

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?
<p>Telemedicine is allowed in Portugal and provided for in Regulation No 707/2016 of 21 July (the 'Medical Deontology Regulation'). Article 46 and the following articles of the mentioned legal diploma outline the regime for telemedicine. However, that legal diploma does not provide a definition of telemedicine.</p> <p>The World Health Organization defines telemedicine as 'the provision of health services through the usage of information and communication technologies, when distance is a critical factor'.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>Telemedicine has to be compliant with the following legal diplomas, among others:</p> <ul style="list-style-type: none">• Portugal's 'Basic Health Law' (Law No 95/2019 of 4 September, which is the base diploma for the Portuguese Health System);• Medical Deontology Regulation;• Decree-Law No 282/77 of 5 July (Statute of the Physicians Association);• Regulation (EU) 2016/679, of the Parliament and the Council, (the 'General Data Protection Regulation' or GDPR);• Law No 58/2019, of 8 August (assures the execution, in the Portuguese Regulatory framework, of the GDPR);• Law No 24/96 of 31 July (Consumer Defence Law); and• Ministry of Health's Dispatch No 8445/2014 regarding telemedicine.
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>The licensing bodies for telemedicine are the same as those responsible for controlling the provision of medical services generally.</p> <p>The key regulatory body for health services in Portugal is Entidade Reguladora da Saúde (ERS or the Health Regulating Entity), which is responsible for both the licensing and control of medical and similar activities in the Portuguese legal framework, and is an independent administrative authority specifically created for this sector.</p> <p>Any establishment or individual liberal professional not integrated into an office or practice that provides medical services in Portugal, needs to register with ERS, also paying an administrative fee and contributions, as long as the services are provided, as per Regulation No 66/2015 and Decree-Law No 126/2014 of 22 August. In addition, ERS is responsible for controlling entities that are subject to the registration requirement and for applying administrative fines for non-compliance with all of these legal and regulatory obligations.</p> <p>As per Decree-Law No 126/2014, ERS's key responsibilities are as follows:</p> <ul style="list-style-type: none">• supervision of activity in the health sector;• controlling compliance with the requirements for the provision of medical services and functioning of establishments in Portugal;• assuring the citizen's rights to access medical care and quality of provision of health services;

- legality and transparency of economic operations among operators, financial entities and users of the services; and
- provide information, studies and legal opinions for questions specifically predicted in law.

To elaborate further, ERS also has the following responsibilities:

- regulation objectives (Article 10 of the aforementioned diploma);
- control over the functioning requirements for health service provision establishments (Article 11);
- assuring access to healthcare (Article 12);
- defence of user's rights (Article 13);
- assuring quality in the provision of health services (Article 14);
- economic regulation in the sector (Article 15);
- promotion and defence of competition in the sector (Article 16); and
- the power to regulate and supervise activity in the sector (Articles 17 and 19).

In addition to this entity, the Physicians Association (Medical Professional Public Association) is responsible for controlling compliance with all legal diplomas that regulate the ethics and compliance of medical legislation when it comes to the conduct of physicians and their respective decision-making, as per the Medical Deontology Regulation and Decree-Law No 282/77 of 5 July (Statute of the Physicians Association).

In addition, the Ministry of Health is responsible for the general oversight of health in Portugal. Nonetheless, it does not specifically oversee telemedicine issues.

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

Yes. Not only was it authorised, it was incentivised by the government through Dispatch 5314/2020 of the Portuguese Ministry of Health.

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?

As of now, no news has arisen in Portugal concerning this matter. Given that the provision of telemedicine services in Portugal is very free and liberal, as of now, being a standard practice, for example, for people with reduced mobility or older people, we predict no significant changes will occur in the future. If they do, better possibilities or tighter requirements will be established in the future when it comes to the provision of telemedicine services.

6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis and telesurgery)?

According to Regulation No 707/2016, teleconsultations in general are allowed.

General duties of care are imposed on doctors when performing teleconsultations (Articles 46, 47 and 48 of the aforementioned regulation):

- The doctor needs to have a clear and justifiable idea of the patient's clinical situation before performing a teleconsultation.
- The doctor must perform a thorough analysis of the information received and can only provide opinions, recommendations or make medical decisions if the quality of the information received is sufficient and relevant.
- The doctor can refuse to perform teleconsultations, if that is to be the case.
- The doctor is not obliged to issue an opinion if he/she does not have enough knowledge to issue an opinion but, if he/she does, he/she is fully responsible for the opinion provided to the patient.
- The doctor can only perform teleconsultations after assuring that the team responsible of its performance assures a sufficient level of quality and evaluation procedures to monitor

the quality of the information received
7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.
Every legal individual person can use teleconsultations under Portuguese law.
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.
Every hospital in the public system offers teleconsultation services, as well as those in the private system. As of now, teleconsultations are not mandatorily included in health insurance, despite the fact that most insurance companies include them in their standard packages in Portugal.
All applicable legislation is the legislation mentioned above.
9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.
No insurance requirements specifically apply to telemedicine service providers.
REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS
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).
<ul style="list-style-type: none"> • In Portugal, telemedicine can be practised by doctors, as per the legislation described above. • Nurses were allowed to provide telenursing consultations during the Covid-19 pandemic; however, no specific legislation has been published concerning this specific issue. • The Association of Psychologists issued recommendations during the pandemic encouraging psychologists to provide consultations online. In general, it has mentioned that the provision of distance-consultations by these professionals is a provision of a psychology service, and is generally permitted and must comply with the applicable legislation. • As for alternative health therapy providers, no specific legislation exists regarding this issue.
11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?
The requirement to provide telemedicine services by any of the professionals mentioned above is the need to have the academic credentials that qualify them as professionals in the mentioned area. Besides the standard qualification for these professionals, no specific requirements are necessary to provide or attend telemedicine services.
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
Not specifically. Physicians need to be registered with the Physicians Association, but the law does not impose a specific registration requirement for the provision of telemedicine services.
13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

No special licenses are necessary for the provision of telemedicine services.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
No. The platform needs to comply with the GDPR and applicable national data protection legislation, as well as the doctor's confidentiality obligations concerning telemedicine, as provided in Articles 46, 47 and 49 of Regulation 707/2016.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
No specific requirements apply, besides the inherent obligation of having equipment that allows doctors to comply with the obligations stated in the fields above.
16. Does legislation provide for specific rules concerning patients' medical records?
No, as explained above, the applicable legislation mentions the obligation to comply with doctor's confidentiality obligations and the applicable data protection legislation. In addition, the rules also need to comply with the applicable law concerning access to medical records, which is Law No 12/2005 of 26 January ('Personal Genetic and Health Information'), which establishes purpose determination and standard confidentiality obligations concerning medical records.
17. Are there geographic location requirements applicable to the provision of telemedicine services?
No, the applicable legislation does not contain any geographic location limitations.
18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?
Yes, because that is the general rule in the practise of medicine under Portuguese Law. Under the telemedicine chapter of Regulation 707/2016, that obligation is reinforced by paragraph 5 of Article 47, which mentions the need to inform and obtain consent from the patient under the terms of the mentioned regulation.
19. Is there any other important requirement that should be highlighted?
No.
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.
Yes. Professionals, in particular, individual/liberal professionals, need to comply with the applicable data protection legislation mentioned in item 2 because they might be considered as either controllers or a processor for the processing of personal data. Nonetheless, the GDPR requirements are an addition to the already existing confidentiality obligations that apply to any of the professionals mentioned in item 10.
21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?
Yes. GDPR requirements apply to this situation because these would be considered personal data processing activities according to the mentioned legal diploma. As the patients are considered data subjects, the diploma applies to them in full.

In addition, Law No 58/2019 applies, as well as Ordinance No 247/2000 of 8 May, Ordinance No 157/2004 of 19 August concerning archives for hospitals and services of the Ministry of Health, Law No 12/2005 of 26 January and Law No 26/2016 of 22 August regarding access to documents and administrative information.

The standards set forth in this diploma, as a whole, set confidentiality and personal data processing rules to be compliant with the GDPR, as well as rules that determine who can access patient information and how that information can be transferred among stakeholders.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

Yes. The GDPR sets out specific obligations concerning personal data transfers when those are made to countries outside of the scope of the GDPR ('International Data Transfers'). Under those rules, both the data exporter and importer need to adopt one of the tools provided for in the regulation in order to assure the safety and legality of data transfers.

However, if transfers are made in the European Economic Area (EEA)/European Union, the GDPR requirements apply in general, but not the specific requirements concerning international personal data transfers.

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?

Yes. All the legislation provided above applies in full.

Article 6 of Law 26/2016 determines the need to establish restrictions to the right of access by stakeholders, setting rules for third-party access to information.

In addition, Article 2 of Ordinance No 247/2000 of 8 May sets the need to establish procedures for hospitals when it comes to the archiving of information, as well as determining specific conservation deadlines in its Annex I and rules for the disclosure of such information in Articles 5 and 6.

In addition, Article 5 of Decree-Law 131/2014 of 29 August establishes requirements for the constitution of databases regarding genetic information, namely demanding the consent of the data subject under the GDPR, the need to perform preventive or healing medicine and authorisation from the National Data Protection Commission, which is the Portuguese Data Protection supervisory authority.

All of these diplomas set even more specific requirements depending on the purpose of the usage of the information.

LIABILITIES

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

Liability for doctors that provide telemedicine is whole. Regulation 707/2016 states, in Article 47, paragraph 3, that doctors are fully responsible for the advice provided in a telemedicine consultation. Generally speaking, doctors can be held liable for the advice provided, under the general provisions of the Portuguese Civil Code.

TELEMEDICINE NUMBERS AND TRENDS

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

Yes. The Portuguese Ministry of Health provides statistics concerning the usage of telemedicine in Portugal. Here are some of the statistics:

- Monthly, an average of 4,254 teleconsultations are performed in our jurisdiction.
- Out of those consultations performed for the first time, 12,892 consultations were subsequently provided in 2022.

Further information can be found on this website: www.sns.gov.pt/monitorizacao-do-sns/consultas-em-telemedicina.

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 general perspective for this issue is of growth in utilisation because the Portuguese population is growing older and has mobility issues, which will determine the need to utilise long-distance service provision methods to attend to patients' clinical needs.

In addition, and because there was a boom in these sorts of practices due to Covid-19, we predict an increase in regulation and the adoption of more specific measures targeted to telemedicine.

As of now, the biggest concern regarding telemedicine practice is how it may affect the evaluations performed by doctors in the first analysis. As must be easy to comprehend, a physical first analysis has a much higher chance of being precise compared with a long-distance evaluation. As such, we predict an increase in use of the tool for standard, routine, check-up medicine. For more complex practices and issues, we believe that doctors will be afraid of providing definitive opinions because of the possible liability issues, thus preferring to go and meet patients at their homes in order to more thoroughly evaluate their condition and issue professional opinions.