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ANALYSIS OF LEGISLATION IN HEALTHCARE SECTOR FROM PERSONAL DATA PROTECTION ASPECTS

Component 1

Activity 1.1.2

FINAL VERSION



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I. INTRODUCTION

National legislation, in particular the Law on Personal Data Protection provides concrete and precise definitions for personal data and special categories of personal data, with the exact enumeration of the data included in the definition of special categories of personal data. Thus, starting with the definitions set forth in Article 2 of the Law on Personal Data Protection, *personal data* shall be any information pertaining to an identified or identifiable natural person, the identifiable entity being an entity whose identity can be determined directly or indirectly, especially as according to the personal identification number of the citizen or on the basis of one or more characteristics, specific for her/his physical, mental, economic, cultural or social identity.

Special categories of personal data shall be personal data revealing the racial or ethnic origin, the political views, religious or other beliefs, membership in a trade union and data relating to the health condition of the people, including genetic data, biometric data or data referring to the sexual life.

From the definition established for special categories of personal data in the Law on Personal Data Protection, it is evident that the data relating to health, including genetic and medical data, enjoy a special level of protection compared to the remaining categories of personal data and they cannot be subject to collection and processing, except in strictly defined cases.

Taking into account the function of the health sector it is undoubtedly that in this sector myriad of personal data are “created”. “Creators” of personal data are health workers in the broadest sense. However, the fact is that health workers while performing their daily duties are not only “creators”, but they also collect numerous personal data, including special categories of personal data.

There is no doubt that the health sector is specific sector in terms of personal data protection. On one side is the public interest - protection of citizen’s health and the exercise of their health care rights and on the other side is their privacy or right of personal data protection.



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Real challenge in the health sector is to make a balance between public interest and the privacy of the individuals.

II. ANALYZED LAWS

For the purposes of this Analysis, the following Laws were taken into consideration:

1. Law on Health Insurance (Official Gazette No. 25/2000; 34/2000; 96/2000; 50/2001; 11/2002; 31/2003; 84/2005; 37/2006; 18/2007; 36/2007; 82/2008; 98/2008; 6/2009; 67/2009; 50/2010; 156/2010 and 53/2011)
2. Law on Health Protection (Official Gazette no.38/1991; 46/1993, 55/1995; 10/2004; 84/2005; 111/2005; 65/2006; 5/2007; 77/2008; 67/2009; 88/2010; 44/2011 и 53/2011)
3. Law on Protection of Patients's Rights (Official Gazette No. 82/2008; 12/2009 and 53/2011)
4. Law on Records in the Health Sector (Official Gazette No. 20/2009 and 54/2011)
5. Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance (Official Gazette No. 161/2008)
6. Law on Biomedical Assisted Insemination (Official Gazette Law on Safety of Blood Supply (Official Gazette No. 110/2007)
7. Specific bylaws of the health legislation



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II. ANALYSIS OF THE HEALTH LEGISLATION

1. LAW ON HEALTH INSURANCE

1.1 General Overview

The Law on Health Insurance generally regulates the issue of health insurance of the citizens, the rights and obligations arising from the health insurance, as well as the manner of the implementation of the health insurance in practice. This Law also determines the institutions responsible for providing health insurance for all citizens of country, as well as the citizens' rights in exercising the health insurance.

The Law on Health Insurance for the first time was enacted in 2000 and to this day has undergone many amendments¹, which among other things regulate the issue of citizens' personal data protection in exercising their right to health insurance.

1.2 Analysis of Specific Provisions of the Law on Health Insurance

Processing of personal data of the insured persons

Article 27-c

The personal data of the insured persons can be processed in accordance with the purposes determined in this Law and in accordance with the regulations governing personal data protection.

¹ Official Gazette of No. 25/2000; 34/2000; 96/2000; 50/2001; 11/2002; 31/2003; 84/2005; 37/2006; 18/2007; 36/2007; 82/2008; 98/2008; 6/2009; 67/2009; 50/2010; 156/2010 and 53/2011



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The personal data included in the processes of recording data shall be immediately deleted in the cases when it is determined that they are not correct or the reasons have ceased, i.e. the conditions why the personal data has been included in those processes.

The personal data of the insured persons contained in the records in the field of health insurance from their entry until their removal can be granted under conditions and in a manner determined in the regulations on health insurance and the regulations governing personal data protection.

The provisions of the Article 27-c in most general terms regulate the issue of personal data protection of the insured persons.

Thus, in paragraph 1 of this Article is pointed out that personal data of the insured persons may be processed in accordance with the objectives set in the Law on Health Insurance and in accordance with the regulations governing personal data protection. These provisions are in line with the data protection principles under Article 5 of the Law on Personal Data Protection, according to which personal data are collected for specific, clear and legally defined purposes and are processed in a manner pursuant to those purposes. Likewise, these provisions represent a reference for the application of personal data protection regulations for processing of personal data of the insured persons.

Paragraph 2 is in accordance with another personal data protection principle, also prescribed in Article 5 of the Law on Personal Data Protection. Namely, the principle of "accuracy" of data – that personal data shall be accurate, complete and, where necessary, updated, whereby all proper measures for deleting and correcting the inaccurate or incomplete data shall be undertaken, considering the purposes for which they have been collected or processed. On the other hand, with this provision has been established the period of storage of personal data of the insured persons – they should be deleted/erased or destroyed immediately after the cessation of the reasons or conditions for which personal data are included in the recording processes.

The third paragraph of Article 27-c generally governs the issue of revealing of personal data - under the conditions and manner specified by the health insurance and personal data protection regulations, which corresponds to a certain extent with the provisions of Articles 34, 35 and 36 of the Law on Personal Data Protection, which precisely define the procedure for revealing personal data for use.



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Scope of work

Article 54

The Fund shall perform the following activities:

...

- 10) develop its own information system with necessary data on mandatory health insurance;*
- 10-a) issue an electronic card for health insurance and keep records on its issuance;*
- 10-b) keeps other records in the field of health insurance;*

...

The provisions of Article 54 precisely define and determine the scope of work of the Health Insurance Fund

, by listing the responsibilities of the Fund. Among other responsibilities, the Fund: develops own information system with necessary data on mandatory health insurance, issue an electronic card for health insurance and keep records on its issuance and keeps other records in the field of health insurance.

These provisions create a direct legal basis for collecting and processing personal data of the insured persons by the Fund, as well as a legal basis for establishing personal data collection, which of course is in accordance with one of the basic principles of personal data protection specified in Article 5 of the Law on Personal Data Protection - personal data are collected and processed fairly and in accordance with law.

But on the other hand, this article does not define the categories of personal data which shall be subject to collection and processing in the defined personal data collections pursuant to this Article. The assumption is that personal data shall be collected and processed in accordance with the provisions of the Law on Registers in the Healthcare Sector. Here, one should note the obligation under Article 27 of the Law on Personal Data Protection that the Fund, acting as a controller is obliged to notify the Directorate for Personal Data Protection for the established collection, i.e. to register the collection in the Central Register of Personal Data Collections run by the Directorate for Personal Data Protection.



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Provisions of Article 54 do not define the term for storage of personal data.

Provisions of the Law on Health Insurance are in conflict regarding the authorizations between the Health Insurance Fund and the Directorate for Personal Data Protection.

Scope of work

Article 54

The Fund shall perform the following activities:

...

12) perform inspection and control of the agreed scope and type of provided health services of the insured persons in the health institutions on the documentation in connection with the indicated health services and enforcement of the medicine based on proofs;

...

Control

Article 71

The Fund shall control the health institutions and the legal entities performing construction, issuing and servicing of orthopedic and other devices that have concluded an agreement regarding the application of general acts of the Fund, fulfillment of the obligations arising from the agreement with the Fund, the agreed type and the scope of the health services, the medical documentation related to the pointed health services, the use of medicine based on proofs and the application of the criteria regarding the temporary working disability.

Misdemeanor sanctions

Article 84-a

A fine in the amount of Euro 2.500 to 5.000 in Denar counter-value shall be imposed for misdemeanor to the health institution and the legal entity performing construction, issuing and servicing of orthopedic and other devices, if it:



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- *does not permit the carrying out of the control by the authorized person from the Fund,*
- *does not allow inspection into the medical documentation related to the performed health services,*
- *gives unfounded assessment regarded the temporary working disability,*
- *agrees health services, but does not provide or partially provide them to the insured persons,*
- *stipulates the insured persons by themselves to buy medical products and other medical supplies, and*
- *does not provide the necessary information to the Fund for initiating the procedure for damage compensation, in accordance with this Law.*

Article 8 paragraph 1 of the Law on Personal Data Protection prohibits processing of special categories of personal data.

According to Article 2 paragraph 1, item 10 of this Law, besides others, special categories of personal data include personal data concerning peoples' health.

According to Article 8 paragraph 2 line 8 of the Law on Personal Data Protection, only by exception, processing of special categories of personal data, including personal data related to peoples' health, can be performed if necessary for purposes of medical prevention, diagnosis, treatment or management with public health institution and is carried out by a person whose profession is to provide healthcare under oath of secrecy on data s/he was acquainted with in exercising of his profession.

Also, under Article 25 paragraph 1 of the Law on Protection of Patients' Rights, the patient has the right to confidentiality (secrecy) of the personal and medical data, which must be kept secret even after her/his death, in accordance with the regulations on personal data protection. By exception of paragraph 1 of this Article, patient's data of paragraph 1 of this Article may be disclosed, if:

- The Patient gave written consent,
- The data are necessary for medical intervention on the patient in another institution,



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- The data are necessary for processing prescribed by law, by the healthcare institution providing health services to the patient,
- The data are being used in historical, scientific, research or educational purposes, provided that the identity of the patient can not be detected and
- It is consistent with other law aimed at protection of the lives, safety or health of others.

From the above, it turns out that the aforesaid provisions of the Law on Health Insurance which provide increasing of the Fund's authorizations in terms of supervision in the healthcare institutions by performing insight into **the medical documentation** of the patients, copying of all necessary documents in connection with health services, as well as imposing fines for preventing of insight **is not in accordance** with Article 8 of the Law on Personal Data Protection that prohibits processing of "sensitive" personal data and is inconsistent with the provisions of Article 25 of the Law on Protection of Patients' Rights, which guarantees the right to confidentiality (secrecy) of personal and medical data of patients.

General conclusions of aspect of the analysis' indicators

Taking into consideration the above mentioned, it could be concluded that:

1. Legal basis for collecting and processing of personal data is established, without specifying in details the categories of personal data subject to processing;
2. Personal Data Collections are defined generally;
3. The term for storage of personal data is not determined;
4. Secrecy and protection of personal data processing is determined indirectly;
5. The subsidiary application of the provisions of the Law on Personal Data Protection is directly established.



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2. LAW ON HEALTH PROTECTION

2.1 General Overview

The Law on Health Protection² regulates the rights of citizens arising from health protection, as well as the system and organization of the health care.

The health protection is consisted of measures, activities and procedures for maintaining and promoting of the health and the living and working environment, rights and obligations exercised in health insurance, as well as measures, activities and procedures undertaken by organizations in the field of health for maintaining and improving human health, preventing and eliminating illnesses, injuries and other health deteriorations, early detection of illnesses and health conditions, timely and efficient treatment and rehabilitation by using expert medical measures, activities and procedures.

In the whole process of citizens' health protection numerous institutions are involved that inevitably process and exchange many personal data.

Hence, the assumption is that the system of organization of health protection requires establishment of a high level of protection of personal data, as well awareness development for this constitutionally guaranteed right by the involved institutions and workers.

Rather, the Law on Health Protection contains minimal provisions for personal data protection which undoubtedly cannot regulate collecting and processing of personal data, even less could provide the necessary level of personal data protection. The provisions of this Law refer on adoption of a myriad of bylaws, which regulate the issue of personal data protection. This approach of the legislator is in contrast to the basic data protection principles - that personal data are collected and processed fairly and in accordance with law.

² Official Gazette no.38/1991; 46/1993, 55/1995; 10/2004; 84/2005; 111/2005; 65/2006; 5/2007; 77/2008; 67/2009; 88/2010; 44/2011 и 53/2011



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However, as was noted before, the Law on Health Protection contains minimum provisions concerning the protection of personal data, subject to further analysis.

2.2 Analysis of Specific Provisions of the Law on Health Protection

Article 80

The health institution shall be obliged to enable a foreign citizen, to whom it has provided urgent medical assistance, to contact the proper diplomatic or consular office or the bank where the foreign citizen has financial funds, in order to pay the compensation for the provided urgent medical assistance.

If the health institution does not charge the provided urgent medical assistance, because the foreign citizen has no financial funds, it shall be obliged for the purpose of charging these funds from the Budget of the Republic, to provide information from the foreign citizen about: the identity and the citizenship; passport number; body of issuance; place of permanent residence in the foreign country, and for the foreign citizen with temporary residence that he is materially unsecured and registration form for his place of permanent, i.e. temporary residence; proof that the foreign citizen has no right to use health protection in accordance with the provisions of this Law; according to international agreements or other basis; to determine the amount of payment and to take statement from the foreign citizen that he has been provided urgent medical assistance he did not pay for, for the obligation that the determined compensation shall be paid personally in determined time period as well as the manner of compensation payment.

Article 80 generally regulates the issue of health protection for foreign nationals. In addition, in situations in which the charging for the medical assistance is not executed directly from the foreign citizen, the institution that provided the medical assistance has right to access and process personal data of the foreign citizen for recovery from the Budget of the country.

Thus, the medical institution has a legal basis for collecting and processing the following personal data of the foreign citizens: the identity and the citizenship; passport number; institution of issuance; place of permanent residence in the foreign country, and for the foreign citizen with temporary residence that is materially unsecured and registration form for his place of



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permanent, i.e. temporary residence; proof that the foreign citizen has no right to use health protection in accordance with the provisions of this Law; according to international agreements or other basis; to determine the amount of payment and to take statement from the foreign citizen that he has been provided urgent medical assistance he did not pay for, for the obligation that the determined compensation shall be paid personally in determined time period, as well as the manner of compensation payment.

The provisions of Article 80 have some shortcomings, in the sense that it is not provided any protection of foreign citizens' personal data or a period of time for keeping them.

General conclusions of aspect of the analysis' indicators

Taking into consideration the above mentioned, it could be concluded that:

1. Legal basis for collecting and processing of personal data is established, without specifying in details the categories of personal data subject to processing;
2. Personal data collections are generally determined;
3. The term for storing personal data is not determined;
4. The secrecy and protection of personal data are determined indirectly;
5. The subsidiary application of the provisions of the Law on Personal Data Protection is not directly established.



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3. LAW ON PROTECTION OF PATIENTS' RIGHTS

3.1 General Overview

The Law on Protection of Patients' Rights³ is relatively new and modern law whose provisions regulate the protection of patients' rights when using healthcare, obligations of the healthcare institutions and health workers and associates, municipalities and the Health Insurance Fund in promotion and protection of patients' rights, the procedure for protecting patients' rights, as well as the supervision over the implementation of the Law.

The purpose of the Law is to provide quality and continual healthcare, in accordance with the current achievements in health and medicine, within the framework of the healthcare protection and health insurance system, appropriate to the individual needs of the patient, with absence of any kind of mental or physical abuse, with total respect for the dignity of patient's personality and in his/her best interest, shall be provided by protecting patient's rights.

The Law on Protection of Patients' Rights stipulates the principles of patients' right protection, in which among others principles the humanity principle is determined. As one of the components on which the humanity principle is based is respect for persons' privacy. The conclusion could be that this Law is "privacy friendly".

In support of this conclusion is the fact that in the part of this Law where definitions of the used terms are provided, the terms "medical record"⁴ and "medical data"⁵ are defined, where it can be clearly observed the positive tendency of the legislator to introduce provisions for personal data protection, which will lead to consistency of the legal system of the country.

³ Official Gazette No. 82/2008; 12/2009 and 53/2011

⁴ "Medical record" for the patient shall be a record where all data and documents referring to the health status of the patient, medical, i.e. clinical condition, diagnosis, prognosis and treatment, as well as all other personal data are stored, and which is kept in accordance with the regulations in the field of health record and this Law.

⁵ "Medical data" shall be data referring to the patient's health. The medical data shall include data referring to patient's anamnesis, diagnosis, prognosis and treatment, as well as data in clear and close connection to the patient's health



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The protection of personal data in the Law on Protection of Patients' Rights can be viewed and analyzed from three aspects:

- the right to privacy of patients by providing an appropriate degree of confidentiality and protection of processing of their personal data;
- the right of the patient to be informed as a personal data subject and
- the right of access to data concerning the patient as a personal data subject.

3.2 Analysis of Specific Provisions of the Law on Protection on Patients' Rights

Right to be informed

Article 7

The patient shall have the right, in all phases of healthcare, to be completely informed of:

- 1) his/her health condition including the medical estimation of the results and the outcome of certain medical intervention, as well as its most frequently expected complications;*
- 2) recommended medical interventions, as well as the scheduled dates for their performing (treatment and rehabilitation program);*
- 3) possible advantages and risks when performing, i.e. not performing the recommended medical interventions;*
- 4) his/her right to decision-making on the recommended medical interventions;*
- 5) possible replacements for the recommended medical interventions;*
- 6) reasons for eventual differences among the result achieved from medical interventions and the expected one;*
- 7) the course of the procedure when providing healthcare;*
- 8) recommended lifestyle; and*



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9) *the rights deriving from healthcare and health insurance, as well as the procedure for exercising those rights.*

Article 8

The information referred to in Article 7 of this Law must be given to the patient in an understandable and appropriate manner for the patient, by minimizing the technical i.e. the professional terminology, in order to acquire information being of importance to the patient's treatment.

Article 9

The patient shall have the right to ask for a second expert opinion on his/her health condition, under conditions prescribed in the healthcare and health insurance regulations for giving first expert opinion.

Every health worker with at least equal expert training as the health worker who gave the first expert opinion and who did not participate directly in the initial medical intervention over the patient shall be obliged to give the second expert opinion referred to in paragraph 1 of this Article, upon an oral or written request from the patient.

Article 10

The patient shall have the right to be informed of the names, expert training and specialization of the health workers providing him/her healthcare directly, by compulsory displaying publicly the practicing license issued by the appropriate chamber in the room where (s)he works.

Article 11



The right to be informed shall also have a patient with permanently reduced reasoning ability, in accordance with his/her physical, mental and psychological condition, as well as his/her guardian or legal representative.

Articles 8 to 11 of this Law regulate the patient's right to be informed as a personal data subject. First of all, the right to be informed regarding the health and health care of the patients, also includes information about patient's personal data, i.e. data relating to the health condition of the patient.

These articles in the broadest sense are in accordance with the Law on Personal Data Protection relating to the right of information of personal data subject, but it should be noted that certain segments are not fully regulated. Thus, for example, it is not defined that patient as a personal data subject is entitled to be informed of:

- the identity of the controller and of its authorized representative in the country, if any;
- the purposes of the processing;
- the users or categories of users of personal data;
- the compulsoriness of responding to questions;
- possible consequences of not responding and
- existence of the right to access and the right to correct his/her personal data.

But on the other hand one should bear in mind the fact that the Law on Personal Data Protection is still *lex generalis* in relation to the Law on Protection of Patients' Rights in terms of data protection and in this case the provisions of the Personal Data Protection Law will be directly applied.

Access to medical record

Article 22

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The patient shall have the right to be informed that a medical record is being kept of him/her and (s)he shall have the right to an insight of that record.

The patient shall have the right at his/her own cost in an appropriate amount to obtain a certificate or a copy of the data and documents from the medical record referred to in paragraph 1 of this Article.

The patient shall have the right to demand explanation of the medical record data that refer to him/her.

The data in the medical record shall be updated in a manner that allows determining the initially input data while inputting new ones.

Article 23

The patient shall have the right to authorize in writing a person that shall exercise on his/her behalf the rights referred to in Article 22 paragraphs 1, 2 and 3 of this Law during as well as after the termination of his/her treatment.

In case of a patient's death, if the patient during his life did not explicitly forbid that, the patient's spouse or unwed partner, adult child, parent, adult sibling of the patient, as well as the legal representative, i.e. patient's guardian shall have the right to an insight of the patient's medical record.

The persons referred to in paragraphs 1 and 2 of this Article shall have the right at their own cost in real amount to get a certificate or a copy of the documents in the medical record of the patient.

Article 24

The regulations in the field of personal data protection shall be applied on everything that has not been regulated by this Law in terms of patient's personal data protection.

The provisions of Articles 22 to 24 of the Law on Protection of Patients' Rights regulate the right of access of patients as a personal data subjects to their personal data.



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Although these articles are entitled as "right of access to medical record", having regard to the definitions in the Law on Protection of Patients' Rights under Article 4, the "medical record" itself contains all data and documents referring to the health status of the patient, medical, i.e. clinical condition, diagnosis, prognosis and treatment, as well as all other stored personal data kept in accordance with the regulations in the field of health records and the Law on Protection of Patients' Rights. Taken this into account it could be concluded, without any doubt, that "right of access to medical record" equals to "the right of access to personal data".

The articles of the Law on Protection of Patients' Rights that regulates the "right of access to medical record" corresponds with the provisions of the Law on Personal Data Protection regarding the "the right of access to personal data".⁶ In case something is not governed by the articles of the Law on Protection of Patients' Rights, regarding the protection of personal data, the provisions of the Law on Personal Data Protection shall apply⁷.

Right to confidentiality

Article 25

The patient shall have the right to confidentiality (secrecy) of the personal and medical data that must be kept in secrecy even after his/her death, in accordance with the regulations for personal data protection.

As an exception to paragraph 1 of this Article, patient's data referred to in paragraph 1 of this Article may be revealed if:

- the patient gives written consent,*
- they are necessary for the patient's medical intervention in another institution,*
- they are necessary for processing prescribed by law, by the healthcare institution providing health services for the patient,*
- they are used for historic, scientific, research or educational purposes, under condition the patient's identity not to be revealed, and*

⁶ For more see *Chapter IV. Rights of the personal data subject* of The Law on Personal Data Protection

⁷ Cross reference provision in Article 24 of The Law on Personal Data Protection



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- *it is in accordance with another law in order to protect lives, safety or health of other people.*

The disclosure of the data referred to in paragraph 2 of this Article shall be performed in a manner and up to the extent to which the aim of the disclosure is achieved and the secrecy of the data is protected to the greatest possible extent.

The patient's data obtained in cases referred to in paragraph 2 of this Article shall be kept in accordance with the regulations for keeping professional and business secret, as well as for personal data protection.

The human substances whereof the patient can be identified must be kept secret, in accordance with the regulations for personal data protection.

The patient should give written or oral statement about the persons who can be given information of his/her admission in healthcare institution, i.e. a statement about a person for further communication, as well as his/her health condition, i.e. the persons who must not be given such information.

The consent for giving information may be assumed only in cases when they are given to another health worker, i.e. institution that continues to give the patient healthcare.

The processing of the patient's personal data shall be performed in accordance with the regulations in the field of personal data protection, provided that it is not regulated otherwise by this Law.

The provisions of Article 25 of the Law on Protection of Patients' Rights fully correspond with the provisions of the Law on Personal Data Protection relating to confidentiality and protection of the processing of personal data.⁸

More specifically, the provisions of this Article shall govern: the right to confidentiality (secrecy) of personal and medical data, as well as the provision revealing of personal data. It is envisaged, inter alia, personal data being processed for the patients should be kept secret after the death of the patient, in accordance with personal data protection regulations.

⁸ For more see *Chapter V. Secrecy and protection of personal data processing* of The Law on Personal Data Protection



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As regards to the provision of revealing of personal data, it is important to stress that Article 25 of the Law on Protection of Patients' Rights identified all situations for revealing of personal data which is in accordance with the provisions of Articles 34, 35 and 36 of the Law on Personal Data Protection⁹. Discovery, i.e. revealing of personal data should be carried out in a manner to accomplish the aim of disclosure of information by providing maximum protection of personal data, which is in accordance with Article 5 of Law on Personal Data Protection, which establishes the principles for personal data protection¹⁰.

Article 25 of the Law on Protection of Patients' Rights contains a reference to the application of the Law on Personal Data Protection.¹¹

An author's general conclusion is that the Law on Protection of Patients' Rights is fully in line with the Law on Personal Data Protection.

General conclusions of aspect of the analysis' indicators

Taking into consideration the above mentioned, it could be concluded that:

1. Legal basis for collecting and processing of personal data is established, without specifying in details the categories of personal data subject to processing;
2. Collections of personal data in accordance with the Law on Protection of Patients' Rights are determined by defining the term "medical record", which in the broadest sense contains all personal data of a patient;
3. The term for storing personal data is not determined;
4. The secrecy and protection of personal data are determined;
5. The subsidiary application of the provisions of the Law on Personal Data Protection is directly established.

⁹ According to these provisions, personal data may be revealed for use only pursuant to precise legal basis

¹⁰ One of the personal data protection principles is that collected for specific, clear and legally determined purposes and processed in a manner pursuant to those purposes

¹¹ Paragraph 8 of Article 25 of the Law on Protection of Patients' Rights



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4. LAW ON RECORDS IN THE HEALTH SECTOR

4.1 General Overview

The Law on Records in the Health Sector is relatively new law enacted in 2009. By the adoption of this Law and its entering into force, finally the application of the Law on Records in the Health Sector (“Official Gazette of SFRY” No 22/78, 18/88 and “Official Gazette” No. 15/95) was ceased, while the Law on Records in the Health Sector (“Official Gazette of SRM” No 37/79 and “Official Gazette” No 15/95) was also nullified.

The new Law on Records in the Health Sector regulates the records, data collections and the registers in the health sector, the manner of collecting, processing, archiving and storage of data, publication data, ensuring data quality and data protection, as well as the rights and obligations related to the records in the health sector.

By adopting the Law on Records in the Health Sector the legal framework for personal data protection in this sector should be completed. Simultaneously, the Law on Records in the Health Sector should be complementary with the legislation on data protection in the country. But on the other hand, the Law on Records in the Health Sector, in terms of personal data protection creates doubts as to its implementation in practice, which will be elaborated in the analysis of the specific provisions of this Law.

4.2 Analysis of Specific Provisions of the Law on Records in the Health Sector

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1. Definition of the terms in the Law on Registers in the Health Sector

Article 2

(1) The terms used in this Law shall have the following meaning:

- 1. "Statistical research" is preparation, collection, storage and keeping of data and analysis and publishing of statistical data;*
- 2. "Reporting unit" is holder of collection of data, legal entity and natural person confirmed as data provider;*
- 3. "Collection of statistical data" is concentration of answers contained in statistical questionnaires, forms, enquiry documents and information contained in other media with data from the field of health;*
- 4. "Records" is entry of certain basic and specific data, structured group of data as determined by law, regardless whether it is centralized or divided on functional or geographic basis, as well as regardless whether it is consisted of individual or collective (aggregate) data;*
- 5. "Individual records" is records of personal and medical data of individuals;*
- 6. "Collective records" is records of collective anonymous data on certain marks;*
- 7. "Health register" is instrument of the health statistics containing basic and specific data on natural persons or legal entities, based on collected, processed and analyzed individual collections of data and is used for statistical, research and public health purposes;*
- 8. "Health data" is data referring to the health of the population and include as well medical data;*
- 9. "Medical data" is data referring to the health of an individual as well including the data referring to anamnesis, diagnosis, prognosis and treatment, as well as data with clear and close relation with the health;*
- 10. "Collection of data" is registers determined by law and records determined by law based on law, basis and banks of data kept on the basis of public and other authorizations;*
- 11. "Database" is collection of data sorted by certain rules and standards with prescribed manner of keeping, updating and time periods for keeping by the holder of the database;*



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12. *"Identification data" are those individual data enabling direct identification of the legal entity or natural person, and referring to the name and surname, address and personal identification number kept in accordance with the regulations;*
13. *"Individual data" are data referring to the legal entity or natural person. Individual data referring to a natural person shall be considered personal data;*
14. *"Personal data" is any information referring to an identified natural person or natural person who can be identified, and person who can be identified is a person whose identity can be directly or indirectly confirmed, especially on the basis of personal identification number of the citizen or on the basis of one or more marks specific for his physical, psychological, economic, cultural or social identity;*
15. *"Special categories of personal data" are personal data revealing the racial or ethnical background, political, religious or other belief, membership in a trade union organization and data referring to the health condition or the sexual life;*
16. *"Unrevealed data" are data that cannot be directly connected to an individual;*
17. *"Anonymous data" are personal or unrevealed data that after their special processing can no longer be directly or indirectly connected to an individual and have no capacity of personal data;*
18. *"Procession of personal data" is each operation or sum of operations being performed on personal data in automatic or in any other manner, such as: collecting, recording, organizing, keeping, adjusting or altering, withdrawing, consulting, using, revealing by transferring, publishing or in any other manner making them available, leveling, combining, blocking, deleting or destroying;*
19. *"Controller" is natural person or legal entity that individually or together with another collects, processes, analysis and delivers health and medical data;*
20. *"User" is natural person or legal entity, state body or other body wherefore the data are being revealed for the purpose of performing regular activities, in accordance with law. The bodies to which data can be revealed within a special investigation, shall not be considered users in terms of this Law;*



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21. *"Consent of the subject of personal data" is freely and explicitly given statement of the will of the subject of personal data wherefore he consents the processing of his personal data for previously determined purposes;*
22. *Authorized holders of the health statistics are the Institute for Public Health and the institutes for health protection, that when collecting, processing and disseminating data apply statistical standards and methods;*
23. *"Health documentary material" is material from its source and reproduced (written, drawn, printed, photographed, filmed, phonographed, magnetically, optically or otherwise written), received or created in the work of the healthcare institutions and directly related to the provision of health protection;*
24. *"Services of information society" are services provided for compensating distance, via electronic means and on personal request of the service receiver. "Distance" means that the service is provided without simultaneous presence of both parties;*
25. *"Service provider" is any natural person or legal entity providing services of information society by establishing trade company on indefinite term in the country, whereas the presence and use of technical means and technologies necessary for providing services of information society, are themselves not considered foundation of the service provider;*
26. *"Service receiver" is any natural person or legal entity that due to professional or other reasons uses services of the information society, for the purpose of searching information or making an information available;*
27. *"Consumer" is any natural person that uses services of information society for purposes apart from its trade activity or profession;*
28. *"Electronic signature" is line of data in electronic form contained or logically related to other data in electronic form and intended for confirming the authenticity of the data and the identity of the signature holder;*
29. *"Infrastructure for managing the health documentary material" is personnel, premises, equipment, education/training and program equipment intended for enabling complete or partial collecting, keeping or processing of health, personal or other data and other health documentary material in digital form and thus related issues;*



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30. *"Bidder (software) of program equipment" is any entity wherefore the health activity providers as final contracting authorities, enables use of program equipment for managing the health documentary material;*
31. *"Information services" are services related to collection, keeping or procession of health documentary material in digital form, including digitalization of the material, but are inseparable related with the offer of the program equipment;*
32. *"Bidder of information services" is any entity performing information services for the health protection providers as final contracting authorities;*
33. *"Information of public character" is information in any form created or at disposal of the information holder, i.e. at disposal only of the information holder, in accordance with his competences;*
34. *"Information seeker" is any legal entity and natural person without discrimination on any basis, in a manner and under conditions determined by the Law on Free Access to Information of Public Character and this Law and*
35. *"Document" is any entry of information regardless of its physical form or characteristics, written or printed texts, charts, schemes, photographs, drawings, sketches, working materials, as well as audio, voice, magnetic or electronic, optical and video recordings in any form, and also transferable equipment for automatic processing of data with built-in or transferable memories for storing data in digital form.*

The *General provisions* part of the Law on Records in the Health Sector defines a great number of terms. This practice of the legislator is positive, starting from the fact that the goal is to perform separation and definition of terms that will be used for purposes of this Law.

But, on the other hand, many of the definitions, modified or used in different context are identical to the definitions set forth in the Law on Personal Data Protection. An example of the same definitions as those in the Law on Personal Data Protection are as follows:

In Article 2 item 14 of the Law on Records in the Health Sector is established that "Personal data" means any information related to identified natural person or natural entity that can be identified and person who identified is a person whose identity can be determined directly



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or indirectly, in particular based on the unique identification number of the citizen or based on one or more features specific to his physical, mental, economic, cultural or social identity.

Item 15 of this Article stipulates that “Special categories of personal data” are personal data revealing racial or ethnic origin, political, religious or other beliefs, trade union membership and data concerning health condition or sex life.

Item 18 of this Article stipulates that “Processing of personal data” means any operation or set of operations performed on personal data automatically or otherwise, such as: collection, recording, organization, storage, adaptation or alteration, withdrawal, consultation, use, revealing by transmission, posting or otherwise making available, aligning, combining, blocking, erasure or destruction.

Item 19 of this Article stipulates that “Controller” means natural or legal person who alone or together with others collects, processes, analyzes and delivers health and medical data.

Item 20 of this Article stipulates that “User” is a natural or legal person, public authority or body to whom data are revealed because of performing regular duties in accordance with law. Bodies that may be disclosed within a separate investigation, are not considered users under this Law.

Item 21 of this Article stipulates that “Consent of the personal data” is freely and explicitly given statement of will of the personal data subject by which s/he agrees with the processing of her/his personal data for predetermined purposes.

“Double” definition of same terms in two different laws certainly creates legal uncertainty and is not in function of the consistency and coherence of the legal system of the country.

2. Basic Principles

Article 4

(1) Health records kept on the basis of the principles of quality, efficiency, effectiveness and economy, whereas the records are proper, relevant and in scope corresponding to the purposes determined by this Law.



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- (2) Medical data shall be processed in accordance with the regulations on personal data protection.*
- (3) Health and medical data shall be collected for particular and clear purposes determined in this Law and shall be processed in a manner being in line with such purposes.*
- (4) Personal data, collected for the purposes of the health records, shall be exclusively used for collection, procession and analysis of health and medical data, in accordance with the regulations on personal data protection and with this Law.*
- (5) The access to information prepared on the basis of processed data from collections of data shall be enabled in accordance with the regulations on free access to information of public character.*
- (6) Processing of health and medical data for scientific or statistical researches shall be considered in accordance with the purposes of collecting data, if certain protection measures are undertaken in accordance with the regulations on personal data protection.*

Analysing the provisions of Article 4, where certain fundamentals principles are defined, we can conclude that the same comply with regulations on personal data protection of the country and the personal data protection principles.

Personal data, in particular medical and health data should be processed solely for the purpose for which they were originally collected and processed, which is consistent with the principle contained in Article 5 of the Law on Personal Data Protection pursuant to which personal data are processed in accordance with the purposes for which they are collected.

Positive feature of the provisions of this Article is that they contain a cross reference provision to the regulations on personal data protection.

3. Registers

Pursuant to the provisions of the Law on Records in the Health Sector, more precisely the defined terms in Article 2, there are aggregate and individual records. The aggregate records contain anonymized data, which according to the Law on Personal Data Protection are not personal data and because of that those reasons they are not subject to analysis.



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On the other hand, individual records, pursuant to the provisions of Article 2 of the Law, represent records of personal and medical data of the patients.

General provisions for records are contained in Articles 5, 6 and 7 of the Law:

Article 5

(1) The Institute for Public Health (for the territory of the country) and the institutes for health protection for the areas they have been founded for (hereinafter: regional centers for public health) shall be authorized holders of the health statistics for the records kept in the healthcare institutions.

(2) Each healthcare institution, for the activity it performs, shall be obliged to submit collective and individual records – statistical reports, through the regional centers for public health to the Institute for Public Health.

(3) Records established by this Law shall be kept as individual records (individual data on natural persons or legal entities) and collective records (aggregate data).

(4) Keeping the records referred to in paragraph (3) of this Article is consisting part of the professional and medical work in the healthcare institutions and health workers and co-workers.

(5) The records shall serve as source of data for statistical researches in the field of health and shall be used for following and studying the health condition of the population, for programming and planning, i.e. undertaking the necessary measures in the field of health protection, for the needs of the scientific research, for the needs of the local self-government in accordance with the regulations regulating the competencies of the local self-government, for the needs of the state defense, for informing the public, for performing international obligations of the state, as well as other official purposes.

(6) The data contained in the individual records can be used by individual to whom those data refer, for the purpose of exercising their rights.

Article 6

(1) Healthcare institutions shall be obliged to keep records in the basic medical documentation.



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(2) The records shall be kept by entering data in the basic medical documentation (individual chart, register, ambulance journal, illness history, means for automatic processing of data and else) and in other forms of keeping the records determined by this Law, on different levels of health protection.

(3) The basic medical documentation of paragraph (1) of this Article shall contain:

- personal data for the individual (PIN, data of birth, sex, name and surname, name of one of the parents, belonging to ethnical community, religion, marital status, education, occupation, date of death, address of permanent place of residence, place, municipality, occupation, employment status (economic status) and basis for health insurance),*
- medical data – data on the health condition (diagnosis, date of visit, planned visits, doctor's code, therapy, referral, reason for temporary working disability, reason for death, reason for processing and social anamnesis of the family) and*
- data on medical care and other data related to patient care (nutrition and alike).*

(4) The basic medical documentation referred to in paragraph (1) of this Article shall also include the findings, statements, opinions and other documents related to the health condition and the provided health protection.

(5) The form and contents of the Forms for keeping the basic medical documentation referred to in paragraph (3) of this Article shall be prescribed by the Minister of Health.

Article 7

(1) The basic medical documentation referred to in Article 6 of this Law shall be used by health workers in the provision of health protection of an individual as well as source of data for the records determined in this Law.

(2) When keeping the basic medical documentation the workers shall be obliged to act in line with this Law, with the regulations on personal data protection and protection of the patients' rights.



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According to the aforementioned provisions, healthcare institutions are obliged to keep records in basic medical documentation containing personal data, medical data and data on medical care.

The provisions of Article 6 paragraph 2 of the Law define exactly which data will be collected and processed for patients as personal data subjects, which is consistent with the basic data protection principle laid down in Article 5 of the Law on Personal Data Protection - that personal data is processed justly and in accordance with law.

Article 7 prescribes the persons that may use or process personal data (health workers) and also contains a reference that states that in the process of keeping of basic medical documentation, i.e. processing of personal data, health workers are obliged to act under this Law, regulations on personal data protection and regulations on protection of patients' rights.

Article 8 precisely defines individual records (that contain personal and medical data of the patients) that healthcare institutions have an obligation to keep:

Article 8

(1) Healthcare institutions, depending on the activity they perform, shall keep the following individual records for:

- 1) malignant neoplasm;*
- 2) revealing pre-cancerous changes of the cervix;*
- 3) revealing breast cancer;*
- 4) colorectal carcinoma;*
- 5) diabetes;*
- 6) innate disruptions of the metabolism and endocrinopathies;*
- 7) innate anomalies;*
- 8) children with special needs;*
- 9) ischemic heart disease;*
- 10) cerebrovascular diseases;*



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- 11) *kidney insufficiency;*
- 12) *psychosis;*
- 13) *drug abusers;*
- 14) *alcohol addicts;*
- 15) *occupational disease;*
- 16) *intoxication;*
- 17) *traffic accident trauma;*
- 18) *violence;*
- 19) *home injuries;*
- 20) *stationary treated person;*
- 21) *childbirth;*
- 22) *in-vitro fertilization;*
- 23) *abortion – termination of pregnancy;*
- 24) *periodical and permanent absence from work;*
- 25) *accident – injury at work;*
- 26) *blood donors;*
- 27) *transplantation of human body parts;*
- 28) *infectious diseases;*
- 29) *immunization;*
- 30) *HIV/AIDS;*
- 31) *tuberculosis;*
- 32) *doctor's report on a deceased person;*
- 33) *perinatal death;*



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34) health workers and

35) units for health protection within the composition of the healthcare institution.

(2) Filled in individual records for healthcare institutions shall be delivered to the regional centers for public health every 5th in the ongoing month for the previous month.

(3) The regional centers for public health shall deliver the filled in individual records to the Institute for Public Health every 10th in the ongoing month for the previous month.

(4) The form and content of the Forms, as well as the manner of their filling in, delivering, processing and keeping of the individual records referred to in paragraph (1) of this Article, shall be prescribed by the Minister of Health.

The provisions of this Article develop another issue which is in accordance with the Law on Personal Data Protection - revealing of personal data for use. Thus, pursuant to *Chapter VIII. Revealing personal data to users* of the Law on Personal Data Protection, the revealing of the personal data for use, in the broadest sense, can be done only if there are precise legal grounds. Certainly when it comes to revealing personal data for use, i.e. exchange of data contained in the records in the health sector, such a legal basis are the provisions of this Article of the the Law on Records in the Health Sector.

4. Authorization over the personal data processing

The Law on Records in the Health Sector contains also the following provisions:

- Article 43 paragraph (2) stipulates that the Ministry of Health performs supervision of the the transfer of health and personal data outside the country.
- Article 44 stipulates that the inspection supervision over the implementation of the organizational and technological procedures and the measures for protection of health and personal data and the keeping of health records, when not done in electronic form, is performed by the State Sanitary and Health Inspectorate.
- Article 45 paragraph (1) stipulates that in performing the inspection supervision, the authorized inspector shall:



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- review the acts governing the personal data protection,
 - examine the content of the health records,
 - inspect premises in which personal data are collected, processed, stored, used and submitted and
 - verify the functionality of the measures for securing personal data and their execution.
- Article 46 paragraph (1) indent 2 determines that the inspector is authorized by a decision to ban the collection, processing, storage, delivery and use of personal data in collections, i.e. their deletion, if not assured their full protection, or if the provisions and procedures of this Law are inconsistently implemented.
 - Article 47 stipulates that the inspection supervision over the implementation of the organizational and technological procedures and measures for protection of the health and personal data and keeping of the health records in electronic form, shall be performed the state institution responsible for the issues of information society of the country.

Although, the idea of the legislator may be well intended, these provisions are not in accordance with the Law on Personal Data Protection.

Namely, the legislator has established, in Article 37 paragraph 1of the Law on Personal Data Protection (“Official Gazette” No. 7/2005, 103/2008, 124/2010 and 135/2011) the Directorate for Personal Data Protection as the only state institution in the country which supervises the legality of actions taken during the processing of personal data protection. In this context, Article 44 paragraph 1 of the Law on Personal Data Protection stipulates that inspection supervision of the implementation of this Law and the regulations adopted pursuant to this Law shall be performed by the Directorate for Personal Data Protection, through inspectors for personal data protection.

By these provisions of the Law on Personal Data Protection, the legislator has fully transposed the provisions of the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data of the European



Parliament and Council of the European Union and has incorporated the provisions of the Law on Ratification of the Additional Protocol to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data regarding supervisory authorities and transborder data flows (“Official Gazette” no.103/08).

However, this coherence in the process of building a unified legal system for personal data protection is brought into question by the provisions of the Law on Records in the Health Sector relating to the established powers, whereby with these processes in the legislative sphere a dualism is established in the field of supervision of personal data protection in the country. Obviously, this dualism is not in accordance with the rules of the international law constructed by the Council of Europe that the country has accepted and are part of its internal legal order by the Law on Ratification of Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (“Official Gazette” No. 7/2005) and the Law on Ratification of the Additional Protocol to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data regarding supervisory authorities and transborder data flows (“Official Gazette” No. 103/2008).

General conclusions of aspect of the analysis’ indicators

Taking into consideration the above mentioned, it could be concluded that:

1. Legal basis for collecting and processing of personal data is established, without specifying in details the categories of personal data subject to processing;
2. Personal data collections are defined precisely;
3. The period of storage of personal data is determined;
4. Confidentiality and protection of personal data processing are determined indirectly;
5. The subsidiary application of the provisions of the Law on Personal Data Protection is directly established.



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5. LAW ON STANDSTILL AND WRITING OFF OF LIABILITIES ON THE BASIS OF CONTRIBUTIONS TO COMPULSORY HEALTH INSURANCE

5.1 General overview

The Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance¹² regulates the standstill of liabilities for payment of due and unpaid contributions for compulsory health insurance, as well as writing off of liabilities on the basis of unpaid contributions for compulsory health insurance.

From chronological point of view, this Law was adopted after the adoption of the Law on Personal Data Protection¹³ which constitutes the basic legal act that determines the "rules of play" regarding the protection of the personal data of individuals. That would mean that the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance, with regard to its content and having in mind that it belongs to a group of laws adopted after the "beginning of the era of personal data protection in the country", should contain provisions governing the protection of personal data in the procedure for determining the standstill of the debt and writing off of liabilities on the basis of contributions. If that is not the case, than the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance should eventually contain provisions that would refer to application of personal data protection regulations. However, the legislator has not prescribed a legal obligation for competent authorities to protect personal data of individuals in the process of implementation of this Law. In this context, we can conclude that the absence of provisions in the the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance which would regulate the issue of personal data protection is a normative oversight of the country legislator.

¹² Official Gazette No. 161/2008

¹³ The basic text of the Law on Personal Data Protection was adopted in 2005 and amended in 2008 and 2011



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However, irrespective of the above, the Law on Personal Data Protection as *lex generalis* in relation to the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance, will always apply in relation to the issues of protection of personal data regardless of the fact that direct legal basis for their protection is not provided, or even when there is no reference for the application of regulations which govern personal data protection.

5.2 Analysis of specific provisions of the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance

Article 9

(1) The request for determination of the standstill of the debt on the basis of contributions under Article 8 of this Law shall be filed within 45 days of entering into force of this Law, to the Health Insurance Fund, with data concerning the amount of calculated and unpaid contribution, which are due to be paid till October 31, 2008.

...

(4) Besides the data from the paragraph 1 of this Article, the applicant which has employees (employer) is obliged to submit a list of insured for whom contributions are not paid.

(5) The list of the insured under paragraph 4 of this Article contains: personal data of the insured, data regarding the place of stay or place of living, data for the period for which contributions are not paid, as well as data on the amount of unpaid contributions collectively for all insured, as well as for each insured, which are due to be paid till 31 October 2008.

The procedure for determination of the standstill of the debt on the basis of contributions, as well as the procedure for writing off of the debt, begins by submitting written requests by the



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taxpayer who is obliged for calculation and payment of contributions¹⁴ that are submitted to the Health Insurance Fund with data on the amount of the calculated, but unpaid contribution, which is due to be paid till 31 October 2008.

In addition to the request the applicant who has employees (employer) is obliged to submit a list of insured for whom contribution is not paid, and this list, in accordance with Article 9 paragraph (5) contains: personal data of the insured, data regarding the place of stay or place of living, data for the period for which contributions are not paid, as well as data on the amount of unpaid contributions collectively for all insured, as well as for each insured, which are due to be paid till 31 October 2008.

Article 9 of the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance explicitly determines that the list of insured which the applicant shall submit together with the request to the Fund contains personal data of the insured, which at the same time represents legal basis for collecting personal data. But, this Law does not further specify which personal data of the insured, the applicant should state in the list. If we extensively interpret this provision, than we can conclude that the applicant is free in the assessment about what personal data of the insured will s/he state in the list, which on the other hand may result in overextension of the personal data contained in the list. The fact that the categories of personal data that will be collected and processed by the Health Insurance Fund are not defined points to the conclusion that this Law is not harmonized with the established principle in Article 5 paragraph 1 item 3 of the Law on Personal Data Protection according to which "personal data shall be appropriate, relevant and not too extensive in relation to the purposes for collecting and processing". Therefore, the author considers it necessary to "decompose" the term "personal data of the insured" by prescribing the categories of personal data of the insured which are collected and processed for the purposes of the aforementioned request, i.e. the list, that are appropriate, relevant and not too extensive and are in accordance with the objectives due to which the list is submitted to the Health Insurance Fund.

¹⁴ According to Article 2 point 3 a Taxpayer who is obliged for calculation and payment of contributions is legal, natural person or state body which is obliged to calculate, keep and pay the contribution for compulsory health insurance



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Article 11

(1) The Health Insurance Fund maintains separate record for each taxpayer for calculation and payment of contributions for whom a decision of Article 10 of this Law is being made.

(2) In the records of paragraph 1 of this Article the following data shall be kept: data on the taxpayer for calculation and payment of contributions, insured for whom the obligation from the decisions on the basis of the contributions of Article 10 of this Law, the amount of the debt on the basis of the contributions that are due to be paid till 31 October 2008, as well as other data that are necessary for keeping the records.

(3) The manner and procedure for keeping the records are prescribed by the Minister of Finance within 15 days of entering into force of this Law.

The Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance, pursuant to Article 11 paragraph (1), provides authorization for the Health Insurance Fund to maintain separate records for each taxpayer who is obliged for calculation and payment of contributions for whom a decision is made by which standstill of the debt on the basis of contributions is confirmed, as well as a decision for writing off of the debt. This record actually is a record that contains information about the taxpayers who are obliged for calculation and payment of contributions – in fact legal persons, which is not an object of interest of this analysis. But, in accordance with Article 11 paragraph (2) of this Law, the records are consisted of data of the insured for which a respective decision for standstill of the liabilities on the basis of contributions is being made. In this sense, having in mind the legal definition (Article 2 point 1) of the term "insured" - a natural person who is insured in accordance with the regulations for health insurance, what can be concluded is that the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance in an indirect manner determines authorization for creation of personal data collection within the existing records of legal entities. However, the Law does not determine which data of the insured will be entered in the said records. But, if this Article is interpreted in correlation with Article 9, in that case it could be concluded that the same categories of personal data that will be entered in the list of Article 9 of this Law, which shall be submitted to the Health Insurance Fund, could be making



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up the personal data collection for the insured, kept by the Fund pursuant to Article 11 paragraph (2).

In the context of the above mentioned, the legislator opted the content of the said records to be determined by bylaw, which certainly does not imply implementation of the principle of Article 5 paragraph 1 item 1 of the Law on Personal Data Protection according to which personal data shall be processed justly and pursuant to law. In this particular case it is the Rulebook on the manner and procedure for keeping the records in the Health Insurance Fund for the taxpayers obliged for calculation and payment of contributions, the form and content of the specimens of the requests for ascertain the debt, and the list of records ("Official Gazette of the Republic " No. 2/2009), adopted by the Minister of Finance. Article 4 paragraph 1 of the Rulebook determines solely data for the taxpayers - legal persons that are stored in the records of the Fund, while the data of the insured – natural persons which should be entered in the records are not at all covered by the Rulebook. From the above mentioned a discrepancy can be noted between the provisions of the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance and the Rulebook on the manner and procedure for keeping the records in the Health Insurance Fund for the taxpayers obliged for calculation and payment of contributions, the form and content of the specimens of the requests for ascertain the debt, and the list of records, as well as a certain legal vacuum with regard to data of the insured for whom the liabilities standstill, which should be contained in the records of Article 11 paragraph (2) of the cited Law.

From the analysis of the provisions of the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance it can be concluded that the it provides legal basis for collecting and processing of personal data and potential indirect basis for establishing and keeping of personal data collection. But, it can also be concluded that the said basis, with respect to the regulations for personal data protection, are "incidental". Namely, a conclusion imposes that during the creation of this Law the principles for personal data protection were not taken into account, despite the fact that the Law provides possibility for collecting and processing of personal data of the insured. Therefore, during the eventual amendments of the Law on Standstill and Writing off of Liabilities on the Basis of Contributions to Compulsory Health Insurance it would be necessary to produce certain interventions so a harmonization with the provisions of the Law on Personal Data Protection could be reached.



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General conclusions of aspect of the analysis' indicators

Taking into consideration the above mentioned, it could be concluded that:

1. "A sort of" legal basis for collecting of personal data is defined, however without precise determination of the personal data categories that should be collected;
2. Secrecy and protection of personal data are not determined;
3. Terms for storing of personal data are not established;
4. The Law does not prescribe direct legal basis for establishing personal data collections;
5. Subsidiary application of the provisions of the Law on Personal Data Protection is not established.



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6. LAW ON BIOMEDICAL ASSISTED INSEMINATION

6.1 General Overview

The Law on Biomedical Assisted Insemination¹⁵ was adopted in 2008 and is a modern law which through regulation of the procedure for biomedical assisted insemination (hereinafter referred to as: “BAI”) offers the prerequisites for ensuring legal security of people seeking medical help for insemination, as well as protection of the rights and interests of all persons involved in these procedures.

This Law regulates the right to BAI, the requirements for exercising the right to BAI, donation safety, provision, testing, processing, preservation, distribution and application of cells during BAI, the rights and obligations of the patients, healthcare workers and healthcare institutions, the requirements for implementation of BAI, as well as the supervision.

The goal of the Law on Biomedical Assisted Insemination is to bring off insemination using the achievements and methods of the scientific, technical and technological progress, the medical science and the positive experiences, with particular emphasis on respect for human rights and protection of the data of the donor and the recipient of biological material.

From its beginning, in the general provisions of the Law, Article 2 affirms the principle of respect for human rights and health standards in the sense that implementation of BAI procedure is done in a manner that ensures protection of human rights, dignity and privacy of the persons subject to medical procedure and the donors of genital cells and embryos. Keeping in secrecy and ensuring protection of personal, medical and genetic data is particularly important segment for ensuring protection of the privacy of patients, especially if the person is a donor or recipient of genital cells in BAI procedure (in vitro), but also for ensuring protection of the identity of the patients who are donors or recipients of genital cells in BAI procedure. Considering the applicability of this principle in this Law, in particular in the protection of

¹⁵ Official Gazette No. 37/2008



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individual privacy part, we can conclude that this Law is also part of the group of "privacy friendly" laws.

To the benefit of the abovementioned conclusion goes the fact that this Law directly implements the right of the subject of personal data to be informed, as well as the principle of collecting and processing of personal data based on the consent of the subject of personal data¹⁶. Thus, the provisions of the Law on Biomedical Assisted Insemination determine that the healthcare institution authorized to carry out BAI procedure shall appoint a person responsible for giving information to the donor prior to the commencement of the procurement procedure. The responsible person pursuant to the Law shall, obligatory, before starting the procedure for the donation, give information to the donor, inter alia, for the purpose and delivery and protection of donor data; medical confidentiality; as well as that the personal data, in the broadest sense, will be collected only on the basis of freely given written consent of the subject. Through these provisions, the Law on Biomedical Assisted Insemination achieves high degree of compliance with the Law on Personal Data Protection, specifically in the part that regulates the rights of the subject of personal data (Article 10), but also in regard to the processing of special categories of personal data (Article 8).

The Law on Biomedical Assisted Insemination contains solid set of provisions that guarantee protection of personal data, as well as provisions that refer to application of personal data protection regulations. This determination of the legislator is certainly welcomed.

6.2 Analysis of specific provisions of the Law on Biomedical Assisted Insemination

Data protection and privacy

Article 17

¹⁶ This principle is laid down in Article 6 of the Law on Personal Data Protection



The authorized healthcare institutions shall be obliged to provide protection of all personal, medical and genetic data of the donor and acceptor and to undertake all necessary measures not to reveal the identity of the donor and his/her family and vice versa.

The data and documents referred to in paragraph 1 of this Article are classified information and shall be kept in accordance with the regulations on classified information and personal data protection.

The authorized healthcare institutions shall be obliged to apply the provisions of this Law and the regulations on patients' rights protection, classified information protection and personal data protection to the data referred to in paragraph 1 of this Article, securing privacy of the personal, medical and genetic data, as well their revealing thereof.

Data confidentiality

Article 46

All participants in the implementation of the BAI procedure shall be obliged to keep all the data related to the procedure as classified information, especially the personal and the data related to the health condition of the man and woman being subject to medical help, the child being conceived in the procedure and the donors of genital cells and embryos.

Data protection and secrecy

Article 50

The authorized healthcare institution shall be obliged to provide protection of all the personal, medical and genetic data of the donors and the individuals contained in the documentation and records.

The data and documents referred to in paragraph 1 of this Article shall be classified information and shall be kept in accordance with the regulations on protection of classified information and personal data protection.

The healthcare institution shall be obliged to apply the regulations on protection of the patients' rights, classified information and personal data protection and this Law for the documentation



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and the records referred to in paragraph 1 of this Article, for the purpose of providing confidentiality of the personal, medical and genetic data, as well as their revealing.

What is evident from the content of Articles 17, 46 and 50 of the Law on Biomedical Assisted Insemination is the tendency of the legislator to provide high degree of secrecy, confidentiality and privacy of all participants in BAI procedure. Basically, the provisions of these articles do not define specific measures for protection of personal data, instead they mainly refer to application of the regulations on protection of patients' rights, personal data protection and the regulations on security of classified information. However, such a reference relating to a wide range of issues (storage, access and revealing) regarding the processing of personal data is more than sufficient legal basis for effective protection of personal data in BAI procedure through subsidiary application of the Law on Personal Data Protection and other regulations in this area.

The abovementioned articles provide a general obligation (duty) for the authorized healthcare institutions, as well as for all persons involved in implementation of the procedure for BAI, to take all necessary measures to protect personal, medical and genetic data of: donors and recipients; woman and man who are provided with medical assistance; a child conceived in the respective procedure; donors of genital cells and embryos and other persons who are part of the documentation and the records of the procedure. Using this approach the Law on Biomedical Assisted Insemination determines the subjects of personal data, but also the controllers of personal data collections, which is of great importance for the correct application of this Law in practice.

Records of authorized healthcare institutions

Article 47

The authorized healthcare institutions shall be obliged to keep records of:

- 1) the personal data of the married or unwed partners, that is the woman subject of the BAI procedure;*
- 2) the type of BAI procedure;*



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- 3) *the personal data of spermatozoids, ova and embryos donors;*
- 4) *each donation and each donation received product for the donors, the spermatozoids, the ova and the embryos;*
- 5) *the results from the controls and laboratory examinations of the donors and the married or unwed partner, that is the woman being subject to the BAI procedure;*
- 6) *the obligatory psychological and legal counselling and informing being performed;*
- 7) *written consent for a certain BAI procedure in accordance with Articles 12 and 15 of this Law;*
- 8) *the withdrawal of the written consent;*
- 9) *the data regarding the course and duration of the procedure, the important circumstances related to the pregnancy and giving birth, as well as the health and development of the child;*
- 10) *the taking, processing, testing and distribution of genital cells and embryos;*
- 11) *the preservation of genital cells and embryos, and*
- 12) *the adverse events and reactions.*

The records referred to in paragraph 1 of this Article shall be classified information and shall be kept by a person authorized by the institution's director.

Register of donors in an authorized healthcare institution

Article 48

In accordance with the provisions of this Law, the authorized healthcare institution shall be obliged to keep register of the donors of spermatozoids, ova and embryos.

In the register referred to in paragraph 1 of this Article, the authorized healthcare institution shall keep records of:

- *The personal data and the data regarding the health condition of the donors of spermatozoids, ova and embryos, as well as data of the donors' parents;*



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- *The day, month and year when the genital cells or embryos are donated, preserved and used;*
- *The results of the donors' controls and analysis of their genital cells, and the data regarding the birth of the child conceived by BAI with donated genital cells or an embryo.*

The register referred to in paragraph 1 of this Article shall be kept a person authorized by the institution's director.

The authorized healthcare institution shall be obliged to preserve the data referred to in paragraph 1 of this Article 30 years as from the day of their entry.

Every six months, the authorized healthcare institution shall be obliged to submit reports containing data of its register to the State Register for the purpose of permanent preservation. All the data from the State Register shall be classified information.

Articles 47 and 48 of the Law on Biomedical Assisted Insemination prescribe legal grounds for establishing and maintaining personal data collections by authorized healthcare institutions. Having in mind the concept of the above cited articles the conclusion arises that the data contained in the records (Article 47) and in the register (Article 48) are personal data while the collections as integrity are classified information. This would practically mean that for the data contained therein shall apply two regimes of protection - protection of personal data and protection of classified information.

Given the fact that Article 47 paragraph 2 and Article 48 paragraph 3 of this Law provide that the records are kept by person authorized by the Director of the institution, it evolves as a necessity for the health institutions to keep their own records of the persons authorized to process personal data¹⁷, so a higher level of protection of personal data stored in the records can be achieved. Of course, determining the responsible qualified person in accordance with Article 43 and the mandatory reporting to the Ministry of Health and the State Commission on BAI for the personal data and contact details of this person, as well as for any change of the responsible person, clearly represents obedience for the obligations stipulated in the Law on Personal Data Protection.

¹⁷ According to Article 25 of the Law on Personal Data Protection



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Positive feature of the Law on Biomedical Assisted Insemination is that it regulates personal data collections which are kept by the authorized healthcare institutions. In this regard, the Law accurately identifies the categories of personal data that are to be collected and processed within the collections. It should also be noted that Article 48 of the Law on Biomedical Assisted Insemination defines the period for keeping the data in the registry, which is 30 years from their date of registration, which directly implements the principle of protection of personal data set out in Article 5 paragraph 1 item 5 of the Law on Personal Data Protection, under which personal data are stored in a form which enables identification of the personal data subject, not longer than necessary to meet the purposes for which the data have been collected for further processing. Determining the legal limit for data storage is a positive step but what it needs to be reviewed is whether the length of the period is in accordance with the purposes for which these data are collected and processed? On the other hand, the question is why the legislator has not prescribed the term for storage of the data in the records of Article 47? In any case, the author concludes that the data collections managed by authorized health institutions in accordance with the provisions of the Law on Biomedical Assisted Insemination still falls under obligation to be enlisted in the Central Register of Personal Data Collections run by the Directorate for Personal Data Protection.

Keeping of data and documents

Article 51

The authorized healthcare institutions shall be obliged to provide keeping of the data and the documents for each donation and each product received by donation, for the donors, the spermatozoids, the ova and the embryos for the purpose of providing traceability during all procedure phases.

The institutions referred to in paragraph 1 of this Article shall be obliged to keep the data and the documents referred to in paragraph 1 of this Article as active for at least 30 years as of the day of their clinical application.

The keeping of the data and documents referred to in paragraph 1 of this Article can be performed, in addition to the written form, in electronic form as well.



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The manner of keeping of the data and the documents referred to in paragraph 1 of this Article shall be prescribed by the Minister of Health.

Measures for data protection

Article 52

The authorized healthcare institutions, for the purpose of protecting the data referred to in Article 17 of this Law, shall be obliged:

- 1) to provide necessary measures for data protection, as well as protection against any kind of unauthorized release, delivery or exchange of the donor's file or information transmission;*
- 2) to implement procedures for solving the data incompatibility, and*
- 3) not to allow unauthorized revealing of information, during the guaranteeing period of traceability of the donations.*

The healthcare institutions, pursuant to Article 51 of the Law on Biomedical Assisted Insemination are obliged to provide storage of data and documents for each donation and each product received by donation, for the donors, the spermatozoids, the ova and the embryos as active at least 30 years of the day of their clinical use. The storage can be done in written or in electronic form. Regarding the personal data protection, the author notes the positive approach of the legislator to determine the period for keeping the abovementioned data, which is consistent with the principle of Article 5 paragraph 1 item 5 of the Law on Personal Data Protection under which personal data are stored in a form which enables identification of the personal data subject, not longer than necessary to meet the purposes for which the data have been collected for further processing. However, the author disputes the period for data storage as active data - at least 30 years - a period set very high, which certainly deserves reassessment in accordance with the objectives of data processing.

As regards to the measures for data protection under Article 52 of the Law on Biomedical Assisted Insemination, the author believes that their review is necessary, as well as possible



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amendment, in terms of whether the prescribed measures provide a level of protection of personal data adequate to the risk of the processing and the nature of the processed data¹⁸.

State Register of Biomedical Assisted Insemination

Article 56

The State Register, in accordance with the provisions of this Law, shall contain data of the beneficiaries of the allogeneic insemination, the children conceived by BAI with donated genital cells or embryos, and data of the donors of genital cells and embryo.

The healthcare institutions authorized for performing BAI procedures shall be obliged, on a regular basis, to submit the data kept in accordance with Article 45 of this Law to the State Register.

The Minister of Health shall authorize the individuals who keep the State Register.

All data in the State Register shall be classified information.

Right to insight in the State Register

Article 57

A child born by insemination with donated genital cells or embryos, who is 18 years of age and is able to judge on his/her own, only due to a medically justified reason and with a previous obtained approval from the State Committee can request insight in the data regarding the health condition of the donor or the donors in the State Register of BAI.

The authorized person who keeps the State Register, after the control of the request and the determination that that is the person referred to in paragraph 1 of this Article, shall be obliged to enable insight solely into the data about the health condition of the donors, without revealing their personal data.

¹⁸ Article 23 paragraph 3 of the Law on Personal Data Protection



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As an exception, the authorized person who keeps the State Register can provide the legal representative of a child born by insemination with donated ova, spermatozoids or embryos, insight into the data for the health condition of the donors without revealing the data of the donors, provided that it is based on his/her request only due to medically justified reason and in the child's interest, after a previously obtained approval from the BAI.

As an exception, the doctor of the child born with insemination with a donated ovum, spermatozoid or embryo, after a previously obtained approval from the BAI, can request insight into the data contained in the State Register, related to the child and the donors, only due to medically justified reason and in the child's interest.

When necessary, the court shall have the right to an insight in the State Register and the data of the child and the donors of genital cells and embryos.

The persons referred to in paragraphs 4 and 5 of this Article, who have the right to an insight in the State Register, shall be obliged to keep the data of the child and the donors of male and female genital cells or embryos as classified information.

Protection of the data in the State Register

Article 58

The data from the State Register can be used exclusively as total statistical indicator that is as an individual in the cases determined by this Law.

The data in the State Register shall be classified information.

Only authorized persons who keep the State Register, authorized employees in the healthcare institution implementing BAI procedures, as well as individuals authorized for insight into the data from the State Register referred to in Article 57 of this Law, shall have insight to certain data, in accordance with this Law.

The regulations on classified information and personal data protection shall be applied to individual data, the measures for data protection and the responsibilities of individuals who have access to the unique databases of the State Register.



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State Register for BAI is another personal (sensitive) data collection that is legally grounded and determined. In this regard, the Law on Biomedical Assisted Insemination defines the content, i.e. the data that are an integral part of this collection (Article 56 paragraph 1). Hereby, Article 56 paragraph 4 of this Law stipulates that "all data in the State Register are classified information". In this context, the author points out to the fact that the determination of the data in the State Register as classified information is repeated in several articles in the Law (Article 48 paragraph 5, Article 56 paragraph 1 and Article 58 paragraph 2). This said and given the nature of data itself (personal) is quite questionable. On the other hand, one may notice a certain inconsistency of the provisions of the Law on Biomedical Assisted Insemination when regulating personal data collections. Namely, in Article 47 the personal data collection (record) as a whole is determined as classified information, while Article 56 paragraph 4 defines the data contained in the personal data collection (register) as classified information, and not the collection itself. From the foresaid, it can be concluded that the Law on Biomedical Assisted Insemination does not accurately distinguish or determine the nature of the data, the nature of the collections, and the regime for their protection. In this regard, the author of this analysis suggests the need for setting a clear concept in terms of defining the nature of personal, medical and genetic data and consequently for determination of the relevant system under which they will be protected.

Given the fact that the Minister of Health is responsible for authorization of the workers obliged to keep the State Register (Article 56 paragraph 3), in order to provide high level of protection of the personal data in the State Register, the Minister of Health should establish its own record of the persons authorized to carry out processing of personal data in the State Register. Also, the State Register, as a separate personal data collection, falls under the obligation for registering in the Central Register of Personal Data Collections run by the Directorate for Personal Data Protection.

The Law on Biomedical Assisted Insemination establishes a legal basis for exercising the right to insight in the data in the State Register (Article 57). However, it should be noted that in fact it is not about the right to insight in the data of the subject of personal data¹⁹, but this article defines the right of insight by third parties and the court in the data related to the medical

¹⁹ Pursuant to Article 12 of the Law on Personal Data Protection



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condition of the donors and in the data for the child born after insemination with donated egg, sperm or embryo, according to the prescribed procedure. In fact, if we take into account Article 48 paragraph 5, Article 56 paragraph 1 and Article 58 paragraph 2 of this Law, we can conclude that it is not about an insight in the personal data, but an insight in classified information, because of which the legislator, the actual dealing with the data subject to an insight, defines as dealing with classified information.

Article 58 of the Law on Biomedical Assisted Insemination regulates protection of the data in the State Register. A positive approach is to limit the use of data from the State Register, i.e. their use only as aggregate statistical indicator, and as an individual only in cases stipulated by law. That would mean that, except for those purposes stipulated in this Law, data can be used as aggregate statistical indicator, i.e. only for statistical purposes. In these cases, all necessary measures must be undertaken so identifying of persons should be prevented, in order to respect the right of privacy, personal and family life of the individual²⁰.

According to Article 58 paragraph 4 for individual data, measures of data protection and accountability of individuals who have access to the unique database in the State Register, the regulations on classified information and protection of personal data shall apply.

General conclusion which emerges from the analysis of the Law on Biomedical Assisted Insemination in terms of protection of personal data and information is that the law allows "dualism" in the implementation of the above protection, i.e. parallel application of the regulations on personal data protection and the regulations on security/protection of classified information - an approach that brings confusion in terms of determining the nature of personal, medical and genetic data of persons, and as a result of this, confusion in determining the regime of their protection. The assumption for this approach may be the intention of the legislator to provide maximum degree of data and information protection by their protection under two regimes - protection of personal data and protection of classified information. However, the question of compatibility of the two regimes and the possibility of their parallel operation in practice remains in place.

²⁰ Article 5 paragraph 3 of the Law on Personal Data Protection



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In the context of the aforementioned, what must be kept in mind is that the system of security of classified information as defined by the Law on Classified Information²¹ is intended to protect against unauthorized access, the classified information of interest for the country, primarily related to: public security; defense; foreign affairs; security, intelligence and counter-intelligence activities of the state administration bodies of the country; systems, appliances, projects and plans of importance to the public security, defense, foreign affairs; scientific research and technological, economic and financial affairs significant to the country.²² For the purpose of protection of this specific range of classified information it is essential to undertake necessary measures and activities for administrative, physical, information and industrial security and security of persons who handle classified information in order to protect them from unauthorized access or use. To perform tasks related to handling of classified information by authorized personell, the Directorate for Security of Classified Information shall issue a security certificate for the appropriate level of classified information in accordance with the principle "need to know".

In essence, taking the above measures, which are obligatory when it comes to implementation of the system of protection and security of classified information, have a complex character. Their implementation in practice is conditioned by availability of substantial financial, technical and human resources. Therefore, one may ask itself about the advisability of determining the data of persons in the BAI procedure as classified information and at the same time the capabilities of the competent authorities to undertake necessary measures and activities for their successful protection.

From the above, the author of this analysis concludes that, basically, there is no constraint information for the people that are part of the BAI procedure to be classified with certain level of classification and thereby to be protected in accordance with standards for security of classified information. However, the author is of view that medical and genetic data of persons, by their nature, are special categories of personal data which enjoy an extra degree of protection in terms of their processing. Thus, the the author recommends for those data the regime of protection of personal data to be applied as a compatible system that also allows full secrecy and protection of

²¹ Law on Classified Information No. 9/2004, 113/2007 and 145/2010

²² Article 6 of the Law on Classified Information



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the personal data by taking the appropriate, legally based, technical and organizational measures by personal data collections controllers.

General conclusions of aspect of the analysis' indicators

Taking into consideration the above mentioned, it could be concluded that:

1. A legal base for collecting and processing of personal data is established, by defining the categories of personal data subject to procession;
2. Personal data collections are directly established by this Law;
3. The term for storing of personal data is established for some of the collections;
4. The secrecy and protection of personal data are regulated in direct manner; and
5. Subsidiary application of the provisions of the Law on Personal Data Protection is directly established.



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7. LAW ON SAFETY OF BLOOD SUPPLY

7.1 General overview

This Law regulates the quality and safety of the human blood and blood components; collection and testing of human blood and blood components regardless of the purpose they are intended for; as well as processing, storage and distribution of the human blood and blood components intended for transfusion²³.

The purpose of the Law on Safety of Blood Supply is to provide a guarantee for self providence of blood and transfusion of blood and blood products on national level; quality and safety of blood and blood products in accordance with the standards of the European Union and reorganization of the system by providing continuous control and traceability of the blood quality and blood components from donation to transfusion to patients.

The determination of the legislator to incorporate the principles of personal data protection in the Law on Safety of Blood Supply can be seen already in the section where the definitions of terms used in this Law are established. Namely, Article 4 defines the notions of "genetic data"²⁴, "medical data"²⁵ and "medical file"²⁶, by which a small introduction of the personal data protection provisions is being presented. In addition to the above statement is the fact that this Law directly implements the right of the blood donor to be informed (personal data subject), as well as the principle of collecting and processing of personal data based on the consent of the personal data subject²⁷. In continuation of the stated, Article 16 of the Law on

²³ Official Gazzete No 110/2007

²⁴ "Genetic data" are data of any kind related to inherited characteristics of the patient or related to the inheritance form of those characteristics in interconnected group of individuals in which the patient stands

²⁵ "Medical data" are personal data related to the health of the patient. Those are data with clear and close connection the patient's health, as well as patient's genetic data

²⁶ "Medical record" is a record consisted of all data and documents related to the patient's health status, medical, i.e. clinical condition, diagnosis, prognosis and the treatment, as well as all other data of personal nature, kept in accordance with the regulations on health records, protection of the patient's rights and this Law

²⁷ This principle is defined in Article 6 of the Law on Personal Data Protection



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Safety of Blood Supply determines that the transfusion medicine institution is required, before starting the procedure of blood donation, to provide blood donors with information about blood donation, to seek from him/her data for personal identification, as well as other data about his medical condition and history of past illnesses and also to obtain written and signed consent that confirms that the blood donor has been informed of the procedure for blood donation and that s/he understood and voluntarily agreed to its execution. Besides the above stated information and consent, the transfusion medicine institution is required to issue guidelines for the blood donors, and to provide professional counseling for the donors, in function of their detailed introduction with the rights and obligations arising from the procedure of blood donation. From the above we can conclude that personal data, in the broadest sense, shall be collected only on the basis of freely given, written and signed consent of the blood donor.

7.2 Analysis of specific provisions of the Law on Safety of Blood Supply

Article 17

Protection and secrecy of data

Transfusion medicine institution is obliged to ensure protection of all personal medical and genetic data of blood donor contained in the medical record of Article 12 paragraph 4 of this Law.

Data and documents referred to in paragraph 1 of this Article are classified information and are stored in accordance with the regulations for protection of classified information and personal data.

To the access to medical record of paragraph 1 of this Article, to the providing confidentiality of the personal, medical and genetic data, as well as their revealing, the transfusion medicine institution is obliged to apply the regulations on patients' rights protection, classified information and personal data protection.



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Article 18

Storage of data and documents of the donors

Transfusion medicine institution is obliged to provide storage of data and documents referred to in Article 17 of this Law.

Transfusion medicine institution is obliged to store the data and the documents referred to in paragraph 1 of this Article as active at least 15 years of the day they were obtained, i.e. 30 years as passive of the day they were obtained.

The Minister of Health shall prescribe the manner for storing data and documents referred to in paragraph 1 of this Article.

Article 31

Records and documentation for the received blood and blood components

The health worker who provided the transfusion of blood and blood components is obliged to keep records for each unit of used blood or blood component in order to contrive data for each applied unit of blood or blood component.

The health worker enters into the patient's medical record the written consent of the patient referred to in Article 30 of this Law; the results of immunohematological examinations, as well as the other examinations; the notes for the positive reactions from blood transfusion and blood components; information and documents for serious adverse events and reactions, as well as other data and documents concerning the blood transfusion and blood components.

The health institution that uses the blood and blood components is obliged to make accessible all data regarding the used blood and blood components, upon request of the transfusion medicine institution, in the process of monitoring the blood.

The Minister of Health shall prescribed the form and the content of the records referred to in paragraph 1 of this Article.



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Article 32

Storing of documentation

Transfusion medicine institution is obliged to keep the documentation obtained or created during its activity at least 30 years.

Storage, handling, archiving and destruction of the documentation of paragraph 1 of this Article shall be performed in a manner that ensures confidentiality and secrecy of the data, in accordance with the regulations on personal data protection and patients' rights protection.

Article 38

Data protection

Transfusion medicine institution and the health institution that performs clinical use of blood and blood components are obliged to provide protective measures and protection for all information they came in contact with during the performance of their activities, by which can be disabled:

- *revealing the identity of the blood donors and recipients of blood and blood components in the process of traceability of blood and blood components,*
- *unauthorized modification or deletion of documents and data on blood donors and*
- *unauthorized providing of information of any kind in connection with blood donors and recipients, as well as other information and documents arising from the performance of the activity.*

Transfusion medicine institution and the health institution that performs clinical use of blood and blood components are obliged to ensure establishment of procedures for resolving cases of differences or inaccuracies in the stored data.

The analysis of the provisions of the Law on Safety of Blood Supply in correlation with the provisions of the Law on Biomedical Assisted Insemination governing issues on protection, confidentiality, secrecy and recording and documenting data of blood donors, can provide the



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author with the conclusion that the legislator has resorted to use conceptually identical approach for regulation of these issues in both laws.

In accordance with the afore mentioned conceptual approach, the legislator prescribed direct legal basis in the Law on Safety of Blood Supply for protection, confidentiality and secrecy of the data of blood donors, by defining obligation for the transfusion medicine institution to ensure protection of all personal, medical and genetic data of blood donors contained in her/his medical record. This approach is welcomed because it provides complementarity with the system of personal data protection determined by the Law on Personal Data Protection. However, what deviates substantially from this system in terms of this analysis is the definition of personal, medical and genetic data of blood donors, as well as the supporting documentation related to them as classified information. Even more confusing is the fact that in the definitions of the terms²⁸ of the Law on Safety of Blood Supply, medical data are defined as personal data. Taking into account most of the definitions specifying the nature of the patient's medical data, the Law on Safety of Blood Supply on the other hand, provides obligation for the transfusion medicine institution to apply regulations concerning protection of patients' rights, classified information protection and personal data protection, regarding their confidentiality, storage, access to them and their revealing.

Regarding the implementation of the principles of data protection, the Law on Safety of Blood Supply sets records (personal data collections) maintained by competent institutions, their content and deadlines for their storage²⁹, which is a positive normative step in exercising of personal data protection in practice. In this sense, Article 31 paragraph 2 provides what information will be entered into the patient's medical record: written consent of the patient referred to in Article 30 of this Law; the results of immunohematological examinations, as well as the other examinations; the notes for the positive reactions from blood transfusion and blood components; information and documents for serious adverse events and reactions, as well as other data and documents concerning the blood transfusion and blood components. But in the same Article paragraph 4 establishes authorization for the Minister of Health to adopt a bylaw that should prescribe the form and the content of the records for each used unit of blood or blood component from paragraph 1. This normative solution - in same article to determine the content

²⁸ Article 4 item 12

²⁹ Defined in Article 5 of the Law on Personal Data Protection



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of personal data collection and authorization for adoption of a bylaw for determining the content of another personal data collection, is inconsistent with the principle of personal data protection, according to which personal data are processed pursuant to law.

Regarding the terms for storage of the data in the collections, i.e. of the documentation, the Law on Safety of Blood Supply defines their storing for at least 30 years. The storage, handling, archiving and destruction of the documentation is done in accordance with the regulations on personal data protection and protection of patients' rights (Article 32). Although, for implementation of these operations, the regulations on personal data protection and protection of patients' rights shall apply, the author believes that the period of at least 30 years is set high, because of what it should be revised in accordance with the purposes of data processing. In this context Article 38 prescribes the measures for data protection. Given the fact that those are personal, medical and genetic data, which according to the Law on Personal Data Protection represent specific categories of personal data, the author disputes the question of the adequacy of the prescribed measures, with a recommendation for revision of the measures and if necessary their amendment, so as to provide a degree of protection of the personal data appropriately to the risk and nature of the processed data³⁰.

Although the Law on Safety of Blood Supply contains provisions that guarantee protection of patients' data, i.e. the blood donors, which provisions are in compliance with the principles of personal data protection provided in the Law on Personal Data Protection, it can be concluded that in terms of data and information protection the Law on Safety of Blood Supply allows "dualism", i.e. parallel application of the regulations on personal data protection and for security/protection of classified information - an approach that brings confusion in terms of determining the nature of personal, medical and genetic data and as a result a confusion in determining the regime of their protection. There is no doubt that it is necessary to approach towards accurately determining of the nature of personal, medical and genetic data and based on it to make a clear conceptual distinction between the regime for the personal data protection and security/protection of classified information. This will allow proper data protection by the authorized institutions in the practice.

³⁰ Pursuant to Article 23 paragraph 3 of the Law on Personal Data Protection



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General conclusions of aspect of the analysis' indicators

Taking into consideration the above mentioned, it could be concluded that:

1. A legal base for collecting and processing of personal data is established, by defining the categories of personal data subject to procession;
2. Personal data collections are directly established;
3. The term for storing (or keeping) of personal data is established;
4. The secrecy and protection of personal data are regulated in direct manner;
5. The subsidiary application of the provisions of the Law on Personal Data Protection is directly established.

IV.GENERAL ASSESSMENT OF THE BYLAWS OF THE HEALTH LEGISLATION FROM PERSONAL DATA PROTECTION ASPECTS

Given the specific character of the health sector, as concluded in this Analysis, the laws of the health legislation in the country elaborated for the purposes of this Analysis, provide wide legal basis for collecting, processing and storing of personal data. On the other hand, the analyzed laws also provide legal basis for more than hundred of bylaws that in details elaborate the issues of health protection. Large number of these bylaws also pay attention to the issues of personal data, i.e. their collection, processing and storage. Now, the question that arises out of these observations is whether the mentioned bylaws provide “enough” measures and standards for appropriate protection of the personal data, which should be in line with the principles set up in the Law on Personal Data Protection?

A general remark for this whole set of bylaws is that they don't provide/prescribe sufficient measures and standards which should be undertaken by the relevant subjects in the health sector, so the vast quantity of the “created” and collected personal data could be safely protected. Most of the bylaws are used only to create registers (collections) of personal data, which are comprised of great deal of data related to the patients. In this regard, the Rulebook on the form and content of each used blood unit and blood components (“Official Gazette of” No 87/2010) provides legal



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basis for establishing two separate registers (collections) of personal data – 1. Register for each used blood unit, which is run by a health worker in the institute for transfusion medicine (Article 3) and 2. Register for requirement of blood and blood components kept by the health institution which uses blood and blood components (Article 4). These registers contain personal data such as: unique identification number, clinical identification number, diagnosis, blood group, blood components and blood quantity, pregnancy, immunisation etc. But, although the registers contain such sensitive data for the health of the individuals, the provisions for protection of the personal data kept in the mentioned registers are left out of this Rulebook.

This practise is in direct conflict with the basic principle of personal data protection prescribed in Article 5 paragraph 1 item 1 of the Law on Personal Data Protection, according to which personal data shall be processed justly and pursuant to law. However, since this is already an established practise, what seems to be a logical approach in these bylaws is to provide certain level of protection, as well as to define the manner, the aim and the deadlines for processing and storing of the collected personal data in the mentioned registers (collections) of personal data. For instance The Rulebook on the form and content of the documentation in the process of usage of blood, the forms and the procedure for notification for occurrence of the seriously unfavourable event and reactions from the usage of blood and blood components (“Official Gazette” No 87/2010) provides only legal grounds for creation of personal data collections (Article 3). In accordance with Article 3 the health institution, among other, may collect the following data: age and sex of the blood recipient; seriously unfavourable reaction connected to full blood, erythrocytes, thrombocyte concentration; plasma etc. In this cases also, the author was unable to detect provisions that handle with issues of protection of the mentioned personal data.

What should also be pointed out is that a lot of personal data “created” and collected within the health sector in legal terms represent “Special category of personal data”, which enjoy special protection. General rule regarding this category/ies of personal data is that their processing is forbidden.³¹ Only in concrete cases provided in Article 8 paragraph 2 of the Law on Personal Data Protection, processing of special categories of personal data may be performed. So, if we take in account the importance that this category of personal data is reflecting and its

³¹ Article 8 paragraph 1 of the Law on Personal Data Protection



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status defined in the Law on Personal Data Protection, it is clear that only in specific cases defined exclusively by law processing of special categories of personal data may be performed. However, it is obvious that within the health legislation number of bylaws do regulate processing of special categories of personal data. In this direction, the Rulebook on conducting, the content of examinations, the types of examinations and the deadlines for conducting of the compulsory health-hygienic examinations of the employees (“Official Gazette” No 152/2007) is worth mentioning. Namely, according to this Rulebook, the employees are subject of examinations on different epidemic diseases (for example: tuberculosis, bacterial diseases, parasite diseases of the skin etc). The results of these examinations are written down in health book, which is kept in the premises of the legal or natural person where the individual is employed (Article 8). However, the Rulebook defines no measures, standards or deadlines for processing and storing of the personal data in the health book which should safeguard their protection. Also, the Rulebook doesn’t contain any specific obligations for the employers, as responsible persons for keeping this health books in their working premises.

The author, on the basis of the conducted analysis, recommends that the issues of collecting, processing and storing of personal data in the health sector should be regulated solely by law, by conformable implementation of the principles stipulated in Article 5 of the Law on Personal Data Protection. In this regard, it must be clear that bylaws can not represent legal basis for collecting, processing and storing of personal data, especially not for special categories of personal data. Because of their positioning in the hierarchy of legal acts, bylaws don’t possess enough legal power to provide adequate level of protection of the personal data. But, still, if they do regulate personal data collecting, processing and storing, in those cases the bylaws must contain more provisions on personal data protection in order to achieve a more acceptable balance between the public and the interest of the individuals.



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