

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>The Regulation on the Provision of Remote Health Services (the Regulation) came into force through publication in the <i>Official Gazette</i> on 10 February 2022. Before the Regulation, there was no specific legislation governing telemedicine in Turkish law, and physicians were not allowed to provide remote healthcare services and issue prescriptions.</p> <p>Within the scope of the Regulation, telemedicine is defined as healthcare services provided by a healthcare professional to a patient requesting healthcare service remotely via the healthcare information system in healthcare facilities that have received an operating permit.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>The Law on Socialisation of Healthcare Services No 224 defines healthcare services as medical activities for: (1) elimination of various factors that harm human health and the protection of society from the effects of these factors; (2) treating patients; (3) rehabilitation of those who have reduced physical, spiritual, and mental abilities.</p> <p>According to the Fundamental Law on Healthcare Services No 3,359, these healthcare services can only be fulfilled by a competent person in a permitted manner. So, the authorised healthcare professional shall operate in a licensed health facility. However, in accordance with the Medical Deontology by-law and the Ethical Principles for Physicians, the regulations requiring physicians to treat patients by examining in-person had been interpreted as banning remote healthcare services.</p> <p>However, in the 2000s, the first telemedicine project was started with the General Directorate of Health Information Systems in Turkey and the telemedicine content was limited to consultation among radiologists and to sharing evaluations with patients through the e-Nabız (e-Pulse) system. During the Covid-19 pandemic, the number of remote medical practices began to increase rapidly. As a result of these practices, the Ministry of Health (MoH) made an effort to regulate the practising of telemedicine services, and consequently, the first subject-specific Regulation was published.</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>The Regulation states that telemedicine services shall be provided through remote healthcare information systems (systems). The MoH authorises interested parties to develop systems and registers the systems developed by authorised developers. The MoH also determines the standards and registration procedures with which the systems shall comply.</p> <p>Healthcare facilities providing telemedicine services are required to use the specified systems. They must comply with criteria for appropriate infrastructure and equipment when using these systems, as determined by the MoH.</p> <p>In addition, the MoH shall manage applications made by healthcare facilities to obtain a remote healthcare service operating permit. Therefore, healthcare facilities shall apply for an operating permit and only perform their services through that permit. However, for public hospitals, the MoH may issue an operating permit <i>ex officio</i> without an application.</p>

<p>The MoH and its affiliated provincial directorates of health audit compliance with permits and standards.</p>
<p><b>4. Was telemedicine authorized during the Covid-19 pandemic?</b></p>
<p>During the pandemic in Turkey, lockdowns, travel restrictions and the workload of health institutions led to disruptions in accessing healthcare. As a result, online physician appointment systems have generally been used by private health institutions.</p> <p>In some ongoing clinical trials, the MoH provided permissions for certain activities to be conducted remotely. However, these services were carried out without any legislative basis until the effective date of the Regulation.</p> <p>Additionally, the 'Life Fits Into Home' app was designed by the MoH during the pandemic. Patient follow-up, filiation and epidemic management activities were carried out through this application.</p>
<p><b>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?</b></p>
<p>The pandemic has significantly accelerated the adoption of telemedicine services. The Regulation has only recently come into force. It can be expected that the MoH will observe common practices and shape telemedicine activities with secondary legislation and its decisions.</p>
<p><b>6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)</b></p>
<p>The Regulation allows for examination, medical observation, follow-up, control of diagnosed diseases, medical counselling, consultation, secondary opinion, evaluation of clinical parameters, treatment and drug management, healthy life and psychosocial support services, monitoring and protection of health, versatile evaluation and follow-up of people with increased health risks or advanced age, necessary medical procedures to protect the health in epidemics, health data measurement and tracking with wearable technologies and other medical devices, issuance of e-prescriptions and preparation of e-reports.</p> <p>Additionally, specified interventional or surgical operation services can be provided remotely, provided that MoH permission is obtained and technological conditions are adequate.</p> <p>Healthcare services that are not listed within the scope of the Regulation cannot be provided as remote healthcare services.</p>
<p><b>7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.</b></p>
<p>According to the Regulation, both doctor-doctor and patient-doctor telemedicine services are allowed.</p>
<p><b>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.</b></p>
<p>Telemedicine services can be provided both at public and private health facilities.</p> <p>The Social Insurance and General Health Insurance Law No 5,510 regulates the persons who shall be protected under mandatory general health insurance in Turkey and which healthcare services shall be financed by the Social Security Institution, in line with the Healthcare Practice Communiqué. Since the Regulation has only recently come into force, there are no specific provisions on coverage of telemedicine services, but we expect the Social Security Institution to clarify the issue shortly with changes to its Healthcare Practice Communiqué.</p>
<p><b>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</b></p>
<p>There are currently no specific insurance requirements for telemedicine services or telemedicine service providers.</p>

<b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b>	
<b>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.)</b>	
	Within the framework of the Law No 1,219 on the Mode of Execution of Medicine and Medical Sciences and Regulation on Job and Job Descriptions of Healthcare Professionals and Other Professionals Working in Healthcare Services, healthcare professionals are listed comprehensively such as physicians, dentists, pharmacists, nurses, clinical psychologist and dieticians. The Regulation determines that healthcare professionals can provide telemedicine services.
<b>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</b>	
	To date, there are no specific education or training requirements.
<b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b>	
	There is no requirement for physicians to register. However, healthcare facilities, including private practices, must obtain permission, as outlined in the response to Question 3.
<b>13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>	
	The MoH shall manage applications made by healthcare facilities to obtain a remote healthcare service operating permit. Therefore, healthcare facilities shall apply for an operating permit and only perform their services through the permit. However, in the case of public hospitals, the MoH may issue an operating permit <i>ex officio</i> without an application.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>	
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>	
	Telemedicine platforms must be developed in a manner which allows for remote healthcare service actions determined by the MoH to be reported and transferred to the information management system of the healthcare institution. The MoH has also published guidelines on platform requirements, which may be further developed in future.
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>	
	Within the scope of the Regulation, it has been decided that the necessary infrastructure and technical equipment for connecting healthcare professionals to the systems shall be met by the healthcare facility. However, detailed criteria regarding the systems to be used in telemedicine services are not determined by the MoH. Nevertheless, the MoH guidelines define cybersecurity measures which must be fulfilled by the platform.
<b>16. Does the legislation provide for specific rules concerning patients' medical records?</b>	
	According to the Regulation, it is regulated that video and audio recordings during telemedicine services can only be taken with the explicit consent of the parties. These records are kept in the serving health facility or in secured data centres permitted by the MoH.
<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>	
	There are no location requirements for the provision of telemedicine services. However, the patient should be capable of having access to the physical healthcare institution if required. Additionally, international health tourism and the provision of healthcare services to tourists are permitted under the Regulation. In this context, the health facility must obtain an international

health tourism authorisation certificate under the Regulation on International Health Tourism and Tourist Health.
<b>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</b>
The healthcare professional must inform the patient: of the identity and expertise of the healthcare professional; whether the healthcare professional will be in the same physical environment as the patient; that the remote service cannot be a substitute to face-to-face services; that the remote healthcare services cannot be used in a manner that disrupts ongoing treatments; that the patient must apply to the nearest hospital emergency services if needed; that they may need to provide camera and microphone access; and the services may not be possible if audio and video cannot be transmitted between the parties; as well as the consequences of providing healthcare services remotely.
<b>19. Is there any other important requirement that should be highlighted?</b>
According to the Personal Data Protection Law No 6,698 (the PDPL) and relevant secondary legislation, it is important to complete the obligation of informing the data subject for the personal data obtained through telemedicine services, and to obtain consent if required.
<b>DATA PRIVACY ASPECTS</b>
<b>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.</b>
The lack of clarity on criteria such as infrastructure and technical equipment required for telemedicine service delivery may lead to data privacy problems. Inadequate security system measures taken by the health facility, failure to regularly provide system controls, deficiencies in personnel and healthcare professionals' training and duty processes may result in data security problems.
<b>21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?</b>
Regarding to the Regulation, health facilities shall be responsible for ensuring the security of the system used has usernames and passwords. In addition, necessary measures shall be taken to ensure the identity of the person receiving the service is verified. The recording audio or video is banned without explicit consent, access permission is required to film and/or record and transfer to the MoH's system in accordance with the legislation are other measures taken. The health facility and the healthcare professional are jointly responsible for the protection of patient privacy and personal data.
<b>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</b>
<p>The PDPL regulates requirements for cross-border data transfers.</p> <p>As a rule, personal data cannot be transferred without the explicit consent of the data subject, or other measures such as authority-approved commitments.</p> <p>Health data, which is considered a type of sensitive/special category data, may be processed without patient consent for purposes of the protection of public health, preventive medicine, medical diagnosis, treatment and nursing services, planning and management of healthcare services. However, the cross-border transfer articles are separate, and must be considered separately.</p>
<b>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?</b>
The Systems used for telemedicine services should be securely integrated with the MoH central data registry. Systems should be configured in a manner that is capable of retaining personal

data domestically. Servers used for systems that allow instant messaging and video calls must be based in Turkey.

The record of information determined by the MoH during services is retained by the health facility for the period specified in the legislation to which the health facility is subject. Consequently, while patient files in private hospitals are kept for at least 20 years, this period varies from between five and 20 years for public hospitals depending on the quality of service.

## LIABILITIES

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

Telemedicine practices are audited by the MoH provincial directorates at least once a year. If these practices are provided without permission from the MoH, they are halted immediately.

Various administrative sanctions are applied within the scope of the Regulation if the obligations are violated by private health facilities. Depending on repeated violations, sanctions may include warning the health facility and providing a deadline for remedies, suspending remote healthcare services for a certain period, withdrawing the authorisation certificate and restricting new applications for services. For healthcare professionals, remote healthcare services are stopped, and the consequences determined, depending on the nature of the violation.

If the obligations are violated while providing services by public health facilities, action is taken mainly in accordance with the Administrative Jurisdiction Procedure Law No 2,577 on behalf of the health facility, and the Civil Servants Law No 657 on behalf of the healthcare professionals.

## TELEMEDICINE NUMBERS AND TRENDS

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

Forecasters expect the telemedicine services sector in Turkey to grow by 25 per cent over the next five years. According to the statement from the MoH, remote healthcare services have and will become increasingly widespread with the Regulation.

If the reports published in 2021 are analysed, it can be ascertained that telemedicine activities are not used in over half the hospitals in Istanbul, which has the highest number of private hospitals in Turkey.

### 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.

It is expected that the use of telemedicine services will become extensive especially by private hospitals and the relevant market will grow. Telemedicine services may facilitate communication between physicians and patients, and accelerate administration of healthcare services. There will also be new developments in the IT sector and the purchasing of software and technological devices that monitor health data are increasing/will particularly increase. In this context, it is likely that there will be a growth in the number of users who want to benefit from telemedicine services.

However, the inequality of access to healthcare services may increase among patient groups especially for the elderly. In addition, there are some ethical concerns in terms of patient privacy, personal data, and service quality.

Consequently, pursuant to the Turkish law, new legislation and opinions about the technical and infrastructure qualifications, pricing and insurance, professionals' and patients' responsibilities regarding telemedicine services should continue to develop. Only if the legal basis is established

comprehensively, will the provision of these services be preferred by healthcare facilities and telemedicine will serve patients well.