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Recently the Commissioner on the Right to Information and Protection of Personal Data (herein referred to as the “*Commissioner*”) has approved Instruction No. 49, dated 02.03.2020 “*On protection of personal health data*” (herein referred to as the “*instruction*”). The Instruction was published in the Official Gazette No.28, dated 05.03.2020.

With the approval of this instruction, instruction No. 5, dated 26.5.2010, “*On the basic rules regarding the protection of personal data in the health care system*” and Instruction No. 23, dated 20.11.2012, “*On the processing of personal data in the health sector*”, of the Commissioner are abolished.

The instruction is intended to regulate the processing of personal and sensitive health related data, and aims at guaranteeing the respect for fundamental rights and freedoms of any individual, in particular, the right to privacy and protection of personal data.

The instruction applies to all physical persons and legal public or private entities operating in the health care system, other responsible bodies for healthcare supervision or control, as well as data processors acting on their behalf.

Some of the most important aspects of this Instruction are as follows:

Principles of health data processing legality

In virtue of the instruction, health related data could be processed only when expressly provided by special legislation, according to appropriate safeguards and when processing is necessary for:

- a) Preventive medical purposes, diagnostic purposes, care management or treatment, management of health services by health professionals and those of health care or social welfare sectors;
- b) Public health protection purposes, such as: protection from health risks, humanitarian

actions or to provide a high quality standard and safety for medical treatment;

- c) The purpose of protecting the vital interests of the data subject or another individual;
- d) Reasons relating to obligations of controllers and the exercise of their rights or those of data subjects, related to employment and social protection;
- e) Processing for archiving purposes in the public interest or for the purposes of scientific, historical or statistical research;

f) The protection of the public interest under the law. In this case, the measures in question should be proportional to the purpose pursued, respect the principles of the right to data protection and provide appropriate and specific measures for protecting fundamental rights and interests of the data subject;

g) When the data subject has given his consent. When the law provides that health related data processing could not be restricted only to the consent of the data subject, the latter is notified on the right to withdraw the consent;

h) When processing is necessary for the implementation of a contract entered into by the data subject or on his behalf, with a health professional, according to the conditions stipulated by law, including the obligation of professional secrecy;

i) When health related data are made public with the consent of the data subject itself. In the case of infant patients who are not able to give consent, legal representatives (parent or legal guardian of minor) give consent.

Genetic data

Genetic data should only be collected when appropriate safeguards exist, when provided by law and/or on the basis of consent expressed by the data subject.

Genetic data processed for preventive purpose, diagnostic, data subject treatment or of a biological family member or for scientific research, should be used for these purposes only.

Genetic data collected during a litigation process should only be processed when there are no alternative means for evidence administration necessary to prevent a real and immediate danger or for processing one certain criminal offense under procedural guarantees provided in the Code of Criminal Procedure.

The data subject has the right to know any information about his genetic data. The controller must guarantee the data subject the right of access in the most convenient form and way. Limitation to this right may be applied only in cases expressly provided by the law.

Health data dissemination

When health related data are disseminated by various health professionals, for health care delivery and administration purposes for an individual, the data subject must be informed in advance, unless this is impossible because of need and urgency.

When dissemination is based on the data subject's consent, this consent may be withdrawn at any time. When dissemination is determined by law, the data subject may object the dissemination of his health data.



Health professionals in various sectors of health care and social welfare must be subject to the rules on maintaining confidentiality.

Data processing rules also apply to electronic medical records and communication with email addresses that enable the dissemination and exchange of health related data.

Archiving and period for health data storage

Health related data should not be stored in a form that allows the identification of data subjects for more than it is necessary or in excess of the purposes for which they are processed, if not used for archiving purposes in the public interest, scientific, historical or statistical purposes.

Manual or electronic health data archiving can be performed by the public or private controller himself, or may be delegated to other processors, in accordance with legal procedures regarding the delegation of processing.

Period of health data storage is determined in accordance with the legislation on personal data protection.

Manually or automatically processed data upon expiry are destroyed or anonymized so that individuals cannot be identified or made identifiable.

Data subject's rights

The data subject has the right to know if his personal data is being processed, receive information without delay in an understandable form about the data, as well as have access in the following information:

a) The purpose or purposes of the processing;

b) The categories of relevant personal data processed;

c) Data recipients or categories of data recipients and projected data transfers to a third country or international organization;

d) Storage period;

e) The reason for data processing.

The data subject has the right to request the data correction or deletion, when put aware that the data about him are not proper, complete or elaborate truths and are collected in violation of the law. An exception is made when the data in question are anonymized, when processing is required by the law or when the controller shows a reason major for continuing the processing.

If the request to correct or delete the data is rejected, the data subject should be given legal reasons for this purpose. In case of unjustified refusal or inaction by the controller, the data subject has the right to file a complaint at the Commissioner's Office.



Controller and processor obligations

The controller must inform the data subjects on the processing of their health related data. The information should include:

- a) The identity and contact details of controllers and processors;
- b) The purpose for which the data are processed and, where appropriate, the relevant legal basis;
- c) Period of data storage;
- d) Data recipients or categories of data recipients and planned data transfers in a third country or in an international organization;
- e) The possibility to object the processing of their data;
- f) The conditions and the means available for the data subject for the exercise, through controllers, of their right of access, correction and deletion of their data.

Confidentiality and security of health data

Health data processing is legal only when performed by health professionals that have the obligation to maintain professional secrecy and confidentiality of data or from other persons who are subjects of such an obligation.

Controllers should take required security measures. These measures should be revised periodically.

Scientific research

Health data processing for scientific research is subject to appropriate protection measures provided by law and in this instruction,

guaranteeing the fundamental rights and freedoms of the data subject.

Need for health data processing for research should be evaluated in terms of research goals, risks to the data subject as well as in regards to the processing of genetic data, in the framework of the risk for the biological family.

Health records should, in principle, only be processed in a scientific research project, if the data subject has provided consent, in accordance with this instruction, unless otherwise provided by law.

Data should be anonymized when the purpose of scientific research allows it. When research purposes do not allow this, it should be applied the pseudonymization of the data in the phase of identification sharing, to protect the rights and the fundamental freedoms of the data subject.



Data processing via mobile electronic devices

For the data collected via mobile electronic devices, which can disclose information on physical and mental health status of the data subject, the same principles and warranties

apply on health related data processing, provided in this instruction.

Any use of mobile electronic devices should be accompanied by appropriate security measures that guarantee the verification of the relevant person and encryption during data transmission.

International transfer of health data

International data transfer can be performed when a convenient level of data protection is ensured, in compliance with the provisions of the legislation in force and bylaws adopted by the Commissioner.

Health records may be transferred to a state that does not have a sufficient level of personal data protection, if:

- a) The data subject has given its consent for international transfer;
- b) Is necessary for the protection of a vital interest of the data subject;
- c) With the authorization of the Commissioner;
- d) In any other case provided by law and bylaws adopted by the Commissioner.

Entry into force

This Instruction has entered into force after its publication in the Official Journal.



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Muja Law is a family-run law office where we work hard for the success of our clients and to provide excellence in legal service. Our roots go back to 2001 when our Managing Partner, Krenare Muja (Sheqeraku), opened her law practice office in Tirana, Albania. Krenare's son Eno joined her in 2014, and the other son Adi entered the practice in 2019. What started in Tirana as a small, family-run law office has grown and flourished in the community for the last 20 years. The office consists of various respected and talented lawyers who possess outstanding educational and community service backgrounds and have a wealth of experience in representing a diverse client base in various areas of the law.

The office is full-service and advises clients on all areas of civil, commercial and administrative law. With significant industry expertise, we strive to provide our clients with practical business driven advice that is clear and straight to the point, constantly up to date, not only with the frequent legislative changes in Albania, but also the developments of international legal practice and domestic case law. The office delivers services to clients in major industries, banks and financial institutions, as well as to companies engaged in insurance, construction, energy and utilities, entertainment and media, mining, oil and gas, professional services, real estate, technology, telecommunications, tourism, transport, infrastructure and consumer goods. In our law office, we also like to help our clients with intermediary services, as an alternative dispute resolution method to their problems.

While we have grown over the past 20 years and become recognized as one of Albania's leading law offices, we are grounded in the essence of "who" we are and "where" we started. We understand the importance of family, hard-work, and dedication.

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