

Disclaimer: Text of the basic regulation

**ACT**  
**REGULATING ARCHIVES CONTAINING PERSONAL DATA FROM MEDICAL RECORDS**  
**(ZAGOPP)**

**Article 1**  
**(Subject)**

This Act lays down a special arrangement for the protection of archives containing personal data from medical records. This Act also lays down the conditions and procedure exceptionally allowing access to such archives.

**Article 2**  
**(Definitions)**

- (1) For the purposes of this Act, the following definitions shall apply:
- according to this Act, “archives” shall be archives in accordance with the act regulating the protection of archives produced by healthcare service providers or the National Institute of Public Health (hereinafter: NIPH) and containing personal data from medical records;
  - “archival commission” shall be the commission that, in accordance with the provisions of the act governing the protection of archives, decides on granting exceptional access to archives;
  - “commission of the competent archival institution” shall be the commission that, in accordance with the provisions of the act governing the protection of archives, adopts written professional instructions for the selection of archives;
  - “public archival institutions” include the National Archives, regional archival institutions and archival institutions of local self-government communities.

(2) The terms “medical record” and “basic medical record” shall have the same meaning as defined by the act governing healthcare databases.

(3) The terms “healthcare activities” and “public healthcare network” shall have the same meaning as defined by the act governing health services.

(4) The term “patient” shall have the same meaning as defined by the act governing patients’ rights.

(5) The term “database” shall have the same meaning as personal data collection as defined by the act governing protection of personal data.

**Article 3**  
**(Contents of archives)**

(1) Archives shall include databases whose retention period is determined as permanent by the act governing healthcare databases.

(2) Basic medical records for which the retention period is not determined as permanent shall be included in the archives if so decided by the commission of the competent archival institution.

(3) Basic medical records produced by healthcare providers outside the public health service network may be classified as archives if they are registered by a competent archival institution.

(4) Other medical records do not belong in the archives.

#### **Article 4 (Subsidiary application)**

Unless otherwise provided by this Act, the provisions of the act governing the protection of archives shall apply, except for provisions that allow the determination of special conditions regarding accessibility and provisions governing the use of private archives by contract.

#### **Article 5 (Time limit for transfer to an archival institution)**

Notwithstanding the provisions of the act governing the protection of archives, healthcare providers within the public health service network and the NIPH shall transfer archives to the competent archival institution no later than 150 years after their creation.

#### **Article 6 (Access to archives)**

(1) The archives shall not be accessible to the public.

(2) The archives shall be accessible to:

- the patient to whom they refer;
- persons who have the right to be acquainted with the patient's medical records after the patient's death in accordance with the act governing patients' rights and act governing health services.

(3) Archives in public archival institutions shall be accessible for scientific research to researchers entered in the register of providers of research and development activity at the agency competent for research activity:

- on the basis of the written consent of the patient to whom it refers;
- after the patient's death and, if there is no written consent of the patient referred to in the preceding indent, on the basis of the written consent of legal heirs of the patient up to the second generation, unless this has been explicitly forbidden by the patient in writing;
- in databases that do not allow for the identification of an individual patient even after disproportionate efforts have been made or disproportionate amount of money or time has been spent.

(4) Archives held in public archival institutions shall be accessible for scientific research purposes to researchers entered in the register of research and development providers at the agency responsible for the research after the death of the patient if there is no written consent of the patient referred to in the first indent of the preceding paragraph or if the patient did not prohibit this and their legal heirs do not oppose it, based on a reasoned decision of the archival commission in accordance with the law governing the protection of

archives, to which a reasoned consent of the committee responsible for medical and ethical issues was issued in accordance with the law governing health services within 60 days of receipt of the request of the archival commission. The commissions may allow access only if this is well-founded from the aspect of public interest in the field of science progress prevailing over the interest in inaccessibility, and if access could achieve a foreseen scientific objective that cannot be achieved in any other way.

(5) The access to materials referred to in Paragraphs 3 and 4 of this Article must be appropriate and its volume suitable for the purpose and scope of the research performed.

#### **Article 7 (Use of materials)**

An individual who accessed archives according to Paragraphs 3 and 4 of the preceding article may use the archives only for the purpose for which they were granted access.

#### **Article 8 (Supervision)**

The supervision of the implementation of the provisions of this Act and the related implementing regulations shall be carried out by the inspectorate responsible for the protection of archives. In the process, the inspectorate may act on the basis of all authorisations of the act governing the protection of archives and archival institutions.

#### **Article 9 (Offence provisions)**

(1) A legal person, sole proprietor or self-employed person shall be fined from EUR 2,000 to EUR 5,000 for the following offences:

1. if they do not transfer complete archives to the competent archival institution within the statutory limit (Article 5);
2. if they allow unauthorised use of or access to archives (Paragraph 2 of Article 6).

(2) A fine ranging from EUR 500 to EUR 2,000 shall be also imposed on the responsible person of a legal person, the responsible person of a sole proprietor or the responsible person of a self-employed person for committing an offence referred to in the preceding paragraph.

(3) An archival institution shall be fined from EUR 2,000 to EUR 5,000 if it allows unauthorised use of or access to archives (Paragraphs 3, 4 and 5 of Article 6).

(4) The responsible person of an archival institution shall be also fined from EUR 500 to EUR 2,000 for an offence referred to in the preceding paragraph.

(5) An individual shall be fined from EUR 500 to EUR 1,200 if they do not use archives for the purpose for which they were granted access (Article 7).

### **TRANSITIONAL AND FINAL PROVISIONS**

#### **Article 10**

### **(Harmonisation of regulations)**

The ministry responsible for archives shall harmonise the Decree on the protection of documentary and archive material (Official Gazette of the Republic of Slovenia [Uradni list RS], no. 86/06) and the Rules on determining retention period for documents of public administration authorities (Official Gazette of the Republic of Slovenia, No. 52/09) within six months of the entry into force of this Act.

### **Article 11 (Final provision)**

This Act shall enter into force on the fifteenth day following its publication in the Official Gazette of the Republic of Slovenia.

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National Assembly  
of the Republic of Slovenia  
**Milan Brglez**, m.p.  
President