitled 'Deontological considerations in relation to information, consent and virtual consultation during the COVID-19 pandemic' and the Madrid Medical Association issued a document in March 2020, providing guidance on the use of telemedicine services as a consequence of the pandemic. These documents insist on the need for medical consultation not to be carried out exclusively by telematic means.</p> |
| <p>5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?</p> |
| <p>Post-pandemic has seen more recommendations and guidance documents aimed at defining the requirements for the legal and appropriate provision of these services, as there was no regulation setting out specific requirements.</p> <p>In addition to these recommendations and guidance documents, we are not aware of any draft regulations proposed or planned to regulate telemedicine services.</p> |
| <p>6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)</p> |
| <p>As there are no specific provisions regulating telemedicine services, there are no permitted and non-permitted teleservices. A specific telemedicine service can be provided in the light of the scientific and professional criteria of the HCP (Art 4.7 of Law 44/2003) in connection with the Code of Ethics. According to the Code, telemedicine shall only be considered appropriate for second medical opinions and medical reviews. Therefore, telemedicine services should exclude first medical diagnosis. See also the response to Question 1, above.</p> |
| <p>7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.</p> |
| <p>See the response to Question 6, above. Both scenarios are commonly used in Spain.</p> |
| <p>8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.</p> |
| <p>There is no specific funding model for telemedicine services as such.</p> <p>Reimbursement will depend, among other things, on the public or private status of the health centre rendering the medical services, and on whether the medical assistance is included in the services portfolio of the National Health System, regulated by Law 16/2003, on the cohesion and quality of the National Health System and Royal Decree 1030/2006, which establishes the portfolio of common services of the National Health System and the procedure for its updating.</p> <p>Please note that it is highly unlikely that a private clinic will be reimbursed by the Spanish public health system in Spain.</p> <p>Reimbursement by the private health system is possible in Spain once an agreement is reached with each private insurance company. To such effect, the healthcare centre in Spain needs to contact private insurance companies in Spain and negotiate an agreement with each of them. Once an agreement has been reached with a particular private insurance company, then such company will include the healthcare centre in its catalogue of service providers, so that the clients of the insurance company can benefit from its services. When that happens, the healthcare centre should be able to receive reimbursement from the private insurance company, pursuant to the terms and conditions contained in the agreement.</p> |
| <p>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</p> |
| <p>There are currently no insurance requirements applicable to telemedicine service providers.</p> |

| REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS |
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| 10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.) |
| <p>Telemedicine services are not limited to a specific healthcare profession.</p> <p>Article 4.7 of Law 44/2003 (mentioned in the responses to questions 2 and 6, above), which establishes the principle of technical and scientific autonomy, is applicable to all health professions regulated therein, that is: medical doctors, pharmacists, odontologists, veterinarians, nurses, physiotherapists, podiatrists, opticians, nutritionists, speech therapists, psychologists, biologists, and chemists, among others.</p> <p>Consequently, all the above-mentioned professions are expected to provide their respective care assistance in full scientific and technical autonomy and in compliance with their respective ethical rules. To our knowledge, only the Code of Ethics (applicable to medical doctors) refers to telemedicine services. However, this does not imply that other health professions are prevented from providing their care services by electronic means.</p> |
| 11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services? |
| <p>There are no education or training requirements for HCPs to provide telemedicine services.</p> |
| 12. Is there any registration requirement applicable to physicians that provide telemedicine services? |
| <p>There are no registration requirements for HCPs providing telemedicine services, apart from the regular registration with the relevant professional association.</p> |
| 13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services. |
| <p>No special licences are required for medical centres or institutions to provide telemedicine services.</p> |
| REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES |
| 14. Are there specific requirements applicable to the telemedicine platform? |
| <p>There are no specific requirements for telemedicine platforms other than those general requirements of the medical devices and data protection regulations.</p> <p>In the event that the telemedicine platform qualifies as a medical device, then European Regulation 2017/745, on medical devices (MDR) and Royal Decree 1591/2009, on medical devices (Royal Decree 1591/2009) and/or Royal Decree 1662/2000, on in vitro diagnostic medical devices (Royal Decree 1662/2000) must apply.</p> <p>In order for a telemedicine platform to qualify as a medical device, the platform must be used, according to Article 2.1 of MDR, for one or more of the following purposes: (1) the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease; (2) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; or (3) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.</p> <p>The most relevant obligation set out in MDR and Royal Decree 1591/2009/Royal Decree 1662/2000 is that medical devices placed on the EU market must bear a CE marking indicating the compliance of the platform/device with MDR.</p> |

The Medical Device Coordination Group of the European Union issued a Guidance document in October 2019 to help manufacturers identify whether their software platforms qualify as medical devices. (MDCG 2019-11. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.)

Telemedicine platforms must also comply with data protection regulations, which would require the data controller and/or the processor to implement (and verify that the telemedicine platforms used allow the implementation of appropriate technical and organisational measures to ensure an adequate level of security. This includes, but is not limited to:

- pseudonymisation and encryption of personal data;
- the ability to ensure the continuing confidentiality, integrity, availability and resilience of processing systems and services;
- the ability to restore the availability of and access to personal data in a timely manner in the event of a physical or technical incident;
- a process for regularly verifying, evaluating and assessing the effectiveness of the technical and organisational measures put in place to ensure the security of the processing.

In addition to data protection regulations, public healthcare centres must comply with the technical instructions on security that – in all areas of the centre – are determined by the National Security Scheme (ENS), in accordance with Royal Decree 311/2022, which regulates the National Security Scheme (Royal Decree 311/2022). The specific requirements applicable to the telemedicine platforms depend on the specific scenario which might be faced, among the following three cases: (1) a case in which the holder of the tool/platform used in telemedicine does not have the status of data processor and therefore does not act on behalf of or under the instructions of the controller; (2) a case in which the owner of the telemedicine tool/platform has the status of data processor and therefore has access to patients' personal data on behalf of and under the guidance of the controller (this case would require a data processor agreement) and; (3) a case in which the healthcare operator, as the data controller, develops the telemedicine tool/platform themselves or with their own company's IT staff.

Most common scenarios would be (1) and (2).

A general overview of the requirements for scenario (1) would be: to select tools that incorporate end-to-end information encryption methods to guarantee security and confidentiality, preferably TLS technologies; to avoid instant messaging services, such as WhatsApp or Telegram, for messages containing health data; to select providers that can guarantee and demonstrate that their tools comply with data protection regulations; to select tools that are designed and recommended for use in the healthcare environment; to encrypt information containing health data in emails with patients or to check that the location of the servers is within the European Union.

A general overview of the requirements for scenario (2) would be, in addition to the relevant and applicable requirements of scenario (1), such as the use of TLS technologies or location of servers within the European Union, the following: to implement measures to ensure data availability; to implement systems to restore availability and access to personal data quickly in the event of a physical or technical incident; to determine measures to ensure data traceability and access to medical record management if the tool/platform provides for it; to limit access by supplier company staff; to oversee subcontracting chains; to check the credentials of suppliers by requesting security certifications or the latest data protection audit; to implement protocols in relation to security breaches both for the company's own staff and for data processors.

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

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| There are no specific requirements for electronic equipment or specific speed for telemedicine services. |
| 16. Does the legislation provide for specific rules concerning patients' medical records? |
| There are no specific rules for patients' medical records other than general requirements set out in Royal Decree 1093/2010, approving the minimum set of data for clinical records in the National Health System (Royal Decree 1093/2010), GDPR and Law 3/2018, as well as specific technical requirements mentioned in the response to Question 14, above. |
| 17. Are there geographic location requirements applicable to the provision of telemedicine services? |
| There are no specific requirements. However, please note that according to recital (19) of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (implemented in Spain by Royal Decree 81/2014), in cases where a patient receives cross-border healthcare, the rules applicable to cross-border healthcare should be those laid down in the legislation of the Member State of treatment. Under Article 3.d) of the Directive, 'Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established. Article 3.8 of Royal Decree 81/2004 connects the definition of 'healthcare provider' established by Directive 2011/24/EU (ie, 'any natural or legal person or any other entity legally providing healthcare on the territory of a Member State') with that of a 'healthcare centre' (ie, the brick-and-mortar premises from which the doctor renders healthcare services, including telematic healthcare services). In view of this, as long as the premises are located in Spain, the healthcare services are deemed to be provided in Spain. |
| 18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth? |
| <p>The use of telemedicine services by an HCP does not require a specific patient consent. However, it is advisable to seek conformity of the patient to use this alternative means for the provision of the medical assistance.</p> <p>From a data protection point of view, there is no obligation to require a new consent of the patient as long as the purpose of the processing remains the same, unless, when introducing telemedicine services for the provision of medical care, the purpose of the processing is changed.</p> |
| 19. Is there any other important requirement that should be highlighted? |
| No additional requirements need to be highlighted. |
| DATA PRIVACY ASPECTS |
| 20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description. |
| <p>Law 3/2018, which complements the GDPR in Spain, does not foresee additional requirements for the processing, collection and hosting of personal health data. Besides, Article 17.1 of Law 41/2002, on Patient's Autonomy (Law 41/2002) states that patients' medical data shall be kept for as long as necessary in each case and for at least five years from the date of discharge of the patient in respect of each healthcare process. In any case, such information shall be stored in a manner that assures that its security, proper retention and recovery is guaranteed (Art 14.2 of Law 41/2002). All persons having access to patients' medical data shall be subject to the duty of confidentiality (Art 16.6 of Law 41/2002).</p> <p>To our knowledge, the Spanish Data Protection Agency has not issued particular guidance/informative notes on data protection particularities for telemedicine/teleconsultation services providers.</p> |

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| 21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information? |
| There are no specific criteria and requirements for the security systems of patient's information other than the general requirements set out in data protection regulations and regulations for the National Security Scheme. See the response to Question 14, above. |
| 22. Does the applicable regulation provide for requirements for the transfer of information abroad? |
| The transfer of personal data is subject to GDPR and Law 3/2018. This means that the controller must inform the data subject of the transfer of personal data to a third country or international organisation, and that such transfer must be based on an adequacy decision of the EU Commission (Art 45 GDPR), or on adequate guarantees offered by controller (Art 46 GDPR) or, in the absence of them, on compliance of conditions indicated in Article 49 GDPR. |
| 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? |
| There are no specific registration obligations for telemedicine providers other than those set out in data protection regulations (ie, Art 30 of GDPR for records of processing activity). There are no specific rules for telemedicine services regarding the recording of data in the patient's medical records. General requirements for the recording of medical records set out in Royal Decree 1093/2010, GDPR and Law 3/2018 apply, together with specific technical requirements mentioned in the response to Question 14, above. |
| LIABILITIES |
| 24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices. |
| Professional civil liability consists of the obligation of medical doctors to make good the consequences of their professional acts and of omissions and errors committed in the exercise of their profession that have caused damage or harm to a patient, provided that the necessary means or due care have not been taken in the care of a patient, whether due to negligent conduct or due to a breach of the <i>lex artis</i> . Professional civil liability is set out in the Spanish Civil Code (Art 1,544 <i>et seq</i> in connection with Art 1,091 of the Civil Code). When a medical act is provided electronically, all legal consequences apply, including the regular regime for the civil professional liability. It must be noted that the liability of doctors is not linked to the results, but to the failure to provide adequate means in accordance with the circumstances and the risks inherent in each procedure. It must also be noted that many professional liability policies expressly exclude from its coverage medical acts carried out by telematic or remote means. Other than the professional civil liability, which may be enforceable to HCPs by courts in the context of a judicial claim, HCPs are also subject to the disciplinary regime of the relevant professional association in case of non-compliance with the applicable ethical rules. |
| TELEMEDICINE NUMBERS AND TRENDS |
| 25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country? |
| We are not aware of any official studies on the prevalence of telemedicine services. The relevant public body for statistical studies in Spain is the National Institute of Statistics or <i>Instituto Nacional de Estadística</i> (INE), but no such studies have been published in the INE database. |

According to the Capterra platform (international telemedicine survey, 2021) 62 per cent of Spanish patients have used teleconsultation systems at least once (<https://www.capterra.es/blog/2053/telemedicina-en-espana-utilizada-por-mayoria-de-pacientes>).

The Council of Medical Associations of Catalonia carried out a market study addressed to HCPs, during March and April 2021 (<https://www.comb.cat/pdf/publicacions/qbp/praxi37-en.pdf>), on the implementation of telemedicine services in private practice. According to the results, 64 per cent of those surveyed provided teleconsultation services (representing the 17.5 per cent of total consultations). The pandemic has been a major boost to non-face-to-face consultation in the private sector. Whereas before the pandemic only 30 per cent of respondents made non-face-to-face visits, (representing an average of only ten per cent of total visits), during the first wave of the pandemic, 74 per cent of respondents did so at some point (an average of 61 per cent of total visits).

On the other hand, 80 per cent of patients' medical records are computerised, can be accessed by other professionals in the team (80 per cent) and are connected to other services in the centre (64 per cent). Only 48 per cent of these professionals have an online diary and 39 per cent have the possibility of writing electronic prescriptions. Only 13 per cent of the professionals consulted have an integrated system of medical records, video consultation and prescription on a telemedicine platform.

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.

We are not aware of any proposed new Spanish legislation aimed at regulating telemedicine services. According to the Council of Medical Associations of Catalonia, for the moment, it does not seem that this regulation is necessary or, at least, indispensable, since in our legal system, and in the EU framework, we find rules that are applicable and that must be observed in the same way in the face-to-face and remote consultation.

This is irrespective of the EU proposal for a Regulation setting out harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain EU legislation, which will affect medical devices regulations.

Expected market trends can be summarised as follows:

- Telemedicine is a growing trend and HealthTech is increasingly accepted by the Spanish population.
- The sector has been shifting the focus of attention towards the consumer, with thousands of apps on the market offering a wealth of information, as well as wearables for tracking information in real time, so that the user can make better health decisions.
- In recent years, a multitude of new Spanish start-ups have emerged with innovative ideas around the digital transformation of healthcare.
- Digitalisation has, in many cases, been rushed, and will need to be improved in the future.