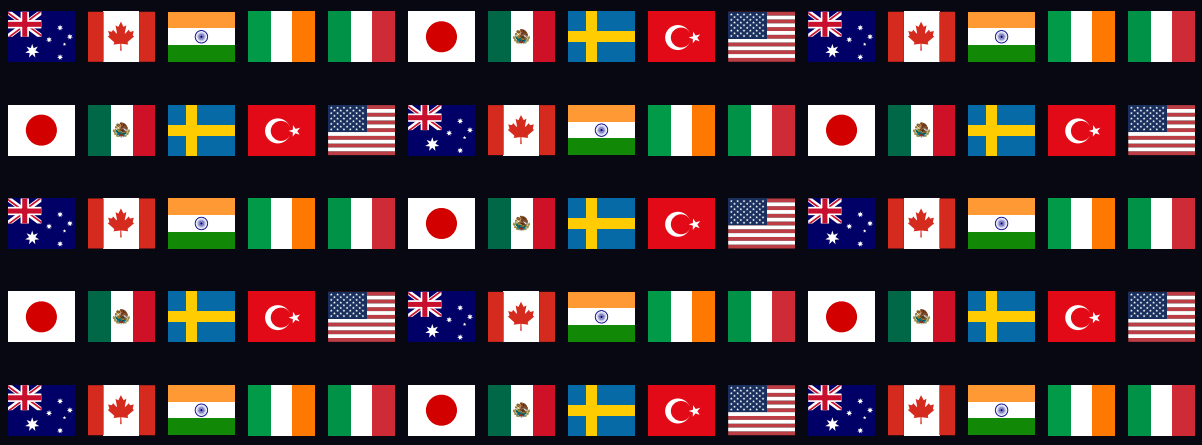
HEALTHCARE REGULATION

Turkey



LEXOLOGY
Getting The Deal Through

Consulting editor
Norton Rose Fulbright

Healthcare Regulation

Consulting editors

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Quick reference guide enabling side-by-side comparison of local insights, including into organisation, financing and structure of the healthcare system; pricing and reimbursement; healthcare organisations and business structures; competition, anti-corruption and transparency; regulation of healthcare services and professionals; data protection, privacy and digital health; and key developments.

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ORGANISATION, FINANCING AND STRUCTURE OF THE HEALTHCARE SYSTEM

Organisation

How is healthcare in your jurisdiction organised? What is the role of government?

The healthcare system is governed principally by the Fundamental Law on Healthcare Services No. 3359 and dated 15 May 1987, which furnishes the Ministry of Health (MoH) with the authority to issue healthcare-related regulations and establish a healthcare system enabling each and every person living in Turkey to have equal and equitable access to the healthcare system.

In addition to public hospitals and healthcare institutions, universities with medical faculties may also establish hospitals under the authority granted to universities by the Higher Education Law No. 2547 and dated 4 November 1981, and this system is also quite common in Turkey.

In accordance with the policies and objectives of the MoH, the Turkish Medicines and Medical Devices Agency (Agency), which is a public legal entity with a special budget, affiliated to the MoH is established, responsible for regulating medicines, active and auxiliary substances used in drug production, substances subject to national and international control, medical devices, extracorporeal medical diagnostic devices, traditional herbal medicinal products, cosmetic products, homeopathic medicinal products, biocidal products in direct contact with the human body and special purpose dietary foods.

The Agency undertakes the following duties in general regarding the products falling under the authority of the Agency:

- granting licences or authorisations; monitoring and imposing sanctions where necessary; setting forth standards for clinical trials, licensing, pricing, manufacturing, storing, sales, import, export, marketing, distribution, promotion, monitoring, recall and usage-related activities; and
- taking the necessary precautions to maintain the accessibility of pharmaceuticals, medical devices and other products that are of vital importance.

Law stated - 25 August 2023

Key legislation

What key legislation governs the provision of healthcare services in your jurisdiction?

The Fundamental Law on Healthcare Services No. 3359, the Higher Education Law No. 2547, Presidential Decree No.1 on the Presidential Organisation and the Presidential Decree No. 4 on the Organisation of Institutions and Organisations Affiliated, Related and Associated to Ministries and Other Institutions and Organisations.

Law stated - 25 August 2023

Financing

How is the healthcare system financed in the various patient care sectors?

The active population, retirees and their dependants are covered by the health insurance provided by the Social Security Institution (SSI). Employers must pay monthly contributions for their employees, who automatically become covered by the health insurance provided by the SSI; the self-employed may also benefit from this insurance coverage by voluntarily paying monthly contributions. The health insurance provided by the SSI covers practically every physical exam, test and treatment option (both outpatient and inpatient) conducted at public healthcare institutions and university hospitals, apart from those that are not necessary for the health of the insured person, such as cosmetic

operations. The SSI also covers emergency services given to the insured at private health institutions.

Law stated - 25 August 2023

Delivery structures

What are the basic structures for the delivery of care to patients in your jurisdiction?

According to the Fundamental Law on Healthcare Services No. 3359, public healthcare institutions are established by the responsible authority, which is the Ministry of Health.

A big proportion of the public is covered by the Social Security Institution (SSI) health insurance, while only a small proportion benefits from private insurance coverage by paying monthly contributions.

A new plan, the General Health Insurance, has been in place since January 2012, and accordingly every citizen in Turkey is now under the SSI health insurance coverage. However, this coverage requires payment of monthly premiums or inclusion in a specific group. The aim is that all citizens who were not covered by the SSI health insurance packages now benefit from public health insurance.

Law stated - 25 August 2023

Access and coverage

What rules govern access to treatment and emergency services? Which items and services are covered and which are not covered?

The Social Security and General Health Insurance Law No. 5,510 regulates the persons who are covered with the public health insurance. In addition, the covered treatments are regulated by the Social Security Institution Health Implementation Communiqué (Communiqué). The Communiqué notifies the principles and procedures of benefiting from the health services, travel, daily and companion expenses financed by the SSI in order to ensure that the persons whose health benefits are covered by the SSI and defined in the scope article remain healthy, regain their health in the case of illness, meet the medically necessary health services as a result of occupational accident and occupational disease, illness and maternity, and eliminate or reduce their incapacity for work, and the prices to be paid by the SSI determined by the Health Services Pricing Commission for these services. In this regard, the Communiqué lists the modalities of provision and payment rules for health services financed with detailed provisions including payment in outpatient treatments, payment in home health services, payment for inpatient treatment, per service payment method, payment method based on diagnosis-based procedure, emergency health services, etc.

Law stated - 25 August 2023

Exclusions from statutory coverage

Are any groups excluded from statutory coverage? Are any groups covered under alternative schemes?

The Social Security and General Health Insurance Law No. 5,510 lists all groups excluded from the public health insurance covered by the SSI. To give an example, the spouse of the employer who works unpaid at the workplace or those working in domestic services (except for those who are insured by payment of the premium and those who work for 10 days or more in a month for the same person) are excluded from statutory coverage.

Law stated - 25 August 2023

Gaps in cost coverage

Are there any gaps in cost coverage?

The Health Implementation Communiqué regulates the situations where the patient contributes to the healthcare costs, which are mainly for:

- outpatient physician and dentist examinations, except for family physicians contracted, assigned or authorised by the MoH;
- drugs provided in outpatient treatment;
- extracorporeal prostheses and orthoses; and
- assisted reproduction method treatments.

The collection method of co-payment fees is explained in the relevant articles of the Communiqué.

Law stated - 25 August 2023

HEALTHCARE PRICING AND REIMBURSEMENT

Pricing

How are prices for healthcare services set and paid for in your jurisdiction? To what extent is the cost of healthcare services governed by law or regulation?

The prices to be paid by the Social Security Institution (SSI) for health services, exemptions and additional fees to be applied are determined by the Health Services Pricing Commission and set in the Health Implementation Communiqué (Communiqué). The Communiqué sets the prices for the healthcare services and the co-payments to be paid by the patients if needed.

In terms of the pharmaceuticals, the principles for determining pharmaceutical prices were set by the Council of Ministers in the Pricing Decree and in the Pricing Communiqué published by the MoH based on the Pricing Decree. However, as a result of the referendum held on 16 April 2017, an amendment has been made to the Constitution and a transition has been made to the Presidential Government System. The most fundamental feature of this system is the transfer of all executive authorities to the President with the annulment of the office of Prime Ministry. The President has become both the head of state and the head of executive power. Consequently, the rules and procedures for the determination of pharmaceutical prices are determined by the President, not by the Cabinet of Ministers.

The MoH is still applying the reference price system. The maximum sale prices of pharmaceutical products are determined by taking into account the lowest price of the product available on the market respectively in the reference countries (France, Greece, Italy, Portugal and Spain) and the countries of batch release and import. Where this is not available, the lowest price of the product available in EU countries – or, failing that, the ex-factory price (the sale price to wholesalers) of the product available on the market in any country across the world. The reference price takes the active substance into consideration for each product. Then it determines the price of different forms and dosages of this active substance by using a proportioning method.

The price of an original pharmaceutical is revised and becomes at most 60 per cent of the reference price upon the launch on the market of its first generic.

One of the most discussed topics relating to pharmaceutical pricing Turkey is the euro and Turkish lira currency rate (Fx rate) determined by the Price Assessment Commission competent for calculating the price of a product. According to

the Pricing Decree, the Fx rate should be adapted to currency fluctuations. The Pricing Decree was amended in 2017 and it was regulated that the Price Evaluation Commission shall gather in the first 45 days of each year and announce the value of €1 based on a calculation of 60 per cent of the average value in the previous year.

However, due to the rapid change in the exchange rates, the exchange rate has been revised a few times with provisional articles. Lastly, in 2022 the value of €1 was increased thrice. For 2023, it was stated that the last amount determined shall be applied for 2023 and that the Price Evaluation Commission would not announce a new value in the first 45 days of the year. However, on 21 July 2023, the exchange rate was increase once again to 14.0387 lira.

Law stated - 25 August 2023

Reimbursement

How is reimbursement for healthcare services structured?

The prices to be paid by the SSI for health services are set in the Health Implementation Communiqué (Communiqué).

In terms of pharmaceuticals, the reimbursement rules are set in the Regulation on Drug Reimbursement (Reimbursement Regulation). The Reimbursement Regulation sets out the types, quantities, usage periods and payment procedures and principles of the drugs financed by the SSI and the drugs for which financing is requested. The Drug Reimbursement Commission established in accordance with this regulation determines the drugs to be financed and the payment procedures and principles for these drugs. These medicines are published in the lists annexed to the Communiqué. These medicines include medicines that are not authorised in Türkiye, prescribed on a patient-by-patient basis and therefore procured from abroad for patients on a prescription basis.

In addition, the Regulation on the Alternative Reimbursement of Pharmaceuticals, allow companies and the SSI to benefit from discussing the terms and conditions of an alternative reimbursement model for particular products in confidentiality and set a confidential discount rate.

Law stated - 25 August 2023

Adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursement of healthcare services?

The MoH, through the Turkish Medicines and Medical Devices Agency, is the competent authority regarding the pricing of medicinal products. The competent body for reimbursement decisions is the SSI. There are also two important commissions:

- the Health Services Pricing Commission consisting of seven members in total, one member representing the Ministry of Labour and Social Security, the Ministry of Finance, the Ministry of Health, the Undersecretariat of State Planning Organisation, the Undersecretariat of Treasury and two members representing the SSI; and
- the Reimbursement Commission, is chaired by the Director General of General Health Insurance and consists of 9 original members, including three department heads, one of whom is the Head of Pharmaceuticals Department, appointed by the President of the Agency, two representatives at least at the level of department head appointed by the Ministry of Treasury and Finance, two representatives at least at the level of department head appointed by the Ministry of Health, and one representative at least at the level of department head appointed by the Presidential Strategy and Budget Presidency.

These commissions review the applications and approve their conformity in line with the related pricing and reimbursement legislation.

Law stated - 25 August 2023

HEALTHCARE ORGANISATIONS AND BUSINESS STRUCTURES

Legal authorisation

What steps are necessary to authorise the provision of healthcare services, and what laws govern this?

The authority to grant licences to private hospitals and healthcare institutions is given to the Ministry of Health (MoH) under the Regulation of Private Hospitals . Additionally, universities with medical faculties may also establish hospitals under the Higher Education Law No. 2547. The authorisation procedure of health services is governed by the Regulation of Private Hospitals , which provides a detailed description of the licence application procedure. According to this Regulation, the MoH is entitled to grant licences for private hospitals. The applicant, who may be a private legal entity or a real person, must obtain preliminary permission from the MoH concerning the construction plan prior to the licence application.

Concerning other types of healthcare institutions, the authorisation procedure may vary slightly as each institution is regulated separately.

Law stated - 25 August 2023

Legal structures

What types of legal entities can offer healthcare services?

Legal entities that are entitled to offer healthcare services are mainly governed by the Fundamental Law on Healthcare Services No. 3359 . However, different entities are regulated by different regulations. Accordingly, public hospitals, private hospitals and training and research hospitals offer full healthcare services. On the other hand, community health centres, homecare services, medical clinics, dental clinics, dialysis centres, assisted reproduction treatment centres and dispensaries generally offer healthcare services limited to their specialisation.

Law stated - 25 August 2023

Foreign companies

What further steps are necessary for foreign companies to offer healthcare services?

The regulatory framework on granting licences for private healthcare does not allow foreign companies to offer healthcare services. According to the Regulation on Private Hospitals , companies shall be established in Turkey and have to be registered to the Turkish Trade Registry to apply for a licence.

Law stated - 25 August 2023

Healthcare arrangements

What regulatory and legal issues commonly arise in relation to healthcare arrangements? What are the main rules and principles that apply to extraterritorial participation in these arrangements?

Decisions on health services covered by the general health insurance are shown in the Health Implementation Communiqué (Communiqué). The balance of patient benefit and public finance is taken into consideration in the planning of health services to be covered by the general health insurance set by the Social Security Institution (SSI). Individual compensation lawsuits can be filed by patients regarding health services that must be covered in accordance with the principle of social state. In these lawsuits, patients demand the reimbursement of the payment that they made for health services by the SSI. The judgments in these cases are individual and may include a decision on the costs of the patient who brought the action. A favourable decision in this case regarding the reimbursement of the healthcare service costs by the SSI sets a precedent for other patients receiving the same treatment.

In terms of extraterritorial participation, the contracts signed with Germany, Netherlands, Belgium, Austria, France, Macedonia, Azerbaijan, Romania, Bosnia-Herzegovina, Czechia, Albania, Serbia, Italy, Luxembourg, Croatia, Montenegro, Hungary and Tunisia include health insurance.

Law stated - 25 August 2023

COMPETITION, ANTI-CORRUPTION AND TRANSPARENCY RULES

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

The Turkish Competition Law is applicable to all undertakings that operate in a market for goods or services within the borders of Turkey and the Turkish Competition Authority (TCA) is the public authority that monitors and maintains competition in the market.

In Türkiye, public hospitals shall not be considered as an undertaking in terms of the Competition Law, as they are non-profit organisations. However, private hospitals and clinics' management are deemed as a market service. Accordingly, companies that operate private hospitals and clinics are subject to the Turkish Competition Law and may be pursued by the TCA. Once the infringement of competition is established, the TCA can impose sanctions including heavy administrative fines on companies and board members and may invalidate the relevant contract or transaction that causes the infringement.

Law stated - 25 August 2023

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

According to article 57 of the Turkish Competition Law , anyone who prevents, distorts or restricts competition through practices, decisions, contracts or agreements contrary to this law, or abuses a dominant position in a particular market for goods or services, is obliged to compensate any damages to injured parties. Parties who claim that they have suffered damages and loss arising from the anticompetitive acts of manufacturers may claim compensation by filing a lawsuit before the courts. Accordingly, the injured party may ask for an amount equal to three times the actual loss incurred.

Law stated - 25 August 2023

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

Under Turkish law, there is no umbrella legislation that covers every type of anti-corruption issue. Crimes such as

bribery and official misconduct are punishable according to Turkish Criminal Code No. 5237 , regardless of the sector in which they are committed. In terms of bribery regulated under article 252 of Turkish Criminal Code No. 5pri237, any kind of benefit provided for executing a legal transaction, which should be executed or vice versa, is prohibited with a zero-tolerance approach. In addition to the Turkish Criminal Code, the Regulation on the Code of Ethics of Public Officials and Application Procedures and Principles establishes the basic principle for public officials not to receive or give gifts and not to derive interest as a result of their duty. This Regulation also defines a blacklist of all sorts of goods and benefits that public officials cannot receive.

To guide pharmaceutical companies interacting with healthcare professionals, the Ministry of Health (MoH) defined sector-specific rules. In this sense, provisions regarding promotional interactions such as congress sponsorship of healthcare professionals, donations made to healthcare organisations, as well as all kinds of promotional materials that can be given to healthcare professionals are regulated under the Regulation on Promotional Activities of Human Medicinal Products . Similarly, pharmaceutical companies shall notify transfers of value made to healthcare professionals or organisations of any value transfers that exceed 10 per cent of the current monthly gross minimum wage.

Law stated - 25 August 2023

REGULATION OF HEALTHCARE SERVICES

Licensing authority and process

Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

The Ministry of Health (MoH) is the main body in charge of health services in Türkiye. It regulates all healthcare institutions in the country, which includes patient care facilities such as hospitals, clinics and diagnostic centres and the practice of medical and other health professions.

The Turkish Medicines and Medical Devices Agency (Agency) is a regulatory agency of the government that acts as the highest sanitary authority in terms of medical safety on medicines, health products, cosmetics and personal care products.

The licensing process of healthcare facilities involves an application to the MoH. The specifics can vary depending on the type of facility; but, the applicant needs to demonstrate that the facility meets the MoH's standards for staffing, equipment, and physical infrastructure. This usually involves an inspection of the facility. Once licensed, the facility will be subject to regular inspections to ensure it continues to meet the standards.

For healthcare professionals, the licensing process depends on the specific profession. For physicians, it involves completing a medical degree from a recognised university, followed by a period of internship, and passing a national licensing examination. Other health professions have similar requirements. Once licensed healthcare professionals are required to participate in ongoing professional development to maintain their licence.

Law stated - 25 August 2023

Cross-border regulation

What requirements and restrictions govern the mobility of licensed health professionals across borders?

Requirements and restrictions regarding the mobility of licensed health professionals are regulated under the Regulation on the Procedures and Principles of Foreign Health Professionals Working in Private Health Institutions. The

application of the person to work in a private health institution shall be submitted to the Provincial Directorate of Health by the responsible manager of the private health institution.

A work permit and residence permit shall be obtained within the scope of the Law on Foreigners and International Protection and an application shall be made to the Provincial Directorate of Health for the issuance of a personnel work certificate and the certificate issued by the Ministry of Health. The foreign healthcare professional may work in a private healthcare organisation as of the date the personnel work certificate is approved by the Directorate.

Law stated - 25 August 2023

Collaboration between healthcare professionals

What authorisations are required for collaboration between healthcare professionals? How is this regulated?

Collaboration between healthcare professionals is managed within the context of specific healthcare settings, such as hospitals, clinics or other health service providers, with various levels of oversight from government bodies such as the MoH. The precise procedures can vary significantly, based on factors such as the specific health professions involved, the nature of the collaboration, and the context in which the collaboration is occurring. The Regulation on Ethical Principles of Conduct and Procedure and Principles of Application shall also apply to a healthcare professional who is a public official.

Law stated - 25 August 2023

Collaboration between patient care facilities and healthcare professionals

What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?

Pursuant to the Regulation on the Provision of Home Health Services by the Ministry of Health (MoH), the MoH provide home healthcare services to individuals in need in order to carry out examinations, analyses, treatment, medical care and rehabilitation at home. Home health care services are mainly provided through training and research hospitals, general hospitals or branch hospitals within the MoH.

The responsible physician, dentist and other personnel for the home care services are assigned by the director of the health institution which establishes the home care services. The personnel assigned to the team shall not be assigned other duties except in cases of necessity.

The responsible physician or dentist is the head of the team and carries out the visits with the team and makes a comprehensive medical assessment of the patient, prepares the home health service plan by taking into account the information and recommendations of the attending physician who makes the diagnosis and performs the treatment. In the absence of the opinions and recommendations of the attending physician, if necessary, it receives support from the relevant branch specialist.

Law stated - 25 August 2023

Training of healthcare professionals

What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?

Regulation on Speciality Training in Medicine and Dentistry governs the principles and procedures of speciality training in the fields of medicine and dentistry, the issuance of speciality certificates and the working procedures and principles of the Board of Medical Specialities.

Accordingly, a prospective physician must first complete a six-year undergraduate medical education programme to obtain a Doctor of Medicine degree from a recognised university.

The physicians are required to pass the Medical Specialty Exam to enter a residency programme. A residency programme typically lasts for three to six years, depending on the specialty.

A prospective dentist, on the other hand, must first complete a five-year undergraduate medical education programme to obtain a degree from a recognised university. Dentists are required to pass the Dentistry Specialty Exam to enter a residency programme. A residency programme typically lasts for three to four years, depending on the specialty.

Other healthcare professionals may practise their professions after graduating from the departments of higher education institutions related to their fields.

Law stated - 25 August 2023

Discipline and enforcement

What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?

The Patient Rights Regulation sets the rules for the sanctions to be applied in case of any violation of patients' rights by civil servants or other public officials and during their duties. These are mainly, disciplinary penalties, criminal complaints, civil or administrative lawsuits.

The authorities of health institutions – are obliged and authorised to take all necessary measures, including making a list, signboard or brochure of the 'patient rights' specified in the Patient Rights Regulation and other legislation, and placing them in appropriate places of the health institution and establishment where they can be easily accessed and read by patients, staff and visitors, in order to help patients exercise their rights in accordance with the letter and spirit of this Regulation and other legislation.

Law stated - 25 August 2023

Patient complaints

How are patient complaints processed and adjudicated?

The patients can make a complaint to the health institutions on wrongful acts of their employee healthcare professionals. The Patients' Rights Regulation regulates the procedure for determining the responsibility of public servants in this regard. Accordingly, when the acts and behaviours of the personnel working in public institutions and organisations that violate patients' rights are detected in the case of a complaint or by the administration itself, an inspector or an investigator shall be appointed directly by the governorships or by the Ministry or the institutions where the personnel are employed in order to follow up, investigate and, if necessary, sanction the incident.

Law stated - 25 August 2023

DATA PROTECTION, PRIVACY AND DIGITAL HEALTH

Responsible authorities and applicable legislation

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation?

On 7 April 2016, Data Protection Law No. 6698 (DPL) came into force. The DPL regulates the protection of personal data and created new obligations that persons or entities dealing with personal data must comply with.

The DPL has been prepared in line with EU Directive 95/46/EC on data protection (EU Data Protection Directive). However, the DPL is not identical to the EU Directive.

The Turkish Data Protection Authority (TDPA) was granted the power to implement the DPL. Accordingly, the TDPA has investigative powers to ascertain whether data controllers and data processors are in compliance with the provisions of the DPL and, if deemed necessary, it may implement temporary preventative measures.

Pursuant to article 6 of the DPL, personal data relating to health, sexual life, biometric and genetic data are deemed sensitive personal data. While sensitive personal data other than data relating to health and sexual life may be processed without seeking explicit consent of the data subject in the cases provided for by other laws, personal data relating to health and sexual life may only be processed without seeking explicit consent of the data subject, by persons or authorised public institutions and organisations that have a confidentiality obligation explicitly for the purposes of:

- protecting public health;
- the facilitation of preventive medicine;
- medical diagnosis;
- treatment and nursing services; and
- the planning and management of healthcare services, including their financing.

Law stated - 25 August 2023

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

On 30 December 2017, the Turkish Data Protection Authority issued the Regulation on Data Controllers' Registry, which provides details of the obligations that data controllers must comply with. Data controllers must appoint either a contact person or an authorised representative, depending on whether the data controller is based inside or outside Turkey. This person's name and contact details shall be published online and they shall be responsible for establishing the communication between the data subjects and the data controllers. However, this person is not a data protection officer as defined by EU Regulation No. 2016/679.

Law stated - 25 August 2023

Regulatory guidance

Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

Restrictions brought under the Turkish Data Protection Law leave limited room for processing health data without explicit consent. Unfortunately, to date, the Turkish Data Protection Authority has issued no specific guidance or rules focusing on data protection in the healthcare sector.

On the other hand, the Ministry of Health (MoH) issued Personal Health Data Regulation No. 30808 , published in the Official Gazette on 21 June 2019, which aims to regulate the procedures and principles to be followed in the processes and practices carried out by the central and provincial organisational units of the MoH and the health service providers operating in conjunction with them.

Law stated - 25 August 2023

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

The Turkish Data Protection Authority investigates and issues decisions on matters brought to the authority's attention and on matters examined ex officio.

In practice, both patients and companies notice that healthcare providers do not convey information to their patients according to the obligations set by the Communiqué on the Obligation of Information . Even if they do, this information lacks important provisions and fails to inform data subjects in a transparent manner. The recent Turkish Data Protection Authority decisions on the healthcare providers including both healthcare institutions and healthcare professionals are on usage, transfer or process of the data of the patient without the consent of the patient.

Law stated - 25 August 2023

Digital health services

Which authorities regulate the provision of digital health services and what is the applicable legislation? What basic requirements are placed on healthcare providers when it comes to digital health services?

The MoH established a system named E-Nabız, for the patients to track their personal health data. The MoH Personal Health Data Regulation No. 30808 , published in the Official Gazette on 21 June 2019, and Circular No. 2016/6 on the E-Nabız Personal Health System are the legal basis governing E-Nabız. The Circular mentions that the fundamental aim of E-Nabız is to ensure a citizen's right to access and manage their personal health records pursuant to article 20 of the Constitution on personal data. The system is accessible 24 hours a day, seven days a week and free of charge through computers, mobile phones and wearable technology.

The MoH prepared the Regulation on the Presentation of Remote Health Services and published it in the Official Gazette dated 10 February 2022 and No. 31,746.

Within the scope of the Regulation on the Provision of Remote Healthcare Services, a remote healthcare information system infrastructure will be developed or authorised by the MoH and healthcare institutions will use this healthcare information system to ensure written, oral or video communication. The developed remote healthcare information system infrastructure will be registered in the database of the MoH.

These services may include many activities such as examination, counselling, prescription writing, clinical parameters such as blood sugar and blood pressure monitoring, providing services that support healthy life and psychological health, performing interventional or surgical operations upon the activity permit obtained from the MoH, protecting the health of people in endemic and epidemic epidemics, monitoring the health status of the elderly and people in high risk

groups and people who want their health status to be controlled through wearable technologies.

Law stated - 25 August 2023

UPDATE AND TRENDS

Key developments

Are there any current or foreseeable legislative initiatives, court cases, laws or other rules that affect the regulation of healthcare? What has recently changed (or will likely change), and what steps need to be taken in preparation?

The Turkish Medicines and Medical Devices Agency continuously work on alignment of the legal framework on medicines and medical devices with the EU legislation. For the medicines, legal framework on licensing, named patient programme and alternative reimbursement has been recently updated. Therefore, we may expect further amendments on the legal framework regulation promotional activities as well.

As for the medical devices, EU MDR led to several amendments on local regulations regarding medical devices and it is 'highly expected' that there will be further amendments.

Law stated - 25 August 2023

Jurisdictions

Australia	Clayton Utz
Canada	Stikeman Elliott LLP
India	LexOrbis
Ireland	Matheson LLP
Italy	CMS Italy
Japan	Anderson Mōri & Tomotsune
Mexico	OLIVARES
Sweden	Cirio Advokatbyrå AB
Turkey	Gün + Partners
USA	Norton Rose Fulbright