

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Ioanna Michalopoulou, Evangelia Manika and George Skampoulos, Michalopoulou & Associates

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LAWS AND REGULATIONS ON TELEMEDICINE

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

Telemedicine is allowed in Greece but is not clearly defined. The World Health Organization (WHO) defines telemedicine as the:

‘delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities’.

Moreover, according to the European Commission, telemedicine can be defined as:

‘the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients’.

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

Extensive legislative initiatives on telemedicine have not yet been undertaken in Greece. There is only one main provision for telemedicine services in the Greek legislation. More specifically, Article 66 paragraph 16 of Law 3984/2011, ‘Regulation of issues of the Health and Welfare Services Inspection Body, E.K.A.B. and hospitals’, foresees that:

‘Telemedicine services are provided as long as there is the possibility and with the responsibility of the attending physician dealing with each case. The attending physician, for reasons of personal data protection, is responsible for requesting from the patient or if this is not possible from a first-degree relative, the signed approval for the use of Telemedicine services. If this is not possible, then the attending physician uses Telemedicine services at his discretion. The instructions of the Hospitals and Health Units that provide Telemedicine services are advisory and in no case mandatory.’

Furthermore, Article 33 of Law 4633/2019 about the Establishment of a National Public Health Organisation, regulations on tobacco products, inter alia, foresees the following:

‘Article 33. Establishment of an Independent Department of Health Operations at E.K.A.B. and a Unified Business Coordination Centre E.K.A.B. 1. is composed at E.K.A.B. Independent Department of Health Operations, which is directly subordinated to its

President. The Department has the following responsibilities: [...] g. the responsibility for the operation of the Telemedicine system’.

It should be noted that the organisation of some public hospitals includes the operation of a telemedicine unit (eg, at the General Hospital of Alexandroupolis), (Ministerial Decision No 39504/2012).

In addition, the Ministerial Decision No 67659/2013 on Modification of the Special Framework for Spatial Planning and Sustainable Development for Tourism states telemedicine as a special technical infrastructure in sector (G) Health, especially for inaccessible mountainous or island regions. In particular, Article 7 states that “in priority tourism areas, the following is required: In mountainous and island areas with poor accessibility, the immediate promotion of telemedicine applications is at least required’.

Moreover, the recent amendment of the Penitentiary Code by Article 28 of Law 4985/2022 provides, inter alia, that “[...] in case of Penitentiary Establishments operating in remote or inaccessible areas, medical monitoring and clinical assistance to prisoners may be provided remotely, using telemedicine services, in accordance with paragraph 16 of Article 66 of Law 3984/2011.

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

There is no special licence for telemedicine services. In general, it should be noted that there are some bodies responsible for the licensing of private clinics, namely the Private Clinics Committee and the relevant Regional Governor, while physicians may render health services only if they are licenced by the Panhellenic Medical Association.

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

During the Covid-19 pandemic, telemedicine was authorised in an exceptional manner and for the duration of the Covid-19 health crisis in Greece by the Legislative Content Act 13/2020 (Article 19), which was ratified by Article 1 of Law 4690/2020. In addition, the Ministerial Decision No 80610/2021 foresees the creation of a Teleconsultation System for patients with Covid-19.

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?

Social distancing guidelines and stay-home orders have led thousands of patients to experience telemedicine for the first time; these changes are expected to apply not only until the end of the pandemic but to make telemedicine mainstream in our everyday lives. In particular, in the post-pandemic scenario there is a likely possibility of telemedicine’s regulatory landscape being changed. Telemedicine should be regarded as a vital tool that could be upgraded and be available for patients and attending physicians in the future. Therefore, a new extensive legal framework for telemedicine is needed in order for the facilitate access and the sustainability of telehealth to be ensured.

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

There is no specific provision. However, there is no legislation that is considered an obstacle to the implementation of telemedicine services. Practically saying, types of teleservices that are used in Greece are, among others, (i) tele-consulting; (ii) remote discussions between the physicians; (iii) telediagnosis; (iv) telesurgery; (v) telemonitoring; (vi) tele-training; (vii) emergency telemedicine and (viii) tele-psychiatry.

7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.

There is no specific provision. In general, anyone who has expressly consented to telemedicine consultation can enjoy telemedicine services, as long as the attending physician does not refuse to telemedicine and indicates, otherwise, the need of in-person medical consultation. Both doctor-doctor and patient-doctor telemedicine services are allowed.

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.

Telemedicine services are mainly (almost exclusively) offered by the public sector in Greece, through the network of hospitals of the National Health Service. It has been published that the government is in the process of drafting new legislation towards this. The Greek National Telemedicine Network (EDIT) is to be extended throughout the whole territory in order to meet the needs of patients residing in remote areas.

In addition, telemedicine services are provided through private hospitals and/or private healthcare units.

As regards the insurance coverage, in general, reimbursement schemes of telemedicine services remain vague, heterogeneous or even non-existent. While some telemedicine services are eligible for reimbursement, patients still bear the cost in the majority of them. In addition, reimbursement from health funds often takes place only if specific conditions are met (eg, the service was provided at a doctor's office, or a patient lived in a rural area). Therefore, telehealth is not under mandatory insurance coverage in Greece.

9. Please indicate whether any insurance requirements applicable to telemedicine services providers.

There are currently no insurance requirements applicable to telemedicine services 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, alternative health therapies providers, etc).

The regulation regarding licensing healthcare professionals is extensive in Greece. Doctors, nurses, dentists, physiotherapists, psychologists, pharmacists and nutritionists, for instance, all must comply with a long list of requirements to be eligible to exercise their profession.

The possibility for physicians to implement telemedicine services is directly derived from paragraph 16 of Article 66 of Law 3984/2011 which, as mentioned above, is the main legislative provision regulating telemedicine.

With regard to other healthcare professionals, the individual codes of conduct in force, do not foresee anything about the provision of services via telemedicine. The silence of the law, however, should not be interpreted as a prohibition on providing services via telemedicine.

Practically saying, many healthcare professionals use telemedicine services, on a daily basis.

11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?

There is no further education or training required for physicians to provide telemedicine services.

The EDIT organises semi-annual training seminars for users of the services of the national telemedicine system. However, this is a practical need rather than a legal commitment.

In particular, with regard to robotic surgery, it is worth mentioning that the necessary knowledge and training is provided to surgeons as part of their medical specialty.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

Any physician facing a related medical case can resort to providing services via telemedicine without the need of any other procedure. According to the above-mentioned paragraph 16 of Article 66 of Law 3984/2011, the attending physician shall use telemedicine services at their discretion.

Telemedicine is simply considered a more specialised form of medical service provision.

13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

There are not any special licences or authorisations.

In general, with regard to the health units that are part of the National Health System, any telemedicine systems are approved by the boards of directors of the relevant Regional Councils.

In the case of private medical service providers, supervision is exercised by the Ministry of Health.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

The most comprehensive effort that has been made so far in terms of the use of telemedicine and its penetration both into the community of healthcare professionals and into the beneficiary population is the EDIT, which is a part of the National Health System.

The Greek National Telemedicine Network is a network of telemedicine stations which connects central hospitals in Athens with remote Aegean islands and which started its productive operation in 2016. Medical staff will be able to be 'transported' digitally to the patient's location, eliminating the distance between central hospitals and remote islands. This obviously reduces unnecessary travel, workload and waiting time in outpatient clinics, as well as transport and hospitalisation costs. Telemedicine units enable uninterrupted and direct communication between doctor and patient, while medical and nursing staff have access to high quality tele-training services wherever they are based.

A public tender was launched in February 2022, in order for the Greek National Telehealth Network to have nationwide coverage.

In addition to the above-mentioned public system, a variety of telemedicine platforms have been created from time to time. A typical example is the first Greek telemedicine application in ophthalmology, which was created in September 2022 in the framework of the 'Low Vision Assistance Programme' of the Department of Medicine of the Aristotle University of Thessaloniki.

Telemedicine platforms must be accurate and safe for the patients who use them, as any error in patient treatment resulting from misuse or maintenance of the platform is a cause of liability for any potential damage.

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

There is no relevant legislative provision, but since there is an individual constitutional right of every patient to receive medical care in accordance with the generally accepted rules of medical science, any defect in the maintenance or operation of the medical equipment may lead to the liability of either the doctor performing the medical act or the clinic for any damage suffered by the patient as a result of these defects.

16. Does the legislation provide for specific rules concerning patients' medical records?

Telemedicine consultation services must be recorded in physical medical records or other information systems, in compliance with rules applicable to medical records in general.

The relevant provision is found in paragraph 1 of Article 14 of Law 3418/2005 which states that: 'the physician is obliged to keep a medical record, in electronic or non-electronic form, which contains data that are properly or causally related to the illness or health of his patients'.

There is no specific provision regarding telemedicine services.

17. Are there geographic location requirements applicable to the provision of telemedicine services?

In principle, distance is a key factor in the provision of telemedicine services. However, due to the wide discretion granted to the physician by paragraph 16 of Article 66 of Law 3984/2011 regarding

the possibility of resorting to telemedicine methods and the rapid spread of the Covid-19 pandemic, the distance factor has, to a large extent, been dampened in practice.

18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?

According to paragraph 1 of Article 12 of Law 3418/2005, 'The physician is not allowed to perform any medical act without the prior consent of the patient'.

The legal necessity of the existence of the patient's prior consent as a prerequisite for the legality of any medical act applies both to acts performed in the physical presence of the patient and to those performed through telemedicine methods. Therefore, that general provision leads to the conclusion that the patient's prior consent would also be necessary for any medical act carried out by telemedicine.

The Greek legislator, however, in paragraph 16 of Article 66 of Law 3984/2011, highlighted the importance of the patient's or first-degree relative's consent in case the latter is not able to consent, stipulating that, 'The attending physician is responsible for requesting from the patient or, if this is not possible from a first-degree relative, the signed consent for the use of telemedicine services'.

19. Is there any other important requirement that should be highlighted?

A necessary condition for the validity of the patient's consent is that the patient must be fully and clearly informed before the medical act is performed by the doctor regarding their actual state of health, the content and results of the proposed medical operation, the consequences and possible risks or complications of its performance, the alternatives, and the possible time of recovery, while a medical operation without consent may be carried out only in urgent cases.

In cases where more than one physician is involved in the patient's care, the attending physician should inform the patient in advance that medical procedures may be mediated by another specialist physician via telemedicine, in order to obtain the corresponding consent.

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.

Yes, there are data privacy issues that should be considered for the exploitation of the telemedicine market. The patients' personal data in the medical records must be preserved, obeying privacy and professional secrecy of the information set forth in the applicable legal framework (particularly, the General Data Protection Regulation (GDPR), Law 4624/2019, Law 3984/2011, Legislative Content Act 13/2020, Law 3418/2005).

21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?

Yes, the applicable legislative framework provides for general criteria and requirements for the security systems to protect the patient's information. In particular, personal data collected during the provision of telemedicine services must comply with the rules set forth in the GDPR and the implementing Greek Law 4624/2019 for the protection of personal data.

In general terms, according to Article 9 paragraph 1 of GDPR, the procession of health data shall be prohibited. GDPR only allows for the processing of special categories of personal data (including health data) in case there is a valid legal basis attributed for the processing (Art 9 para 2, GDPR). In particular, in the case of telemedicine, the processing of patient's data and their companions' data, could also be based on the provisions of paragraphs (c), (h) and (i) of paragraph 2 of Article 9 of GDPR. Also, GDPR establishes some principles (Art 5, GDPR), which must be observed in all data processing operations (eg, lawfulness, fairness and transparency, among others) and the obligation of guaranteeing all data subjects' rights set forth by GDPR.

Particularly regarding the security of systems, GDPR foresees some criteria and requirements to be adopted in order to ensure the protection of personal information. In particular, either the 'Controller' or the 'Processor' shall adopt appropriate technical and organisational measures to ensure a level of security appropriate to the risk, including, inter alia, as appropriate:

- (a) the pseudonymisation and encryption of personal data;
- (b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
- (c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident; and
- (d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing (Article 32, of GDPR).

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

Yes, according to GDPR (Art 44–50) 'a transfer of personal data to a third country or an international organisation may take place where the Commission has decided that the third country, a territory or one or more specified sectors within that third country, or the international organisation in question ensures an adequate level of protection.' Such a transfer shall not require any specific authorisation.

Alternatively, in the absence of the above-mentioned decision, a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available. The appropriate safeguards may be provided for, without requiring any specific authorisation from a supervisory authority, by:

- (a) a legally binding and enforceable instrument between public authorities or bodies;
- (b) binding corporate rules in accordance with Article 47 of GDPR;
- (c) standard data protection clauses adopted by the Commission in accordance with the examination procedure referred to in Article 93(2) of GDPR;
- (d) standard data protection clauses adopted by a supervisory authority and approved by the Commission pursuant to the examination procedure referred to in Article 93(2) of GDPR;

- (e) an approved code of conduct pursuant to Article 40 of GDPR together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights; or
- (f) an approved certification mechanism pursuant to Article 42 of GDPR together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights.

Furthermore, subject to the authorisation from the competent supervisory authority, the appropriate safeguards may also be provided for, in particular, by:

- (a) contractual clauses between the controller or processor and the controller, processor or the recipient of the personal data in the third country or international organisation; or
- (b) provisions to be inserted into administrative arrangements between public authorities or bodies which include enforceable and effective data subject rights.

It should be noted that the Commission issued an updated version of standard contractual clauses under the GDPR (Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council) for data transfers from controllers or processors in the European Union/European Economic Area (EEA) (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR), which replace the three sets of standard contractual clauses (SCCs) that were adopted under the previous Data Protection Directive 95/46. The new SCCs reflect the requirements of GDPR, as well as the judgments reached by the Court of Justice of the European Union (CJEU) in the *Schrems II* judgment and ensure a high level of protection of personal data, taking into account the challenges faced by businesses in the modern digital era.

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 is no special registration of databases requirement regarding telemedicine that companies must observe.

Regarding the recording of data, in accordance with Article 14 of Law 3418/2005, the physician is obliged to keep a medical record, in an electronic or non-electronic form, which contains data that are properly or causally related to the illness or health of his patients. As stipulated in the above-mentioned article, the patient's record must be kept for ten years from the last visit of the patient in private practices and for 20 years in other cases.

Moreover, the provisions regarding the protection of personal data shall apply. In particular, GDPR and Law 4624/2019 must be observed. The way in which the confidentiality of patient data is ensured varies depending mainly on the way that the records are kept. For example, in case of the hardcopy record, it should be ensured that it is not accessible to any unauthorised third party. In addition, regarding the electronic record, the physician must in any case apply technical security measures such as using a strong, difficult password to access systems and applications or encryption.

LIABILITIES

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

First and foremost, a distinction must be made between healthcare professionals working in the public and private sector.

Doctors and healthcare professionals in general who work in public healthcare facilities are considered to be public employees. As a result, they are not personally liable to patients for any fault occurred in the patient's treatment. In this context, the patient can take action against the public healthcare facility (eg, hospital, clinic) and claim compensation for the damage caused by the incorrect or defective provision of services through telemedicine. The public healthcare facility, after compensating the patient, is able to take action against the natural person only if the latter was fraudulent or grossly negligent regarding the defective provision of medical services (Article 38 paragraph 1, Law 3528/2007).

Regarding doctors working in the private sector, it is worth mentioning the following:

The doctor and the patient are linked by a medical treatment contract. The physician's basic contractual obligation is to provide the agreed medical services in accordance with the generally accepted rules of medical science. If the provision of medical services is for any reason defective, then the doctor is in breach of contract and is liable to compensate the patient for the damage caused.

The defective fulfilment of medical services via telemedicine falls within the broader concept of medical malpractice. Therefore, in addition to the intra-contractual liability of the doctor, the physician is also liable to the patient under the provisions of tort liability (Article 914 of the Greek Civil Code). Tort liability is a form of extra-contractual liability and may lead to compensation of the patient whenever the physician has committed a medical malpractice.

When more than one doctor has been involved in the treatment process and commits a medical malpractice either jointly or separately, they are severally liable to the patient (Article 926 of the Greek Civil Code).

Finally, when the physician works in an organised, private medical services unit and there is a defective performance of services through telemedicine, then the patient can also take action against the private unit in order to recover damages.

In all the above cases, the healthcare professional must be at fault, so as the liability could be established.

TELEMEDICINE NUMBERS AND TRENDS

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

Through the Greek National Telemedicine Network, more than 10,000 telemedicine appointments in ten different specialties have been made from 2016 until 2022 with the cooperation of 200 certified doctors and nurses of the National Health System.

Although telemedicine services are increasingly being used in practice (creation and expansion of the Greek National Telemedicine Network, telemedicine has not sufficiently replaced the traditional methods of providing medical services so far.

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 most important trends/proposed solutions/unresolved issues are the following:

1. establishment of a new, modern and uniform legal framework that will define the general conditions for the provision of telemedicine services in Greece;
2. mandatory training of healthcare professionals in the use of the relevant technology systems; and
3. completion of the expansion of the Greek National Telemedicine Network so as to cover more geographical areas.