

Implementing Regulation on the Processing and Privacy of Personal Health Data

From the Ministry of Health:

PROCESSING AND PRIVACY OF PERSONAL HEALTH DATA

REGULATION ON PROVISION

FIRST PART

Purpose, Scope, Basis and Definitions

Goal

ARTICLE 1 - (1) The purpose of this Regulation; protection of personal data and confidentiality of data, collection, processing, transmission of personal health data, access to this data, personal health data record keeping systems and the procedures for notifying the Ministry of personnel movements in the provision of health services.

Scope

ARTICLE 2 - (1) This Regulation shall be amended as follows:

- a) Healthcare providers,
- b) The actual persons whose personal health data are processed,
- c) Real and legal persons who provide services such as data processing systems, software and hardware and filing system of health service providers,
- d) Includes provisions related to public institutions and organizations and private law real persons and legal entities, except for these, which process personal health data within the framework of a legislation.

Base

ARTICLE 3 - (1) This Regulation shall be amended as follows: The Ministry of Health and its affiliated organizations, dated 10/11/2011 and numbered 663,

(J) and Article 47 of the first paragraph of Article 8 of the Decree Law on the Duties of the Ministry of Health, dated 7/5/1987 and paragraph 3 of the third paragraph of the Basic Law on Health Services No. 3359 dated 24/3/2016

and 6698 on the Protection of Personal Data.

Definitions

ARTICLE 4 - (1) In this Regulation;

- a) Anonymization: To ensure that personal health data, even if paired with other data, is in no way associated with an identifiable or identifiable real person,
- b) Ministry: Ministry of Health,
- c) Information security authority: The person authorized by the senior manager of the relevant institution to implement information security policies,
- d) Headquarters: General Directorate of Health Information Systems,
- e) Contact person: The personal health data is the actual person,

f) Law: Law No. 6698,

g) Personal health record system: A system established in accordance with e-government practices that provides access to third parties to whom they or their authorized representatives have access to health data,

h) Personal health data: The identity of any health information relating to a specific or identifiable real person,

i) Processing of personal health data: The acquisition, recording, storage, storage of personal health data in non-automatic ways, whether fully or partially automatic or part of any data recording system

any kind of actions taken on the health data such as taking, changing, rearranging, disclosing, transferring, taking over, making available, classifying or using it,

j) Commission: The Personal Health Data Commission established within the Ministry,

k) Board: Personal Data Protection Board,

l) Central health data system: The data system of personal health data created by the Ministry,

m) Undersecretary: The Undersecretary of the Ministry of Health,

n) Health care provider: Provides real persons who provide or produce health care services, public and private law legal entities,

o) Intervention Team to Cyber Events: Taking or taking precautions against direct or indirect cyber attacks, which may or may not be done,

establishing or re-establishing systems and establishing or carrying out studies aimed at ensuring information security of their institutions,

p) USVS: Ministry of Health published National Health Data Dictionary,

q) Data originator: any real or legal entity that processes personal data on its behalf based on the authority granted by the data officer,

r) Data Responsibility: A natural or legal person who is responsible for the establishment and management of the data record system, which determines the purposes and means of processing personal health data,

s) Directive: means the Directive on Information Security Policy issued by the Ministry.

SECOND PART

General Principles and Principles in the Handling of Personal Health Data

General principles and principles

ARTICLE 5 - (1) Personal health data may only be processed in accordance with the procedures and principles stipulated in this Regulation and the Law.

(2) It is imperative to comply with the following principles in the processing of personal health data:

a) To comply with the rules of law and honesty,

b) To be up-to-date and correct when necessary,

c) treatment for specific, clear and legitimate purposes,

d) To be connected, limited and measured,

e) Maintain for the time required for the purpose for which they are conducted.

(3) Personnel in health service providers may operate and access the health care provider concerned only to the extent of the health service to be provided.

(4) Anyone who processes personal health data or who has access to personal health data in accordance with his / her duties is under an obligation to maintain confidentiality regarding this data.

(5) The persons who process the data on the health service providers may use the personal health data for all kinds of systems which are completely or partially automatic or non-automatic of the health service providers, systems at any time.

(6) Establishment and operation of electronic registration systems in accordance with the standards set by the health service providers, the Ministry and the Personal Data Protection Board, from the provision of security and privacy, is responsible for transferring health records to the central health data system.

(7) To make personal health data anonymous; determination of health policies, calculation of health costs, development of health services, use in scientific activities and statistical studies can be published and transmitted.

(8) Personal health data from health service providers shall be communicated to the central health data system in accordance with the procedures and principles specified by the Ministry.

(9) In the event that the person concerned is informed in detail, the written consent is received and the relevant consent is kept, the health data of the person concerned can be processed and transmitted in consent.

THIRD PART

Protecting, Processing, Transferring and Deletion of Personal Health Data

Protection of personal health data

ARTICLE 6 - (1) The data processor is obliged to comply with the rules and standards set forth with respect to the data processing process, while protecting the privacy of the data that it learns as the requirement of this task.

(2) Health service providers shall take all measures prescribed by the Ministry in order to ensure the confidentiality of personal health data.

(3) In case of suspected violation of personal health data, the Ministry shall be informed and the violation notification form prepared by the General Directorate shall be used. Notification may also be made electronically.

(4) Officer receiving notification; without delay, informed sequential managers to start with the closest manager about the data categories being breached, the number of persons infringing, the possible consequences of violations and the precautions to be taken. The system is communicated with the data responsibility and data processing tasks.

(5) Administrative examination of the General Directorate is made in relation to the notification of the violation, and the result of the administrative examination is reported to the Personal Health Data Commission by a report.

(6) The relevant persons whose personal health data are violated as a result of the administrative investigation carried out shall be informed by a method approved by the Commission.

(7) The information systems in which personal health data are used are used within the user identification and authorization.

Any transaction related to user identification and authorization is recorded and maintained. The matters concerning authorization, registration and preservation of the data shall be determined by the General Directorate.

(8) The access record of users accessing information systems in which personal health data is available shall be maintained in accordance with the standards set by the Ministry in the systems of health service providers.

Processing of personal health data

ARTICLE 7 - (1) Personal health data; obligation to keep secrets for the protection of public health, preventive medicine, medical diagnosis, treatment and maintenance services, planning and management of health services and financing.

The persons concerned or the authorized institutions and organizations may be treated without regard to the open source of interest.

(2) In order to process personal health data without anonymization except for the purposes mentioned in the first paragraph, informing the details of the data, which must be kept, belonging to the person concerned in detail about the reason for disposal,

(3) The person concerned may withdraw the request for the processing and transfer of the data at any time, if there is no legal regulation or judicial decision otherwise. Reimbursement of receivables, transactions made up to that date.

(4) In the processing of personal health data, adequate measures as determined by the Board are also taken.
Transfer of personal health data

ARTICLE 8 - (1) Personal health data; for the protection of public health, preventive medicine, medical diagnosis, treatment and care services, planning and management of health services and financing, by taking the measures and by fulfilling the conditions stipulated in the third paragraph, it can be transferred to the related public institutions and organizations if it is explicitly provided in the law.

(2) Personal health data; except in the cases provided for in the first paragraph.

(3) Data transfer between the public institutions and organizations requesting data to fulfill the duties and responsibilities specified by law and the Ministry or affiliated institutions and organizations; the method of transfer and other necessary by means of a protocol setting out the particulars.

(4) Any request for the international transfer of personal health data and data transfer requests other than those mentioned in this article shall be made within the framework of the provisions of the law, taking into account the sensitivity of genetic data

It is evaluated by the Commission.

Deletion of personal health data

ARTICLE 9 - (1) In the event that this Regulation is processed in accordance with the provisions of Law no. 6698 and other related laws, if the reasons which require to be processed are left behind, personal health data, data anonymized or deleted by the responsible person.

(2) Data requested to be deleted; data integrity shall be archived in a centralized system established by the Ministry in order to enable the establishment, use or protection of a right, or the granting of data to judicial authorities in case of need.

Access to the archived data is blocked except for these purposes.

(3) Data transferred to the central health data system may be deleted from the local database after 10 years from the date of transfer.

(4) The provisions of other laws relating to the deletion, destruction or anonymization of personal data are reserved.

SECTION FOUR

Data Owner and Data Responsibility

Data owner

ARTICLE 10 - (1) Data owner is the person identified in the fourth item.

(2) The data owner is related to himself by applying for data responsibility;

a) learning whether personal health data is processed or not,

b) requesting information on personal health data if it has been processed,

c) access to personal health data and requesting such data,

d) To learn the purpose of personal health data treatment and whether it is used appropriately for its purpose,

e) To know the third parties to whom the personal health data are transferred in the country or abroad,

f) requesting correction of personal health data if it is incomplete or incorrectly processed,

g) requesting the deletion of personal data in accordance with the conditions stipulated in Article 9,

h) requesting that actions taken in accordance with subparagraphs (e) and (f) be communicated to a third party to whom personal health data are transmitted,

i) Objection to the appearance of a result against the person himself by analyzing the processed personal health data exclusively through automated systems,

j) have the right to claim damages in case of personal injury due to the illegal processing of personal health data.

(3) If the data owner uses one or more of the rights enumerated in subparagraph (a), (b), (c), (d) or (e) of the second paragraph, the relevant information shall be disclosed to him in a clear and understandable manner, reported.

Data responsibility

ARTICLE 11 - (1) The person in charge of data or the person authorized by the person during the acquisition of personal data shall not be responsible to the person concerned;

a) the identity of the data responsibility and, if any,

b) the purpose for which the personal data will be processed,

c) the person and the purpose for which the processed personal data can be transferred,

d) The method and legal cause of collecting personal data,

e) other rights enumerated in the 10th article,

to provide information on their subjects.

(2) Data responsibility;

- a) Preventing illegal processing of personal health data,
 - b) Preventing access to personal health data unlawfully,
 - c) Providing the safekeeping of personal health data,
 - d) In order to prevent possible data loss which may be experienced in the systems in which it is responsible, it is obliged to take all kinds of measures determined by the Ministry in order to ensure appropriate security level.
- (3) The data responsibility is jointly with these persons, in the case of personal health data being processed by another natural or legal person on their behalf, to take the measures mentioned in the first paragraph.
- (4) The Data Officer is obliged to make or carry out the necessary inspections in order to ensure the implementation of the provisions of the Law and this Regulation in his own institution or organization.
- (5) The persons who process the data responsibilities and data may not disclose the personal health data they learn to others in contradiction with the provisions of the Law and this Regulation and can not use them outside of the processing purpose. This obligation continues after leaving the office.
- (6) If the processed personal data is obtained by others in unlawful ways, the Data Officer shall notify the Commission as soon as possible. If the Commission finds it necessary, it can be found on the Ministry's website or it may declare it in another way.
- (7) The Data Officer shall cooperate with the Information Security Officer and the Cipher Intervention Team Officer, who are in the position of need.

PART FIVE

Personal Health Data Commission and General Directorate

Personal Health Data Commission

ARTICLE 12 - (1) To assist in the determination of the policy of the Ministry in accordance with the principles set out by the Law and the Personal Data Protection Board,

a Personal Health Data Commission to serve as a subordinate to the Undersecretary shall be established to analyze the complaints, to evaluate the applications related to the data transfer, to examine the complaints and to carry out the necessary inspections.

(2) The Commission, under the chairmanship of the Undersecretary or the Deputy Undersecretary appointed by the Deputy Undersecretary, consists of Legal Counsel, General Directorate of Health Services, General Directorate of Health Information Systems, General Directorate of Administration Services,

Services General Directorate, Turkey Public Hospitals Authority, the Public Health Agency of Turkey, Turkey Turkey Pharmaceuticals and Medical Devices Agency and the Border and Coastal consists of a member of the Directorate General of Health about the business they authorize.

(3) The Commission shall be invited to the meeting if necessary. Decisions to be taken by the Commission shall be sent to interested parties for consideration.

(4) The Commission may inspect the places covered by the law for the processing of personal health data and for the protection of its privacy. The procedures and principles relating to this denial shall be determined by the Ministry.

Duties of the General Directorate

ARTICLE 13 - (1) The duties stated below shall be carried out by the General Directorate.

- a) Establishes a central data system for the holding of personal health data,
- b) Ensure that records kept by all public and private health institutions and healthcare professionals providing health services are sent by the service providers to the central health data system,
- c) make the necessary technical arrangements for the integration of all systems,
- d) Establish standards related to information systems that enable the storage and transmission of all kinds of data related to health status and health services nationwide,
- e) Establish a personal health record system that provides access to the health data of the persons concerned by them or by third parties authorized by them,
- f) Ensure that high-level security measures are taken to prevent unauthorized access to the systems, either internally or externally,
- g) Publish the documents related to the management and organization of the systems on the internet page and if necessary,
- h) Prepare an internet page on which all content related to this Regulation contains informational content,
- i) Establish or establish a call center for the solution of technical problems that may arise in the use of the systems and support it via the internet.

PART SIX

Central Health Data System and Personal Health Record System

Central health data system

ARTICLE 14 - (1) The health service providers shall be informed about the data about the persons who applied to them for health services,

Within the time limit set by the legislation issued by the Ministry, to record in writing in accordance with the standards set by the Ministry and to use these data in accordance with the standards set by the Ministry.

The transfer of personal health data to the central health data system is the task and authority of the data authority.

(2) The software used by healthcare providers must be in compliance with the standards set by the Ministry in order to ensure that the central health data system operates correctly, the new service integration and the data recorded by the health service providers are transferred accurately, completely and without delay to this system.

(3) Persons and institutions within the scope of this Regulation;

- a) Having the authority document given to the Ministry,
- b) Minimally published software release notes, in accordance with the new standards and developments,
- c) use software that is compatible with the systems used by the Ministry.

(4) The compliance of the software to be used in accordance with this article to the requirements set by the Ministry and to the published standards shall be inspected by the Ministry.

(5) In case of failure to fulfill the obligations set forth in the third paragraph, or in case of incomplete or faulty fulfillment, the relevant data responsibility is warned in writing. If the warning is not remedied within seven days, the warning is repeated. If, at the end of seven days after the second warning, the

warning is not remedied, in accordance with Article 14 of the Law, the Board shall be informed about the data responsibility. Disciplinary provisions apply if the data officer is a public employee.

Personal health record system

ARTICLE 15 - (1) Every citizen requesting; create a user account on the personal health record system prepared by the Ministry to monitor the health services provided to him, manage his / her health records, examine the procedures and results applied to him / her in the health facilities, access the personal health data everywhere and share this data with the authorized third parties.

(2) The user account can be created through e-government or by the family physician on the application of the person concerned.

(3) Where authorized by the person concerned, personal health data may also be accessed by the person designated by the person concerned.

(4) The consent of the parent (s) of the parent (s) to access the personal health data of children under fifteen years of age is required. If your marriage has ended, the parent or father, who has the authority to use the parental right does not need the other party's approval for access to health data.

(5) The person may administer health data related to him / her via the personal health record system, which may request deletion, correction of the missing information, or the user account.

CHAPTER SEVEN

Notification Obligation

Notification obligation

ARTICLE 16 - (1) The health service providers employing the health personnel are obliged to inform the Ministry within fifteen days of the personnel information and personnel movements that they employ.

(2) The notification shall be made through the method to be determined by the Ministry.

(3) The responsible person, institution or organization shall be notified in writing if the obligations foreseen in the first paragraph are not fulfilled within the specified period or if they are carried out incompletely or incorrectly. The problem you need to warn is five days and the warning is repeated. At the end of fifteen days after the second warning, if the problem is not remedied, the procedure shall be established according to the general provisions of the responsible person, institution or organization.

SECTION EIGHT

Miscellaneous and Final Provisions

Sanction

ARTICLE 17 - (1) For the crimes and misdemeanors related to the personal data protected by this Regulation, transactions shall be carried out according to the 17th and 18th articles of the Act.

(2) Public officials who fail to comply with the requirements of this Regulation shall be notified of their disciplinary authority and if so, the authorities shall be revoked. Private legal persons are treated according to the relevant legislation.

Conditions without provision

ARTICLE 18 - (1) Regarding the processing of personal health data, the relevant regulations to be issued by the Board shall be applied in cases where there is no provision in this Regulation.

Force

ARTICLE 19 - (1) This Regulation shall enter into force on the date of its publication.

Executive

ARTICLE 20 - (1) The provisions of this Regulation shall be executed by the Minister of Health.