

**28 Annex - Consumer and health protection**

**210. LAW ON DATA COLLECTIONS IN THE FIELD OF  
HEALTH CARE**

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**LAW ON DATA COLLECTIONS IN THE FIELD OF HEALTH CARE<sup>1</sup>**

I BASIC PROVISIONS

Article 1

This law provides for types, contents and the manner of keeping data collections in the field of health care as elements of unique health care statistics, and the manner of collecting, processing, use, protection and storage of collected data.

Article 2

Data collections in the field of health care (hereinafter referred to as: data collections) are groups of data with precise definitions, used for: monitoring and studying the health status of the population; planning and programming health care; conducting statistical and scientific research; performing obligations of all entities in the field of health care as well as providing assistance to state authorities in conducting health policy.

Article 3

Keeping data collections provides prerequisites for obtaining quantitative and qualitative information on the health status and health care of the population, the scope and the quality of work of the health service and other relevant information necessary for conducting health policy and standardization of reporting to relevant national and international institutions.

Article 4

The administrator of data collections shall be the Institute of Public Health (hereinafter referred to as the Administrator).

By way of exception from paragraph 1 of this Article, Brezovik Specialized Hospital for Pulmonary Diseases shall keep a tuberculosis registry, as a data collection.

The administrator shall collect data and be responsible for their processing, storage and publication within delegated competences and authorizations.

Article 5

Keeping data collections shall be based on principles of relevance, impartiality, reliability, timeliness, rationality, consistency and confidentiality, which imply that:

- Each defined data has to satisfy clearly given conditions related to providing for a purpose that is of significance for the health of citizens and for the health care system;
- Definitions and methods of collecting, processing and using data shall be established in an objective manner, independent from any type of influence;
- The establishment of methods and procedures related to collecting, processing and the use of data is conducted on the basis of professional standards, scientific methods and principles, thus the results obtained by maintaining data collections fully reflect the health status of the population;
- Maintaining data collections is conducted within prescribed time limits;
- All resources are used optimally, taking into account the scope of work and costs of keeping records.

Article 6

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<sup>1</sup> Official Gazette of Montenegro No 80/08, dated December 26, 2008

Provisions of the law regulating the protection of personal data and the law regulating statistical research shall be applied on the issues related to collecting, processing and giving personal data that are contained in data collections.

#### Article 7

Specific terms used in this law shall have the following meaning:

- 1) **The registry** represents a longitudinal and continuous data collection. It is a defined and organized system for collecting, storage, processing, analyzing and using data on a certain illness, groups of illnesses and other conditions related to health on a national level or a system for collecting, storage, processing, analyzing and using data from the health care system on staffing and other capacities in health care;
- 2) **Data set** represents a part of the data collection containing demographic, socio-economic, medical or other data related to the health of the population;
- 3) **Medical documents** represent a group of resources for harmonized recording and collection of data on events and activities in the health care system;
- 4) **Report** represents data grouped according to methodology established in advance, on the diagnosed disease or condition and activities implemented in the field of health care;
- 5) **Health care providers** are medical institutions registered for performing a medical activity;
- 6) **Contact** between the beneficiaries and providers of health care is indirect or direct manner of collecting data on the group of registered health problems, activities conducted, use of resources, object of protection, health care providers involved, etc;
- 7) **Personal medical data** are personal data on the health status of an individual and personal data related to providing health care for the population and individuals.

## II TYPES, CONTENT AND MANNER OF MAINTAINING DATA COLLECTIONS

#### Article 8

The following data collections and registries as a special type of data collections shall be kept in the field of health care:

- Registries of illnesses of a higher socio-medical significance, contagious diseases and other conditions related to the health of the population;
- Registries of resources in the health care system;
- Data collections
  - outpatient health care;
  - inpatient health care;
  - in the field of health care of employees;
  - on laboratory services;
  - on radiological services;
  - on transfusiology;
  - on physical medicine and rehabilitation;
  - on the activities of pharmacies;
  - on the organizational structure and personnel within the health care system;

- on the impact of the environment on the life and health of people; and
- 1) Other data collections for which the public administration authority in charge of health care affairs (hereinafter referred to as the Ministry) determines to be of interest for the health of the population.

#### Article 9

Registries of illnesses of greater socio-medical significance, contagious diseases and other conditions related to the health of population shall include:

contagious diseases;

- immunization;
- tuberculosis;
- HIV/AIDS;
- malignant neoplasms;
- drug addiction;
- diabetes;
- cerebrovascular diseases;
- ischemic heart diseases/acute coronary syndrome;
- psychosis;
- traumatisms;
- occupational diseases;
- health care of children and young people with psychophysical developmental disabilities and psychosocial disabilities;
- growth and development of children and young people, and
- other registries for which the Ministry establishes to be of interest for the health of the population.

#### Article 10

The registries referred to in Article 9 of this Law shall contain personal data on the individual: name and surname, date and place of birth, sex, place of residence and address, marital status, qualifications, profession, employment, user identification (Personal Identification Number) and health insurance.

The registries referred to in paragraph 1 of this Article shall also contain specific health data that will be regulated by an act of the Ministry.

#### Article 11

Registries of resources in the health care system shall be:

- 1) the registry of health care personnel, and
- 2) the registry of medical institutions.

The form, contents and the manner of keeping registries referred to in paragraph 1 of this Article shall be regulated by an act of the Ministry.

#### Article 12

Data collections of outpatient health care shall be:

- 1) data collection on preventive health care;
- 2) data collection on curative health care (at the primary level);
- 3) data collection on specialist health care;
- 4) data collection on health education;
- 5) data collection on emergency medical assistance.

#### Article 13

The basic data set of outpatient health care shall contain: user identification (Personal Identification Number), health insurance, name, name of a parent and surname, place of residence, marital status, qualifications, employment, health status, contacts data, as well as data on health care providers.

Contacts referred to in paragraph 1 of this Article shall be classified according to sex, age group, MKB-10 or diagnostic group and activity that has been undertaken to provide health care to an individual.

#### Article 14

Data collection on preventive health care shall contain a data set on:

- 1) preventive health care of children;
- 2) preventive health care of adults;
- 3) preventive health care of women;
- 4) preventive health care of the employed, and
- 5) preventive dental care.

In addition to the data referred to in Article 13 of this Law, the basic data set of preventive health care shall contain the data on the type of preventive activity, the contents of preventive examination and the result of a preventive examination.

#### Article 15

Data collection of curative health care shall contain a data set on:

- 1) curative health care of children;
- 2) curative health care of adults;
- 3) curative health care of women;
- 4) curative health care of the employed, and
- 5) curative dental care.

#### Article 16

In addition to the data referred to in Article 13 of this Law, the basic data set of curative health care shall contain the data on the type of curative examination, health status, working diagnosis, final diagnosis, referral to other health care units for the purpose of analysis, referral to other health care levels for the purpose of treatment, therapy and the result of treatment.

#### Article 17

In addition to the data referred to in Article 13 of this Law, data collection of specialist health care shall contain the data on the type of specialist examination, the activity conducted, diagnostic procedure, diagnosis, therapy and the result of treatment.

#### Article 18

Data collection on work on health education shall contain the data on the type, time, place of provider and the content of activity, population covered, duration of activity, applied strategies and health care provider.

#### Article 19

In addition to the referred to in Article 13 of this Law, data collection on emergency medical assistance shall contain the data on examinations that were carried out, diagnosed disease or condition, results, conducted resuscitations and transports and health care provider.

#### Article 20

Data collections of inpatient health care shall include:

- 1) data collection on the organization and work of hospitals;
- 2) data collection on hospitalizations (patients treated in hospitals);
- 3) data collection on labours and
- 4) data collection on conducted abortions.

#### Article 21

Data collection on the organization and work of hospitals shall contain the data on organizational units, medical workers, medical associates and other employees, the number of beds, days of treatment and movements of treated patients.

#### Article 22

The basic data set of institutional health care for data collections referred to in Article 20, Items 2, 3 and 4 of this law shall contain the data on user identification (Personal Identification Number), health insurance, name, name of a parent and surname, place of residence and address, marital status, qualifications, employment, job, name of a medical institution, health care providers, type of admission, ordinal number of entry and date of admission to the hospital.

#### Article 23

Data collection on hospitalizations (patients treated in hospitals), in addition to data referred to in Article 22 of this Law, shall contain the data on the date the session started, the ordinal number of the session, main diagnosis, secondary diagnosis, complications, operation, date of operation, daily treatment, date of session conclusion, result, date of patient's death, basic cause of death, immediate cause of death and date of discharge from the hospital.

Article 24

In addition to the data referred to in Article 22 of this Law, the data collection on labours shall contain the data on case history of the woman in childbirth, course of pregnancy, potential pathological condition during pregnancy, diagnosis of labour, vital status of the newborn child, pathological status of the newborn child at birth and the basic cause of death, if the newborn child has died.

Article 25

In addition to the data referred to in Article 22 of this Law, the data collection on conducted abortions shall contain the data on case history, type of abortion, how advanced the pregnancy was, status, manner of execution and result of abortion.

Article 26

Health care data collections of the employed include:

- 1) data collection on occupational injuries, and
- 2) data collection on absenteeism.

Article 27

The basic data set for health care data collections of the employed shall contain user identification (Personal Identification Number), health insurance, name, name of a parent and surname, place of residence, marital status, qualifications, employment, branch of activity, job description, diagnosis, as well as data on health care providers.

Article 28

In addition to the data referred to in Article 27 of this Law, the data collection on occupational injuries shall contain the data on type of injury, place and time of injury, cause of injury and further medical procedure.

In addition to the data referred to in Article 27 of this Law, the collection of data on absenteeism shall contain the data on the length of absence from work, reasons for absence from work, further procedure of absence from work and potential disability.

Article 29

Data collection on laboratory services shall contain the data on the type of laboratory, the seat, the type of testing and the number of tested samples.

Article 30

The collection of data on radiological services shall contain the data on the place of provided service, the type of radiological service and the number of services.

Article 31

The collection of data on transfusiology shall contain the data on: the number of blood samples, the quantity of taken blood, blood products and the status of a blood donor.

Article 32

Data collection on physical medicine and rehabilitation shall contain the data on performed physical therapy and rehabilitation, contacts, diagnosis, treatment status, type of rehabilitation and health care providers.

Article 33

Data collection on the work of pharmacies shall contain the data on the quantity of dispensed medicines, the type of medicines and the manner of dispensing them.

Article 34

The data collection on the organizational structure and personnel of the health care system shall contain the data on health care provider, medical workers and medical associates, professional profile of personnel, qualification level and occupation, age and sex structure of the personnel, status, and the type of specialty.

Article 35

Data collections on the impact of the environment on the life and health of people shall include:

- 1) data collection on the hygienic adequacy of potable water;
- 2) data collection on the level of air pollution and its impact on the health status of the population;
- 3) data collection on the safety of foodstuffs and on health adequacy of consumer goods.

Article 36

The basic data set for data collections on the impact of the environment on the life and health of people shall contain the data on venue, time, testing type, and testing results.

In addition to the data referred to in Paragraph 1 of this Article, data collections referred to in Article 35, items 1, 2 and of this law shall contain the data on physical and chemical characteristics of the tested water or air sample.

In addition to the data referred to in paragraph 1 of this Law, the data collection referred to in Article 35 item 3 of this Law shall also contain the data on the type of foodstuffs or consumer goods.

Article 37

More detailed contents, form and manner of maintaining data collections referred to in Article 8 of this Law shall be prescribed by an act of the Ministry.

Article 38

Data collections shall be kept in written and electronic form.

Uniform methodological principles, uniform standards and standard procedures for elaborating and sending reports that are prescribed by the Ministry, upon motion of the Institute of Public Health shall be used for keeping data collections.

With the objective of maintaining and establishing the information system for the field of health care, the Institute of Public Health shall:



- harmonize definitions of data terms:
- introduce and cancel data terms;
- harmonize classifications, nomenclatures and codes.

### III MANNER OF COLLECTING AND ENTERING DATA

#### Article 39

The entry of data into medical documents, an integral part of which are basic medical documents and documentary reporting forms (notifications and reports) shall be performed by health care providers.

The basic medical documents shall contain data on:

- the individual patient (PIN, surname, name, name of a parent, marital status, qualifications, occupation, permanent residence address, municipality, employment, insurance, date of death);
- health care (diagnosis, date of contact, planned contacts, doctor's identification, therapy, referral, reasons for temporary work incapacity, cause of death, reason of treatment, family case history, health care plan);
- care and other related activities (care, nutrition, etc.), and
- other data on health care (findings, statements, opinions, and other documents).

The basic medical documents that are used by health care providers while providing health care shall be the basic source of data to be entered into data collections.

Medical documents referred to in Paragraph 1 of this Article shall be maintained in written and electronic form.

The contents and manner of keeping medical documents shall be prescribed in more detail by an act of the Ministry.

#### Article 40

The entry of data into medical documents referred to in Article 39 of this Law shall be based on examination results, public and other documents or statements of persons whose data are being entered into medical documents.

In case the data cannot be entered into medical documents in a manner prescribed in Paragraph 1 of this Article, they shall be entered on the basis of a signed statement of the person from whom data are taken.

#### Article 41

Medical workers and medical associates shall confirm with their signature the assertions and results of examinations and other services.

The medical worker and the medical associate entering the data shall be responsible for the accuracy and completeness of data entered into medical documents.

The person who has given the statement shall be responsible for the accuracy of data given therein.

#### Article 42

Health care providers are obliged to deliver data from medical documents to data collection administrators through reports and notifications, in written and electronic form.

The data referred to in paragraph 1 of this Article shall be delivered by health care providers in electronic form to the Data Exchange Center of the Republic Health Insurance Fund (hereinafter: referred to as the Center).

The Center shall enable electronic data exchange between the health care provider and the data collections administrator, to develop and maintain the information and communication infrastructure and enable protection and data storage, in accordance with the law.

The terms, manner and the procedure of accessing data at the Centre shall be prescribed by an act of the Ministry.

#### Article 43

Accuracy and completeness of data stated the reports referred to in Article 42 Paragraph 1 of this Law shall be confirmed by a responsible person of the health care provider who delivers data, whereas a medical worker or medical associate entering the data into the notification shall be responsible for accuracy and completeness of data given in notifications.

#### Article 44

Reports and notifications referred to in Article 42 of this Law shall include:

- 1) Notification of conducting mandatory immunization against a contagious disease;
- 2) Notification of a case and epidemic of a contagious disease;
- 3) Notification of HIV/AIDS;
- 4) Notification of tuberculosis;
- 5) Notification of patients treated in hospitals;
- 6) Notification of pregnancy terminations;
- 7) Notification of labours;
- 8) Notification of treated psychoactive substance addicts;
- 9) Notification of malignant neoplasms;
- 10) Notification of diabetes;
- 11) Notification of ischemic heart disease (acute coronary syndrome);
- 12) Notification of cerebrovascular diseases;
- 13) Notification of psychosis;
- 14) Notification of traumatisms;
- 15) Notification of occupational diseases;
- 16) Report on the implementation of preventive and special examinations for children, women, adults, dental preventive examinations for children and young persons;
- 17) Report on work and diagnosed illnesses and conditions in primary health care;
- 18) Report on work and diagnosed illnesses and conditions in specialist health care;
- 19) Report on work in health training;
- 20) Report on the work of the health visiting nurse unit;
- 21) Report on work and diagnosed illnesses and conditions in emergency medical wards;
- 22) Report on the implementation of preventive and specific examinations of employees' health care;

- 23) Report on occupational injuries;
- 24) Report on absenteeism;
- 25) Report on the organization and work of hospitals;
- 26) Report on the health care of children and young persons with psychophysical developmental disabilities and psychosocial disabilities;
- 27) Report on the growth and development of children and young people;
- 28) Report on the work of laboratories;
- 29) Report on radiological services;
- 30) Report on physical medicine and rehabilitation;
- 31) Report on transfusiology;
- 32) Report on the organizational structure and personnel in health care;
- 33) Report on the work of pharmacies;
- 34) Report on hygienic adequacy of potable water;
- 35) Report on air pollution and its impact on the health status of the population;
- 36) Report on the safety of foodstuffs and health propriety of consumer goods; and
- 37) Other notifications and reports for which the Ministry determines to be of significance for maintaining data collections.

The manner, delivery terms and the forms of notifications and reports referred to in Paragraph 1 of this Article shall be prescribed by the Ministry, upon motion of the Institute of Public Health.

#### Article 45

Person authorized for keeping data collections of the administrator shall be responsible for accuracy and completeness of entered data.

If there is suspicion about the accuracy of delivered data, the administrator shall inform the health care provider thereof.

The health care provider shall check the accuracy of data referred to in Paragraph 2 of this Article and amend potential mistakes.

The amendment of any data should be conducted in a manner which enables insight into the previous data, time when the data was amended and by whom.

Amendment of data in the data collection shall be done by the authorized person of the administrator.

### IV PROCESSING, USE AND EXCHANGE OF DATA

#### Article 46

The Institute of Public Health shall develop, upgrade and maintain its information and statistical infrastructure in line with technical standards in that area, for the purpose of providing data processing and elaboration of appropriate reports, in line with the reporting needs and standards to national and international entities.

#### Article 47

The administrator may exchange data among certain data collections from the data collections containing personal medical data in order to ensure the quality and uniformity of data, for scientific and statistical research.

The administrator shall regulate the manner of providing data referred to in paragraph 1 of this Article.

#### Article 48

The administrator shall enable provision and linking of data from data collections to health care providers who are carrying out screening tests for early detection of illnesses.

The Institute of Public Health may also collect data related to health care of individuals for the need of epidemiologic and other research.

In the event referred to in Paragraph 2 of this Article, health care providers shall also deliver other data, upon the request of the Institute of Public Health, in addition to the data stipulated by this law.

#### Article 49

Health care providers and administrators shall deliver data from the medical documents and data collections upon the request of the Ministry.

The data referred to in Paragraph 1 of this Article shall be delivered without the personal data of an individual.

By way of exception, health care providers and administrators may also deliver personal data to the Ministry, if a specific obligation of the Ministry cannot be performed by using anonymous data, in accordance with the law.

### V STORAGE OF PERSONAL MEDICAL DATA

#### Article 50

Medical documents shall be stored for 15 years after the last data entry, with the exception of a dental records, which are kept permanently, and medical records and case history, which are kept even after the patient's death.

Health care providers shall keep medical documents in written and electronic form, in accordance with this law and regulations on archive material.

### VI SUPERVISION

#### Article 51

Supervision over the implementation of this law and regulations adopted on the basis of this law shall be conducted by the Ministry, through a health inspector, in accordance with the law.

### VII PENALTY PROVISIONS

#### Article 52

A fine in the amount of thirty to two hundred minimum wage rates in Montenegro shall be imposed for an offence on the legal person if it:

- fails to maintain data collections or fails to maintain them under prescribed methodological principles for data collections (Articles 8 and 39).

The responsible person in the legal entity shall also be punished for the offense referred to in Paragraph 1 of this Article with a fine in the amount of ten to twenty minimum wage rates in Montenegro.

#### Article 53

A fine in the amount of thirty to two hundred minimum wage rates in Montenegro shall be imposed for an offense on the legal person which:

- fails to submit notifications, reports and other data or fails to deliver them in the prescribed manner and within prescribed deadlines (Articles 42 and 44);
- fails to store medical documents (Article 50, Paragraphs 1 and 2);

The responsible person in the legal entity shall also be punished for the offence referred to in Paragraph 1 of this Article with a fine in the amount of ten to twenty minimum wage rates in Montenegro.

#### Article 54

A fine in the amount of one to twenty minimum wage rates in Montenegro shall be imposed both on the natural person and the responsible person in the legal entity which:

- enters data incorrectly or incompletely into the medical documents (Article 41, Paragraph 2);
- enters data incorrectly or incompletely into the reports (Article 41, Paragraph 1).

#### Article 55

A natural person which has given incomplete or incorrect data in the statement signed by him/her (Article 41, Paragraph 3) shall be punished with a fine in the amount of one to twenty minimum wage rates in Montenegro.

### VIII TRANSITIONAL AND FINAL PROVISIONS

#### Article 56

Secondary legislation for implementation of this law shall be passed within a year from the day of entry into force of this law.

Currently valid regulations shall be applied until the adoption of acts referred to in Paragraph 1 of this Article, if they are not contrary to this law.

#### Article 57

The Law on Records in the Field of Health Care (Off. Gazette of SRM, No. 13/79) shall cease to be valid on the day of entry into force of this law as well as the implementation of the Law on Records in the Field of Health Care (Off. Gazette of FRY, No. 12/98 and 37/02).

#### Article 58

This law shall enter into force on the eighth day following that of its publication in the Official Gazette of Montenegro.

### RATIONALE

## I CONSTITUTIONAL BASIS FOR ADOPTION OF THE LAW

The Constitutional basis for adoption of this law is comprised in Article 16, Paragraph 1, Item 5 of the Constitution of Montenegro, which stipulates that the law shall also regulate other issues of interest for Montenegro, in accordance with the Constitution.

## II REASONS FOR THE ADOPTION OF THE LAW AND OBJECTIVES TO BE ACHIEVED THEREWITH

The basic reason for the adoption of the Law on Data collections in the Field of Health Care is the need to provide conditions for obtaining quantitative and qualitative information on health and health status of the population, on the health system, scope and quality of work of the health service and other relevant information for maintaining health policy and standardization of reporting to relevant national and international institutions.

At the same time, the adoption of a series of laws in the field of health care, such as the Law on Health Care, the Law on Health Insurance, the Law on the Protection of Population from Contagious Diseases, the Law on Blood Supply, the Law on Protection and Exercise of Rights of the Mentally Ill, etc., has imposed the need to adopt a new law that shall regulate the collection of data that are of significance for monitoring the state of affairs in areas regulated by these laws.

In addition to that, in line with European standards, Montenegro, as other countries, shall develop a comprehensive statistical system that will cover a complex and significant fields such as the field of health care, starting from the existing and acknowledged international statistical standards in maintaining records in the field of health care.

The concept of the Bill on Data Collections in the Field of Health Care has as its primary objective to monitor the health status of the population, the fulfilment of obligations of all entities in the field of health care and exercise of the right to health care, as a basis for adoption of a short term and long term policy and measures in that field. Data collections, as stipulated by the Bill, shall be used to achieve the stated objective and simultaneously provide for the data for the system of statistical research, a unique information system and a unique information system in the field of health care.

## III HARMONIZATION WITH EUROPEAN LAWS AND RATIFIED INTERNATIONAL CONVENTIONS

The Bill has no direct source in the European legislation. However, special paid to the endorsement of the European Parliament and Council Directive 95/46/EC on the protection of citizens related to personal data processing and freedom of movement of such data, given that personal medical data are a part of the citizens' personal data, which imposes the implementation of special protection standards of such data. Furthermore, recommendations of the International Conference of Statisticians were taken into account, which deal with statistical data related to health care and impose the necessity of collection, processing and publication of this type of data, the necessity to conduct it on a state level, and the necessity to determine sources of definitions and methodologies used for such purposes.

## IV EXPLANATION OF THE BASIC LEGAL INSTITUTES AND OF BASIC LEGAL SOLUTIONS

The concept of the Bill is based on principles of relevance, impartiality, reliability, timeliness, rationality, consistency and confidentiality.

The stated principles are a prerequisite for each defined data to satisfy clearly established objectives related to providing the purpose of significance for the health of citizens and for the health system, the objective manner of establishing a definition, methods of data collection and

processing, on the basis of professional standards. Thus the results obtained by keeping data collections shall fully reflect the health status of the population with a defined accuracy level.

The activities stipulated by this law and regulations adopted thereupon are implemented and executed within prescribed time limits, with the optimum use of all resources and the reduction in burden of reporting units, with mandatory protection of data on the health status of citizens in accordance with this law, the Law on Personal Data Protection and statistical anonymity.

The provisions on keeping data collections, contained in this law, are based on the following basic concepts, as follows:

- a) that all types of data collections kept in the field of health care shall be established;
- b) that the entity keeping data collection shall be regulated;
- v) that each collection shall contain an overall information course, by establishing:
  - the contents of the data collection (feature),
  - funds and time limits for submitting data and reports,
  - the commencement and the end of keeping data collections,
  - the time and storage of data.
- g) to prescribe an obligation to keep data collections under uniform methodological principles, so as to ensure the uniformity of data and their linking,
- d) to prescribe the manner and the funds for keeping data collections with the possibility of processing data electronically,
- đ) to prescribe basic standards and mechanisms for retrieving and processing data from data collections, and the responsibility for data accuracy, and
- e) to define basic objectives and purpose of data collections in the field of health care.

In terms of their contents, manner of data collection, and the manner of reporting, most data collections in the field of health care are mutually functionally linked.

- 1) The part entitled "Basic Provisions" (Art. 1 to 7 of the Bill) defines the subject of this law, the meaning of specific terms and the basic conceptual principles of the law whose implementation provides for an objective manner of establishing definitions, methods of data collection and processing, on the basis of professional standards, so that the results obtained by keeping data collections fully reflect the health status of the population. Activities stipulated by this law and by the regulations adopted thereupon shall be implemented and exercised within prescribed time limits, with optimum use of all resources and obligatory protection of data on the health status of citizens in accordance with this law, provisions on the protection of personal data and statistical anonymity.
- 2) The part entitled "Types, Contents and Manner of Keeping Data collections" (Art. 7 to 39 of the Bill) stipulates the types and the contents of prescribed data collections, by establishing the basic contents for each of them, whereas the specific contents of established collections shall be prescribed by a bylaw based on this law.

The same provisions stipulate that single methodological principles shall be used to keep data collections in the field of health care, as well as single standards and standard procedures that are prescribed by the Ministry.

- 3) The part entitled "The Manner of Collecting and Entering Data" (Art. 39 to 46 of the Bill) stipulates the obligation of the health care provider to collect data by entering them into medical documents, as a means for maintaining data collections.

The stated provisions also prescribe the responsibility of medical workers and associates for the accuracy of given data and that of the person who provides the data. These provisions also stipulate the obligation of delivering data to data collection administrators – the Institute of Public Health and Brezovik Specialized Hospital for Pulmonary Diseases, as well as the obligation to

prescribe forms and time limits for the delivery of data, notifications, reports and for keeping data collections in written and electronic form.

The Strategy on Development of the Health Care System stipulates the establishment of integral information system of health care and health insurance. Accordingly, and taking into consideration the technical, staffing and infrastructural potentials, it is envisaged that the Data Exchange Centre of the Health Insurance Fund shall enable electronic exchange of data between the health care provider and the data collection administrator and provide a high level of data storage and protection.

- 4) The part entitled “Processing, Use and Exchange of Data” (Art. 46 to 50 of the Bill) provides for quality assurance and uniformity of data for scientific and statistical research, exchange of data across specific collections, as well as data delivery in protected (anonymous) form to the Ministry. By way of exception, data administrators may also deliver an individual’s personal medical data to the Ministry, for the purpose of fulfilling some of Ministry’s obligations.
- 5) As regards the part entitled “Protection and Storage of Personal Medical Data” (Art. 50 of the Bill), this provision also stipulates the period of storing medical documents that are kept in written and electronic form in accordance with this law and regulations on the protection of archive material.
- 6) A part of the section entitled “Supervision” (Art. 51 of the Bill) contains a provision which stipulates that the supervision over the implementation of this Law shall be conducted by the Ministry, through a health inspector.
- 7) The part entitled “Penalty Provisions” (Art. 52 to 54 of the Bill) contains provisions that lay down fines for failing to fulfil obligations regarding proper maintenance, use and exchange of data for prescribed purposes, failure to comply with time limits for delivering reports by medical institutions and other legal entities, as well as responsible persons who have been appointed as administrators of keeping data collections.
- 8) The part entitled “Transitional and Final Provisions” (Art. 56 to 58 of the Bill) regulates the issue of implementation and validity of the Law, as well as the adoption of bylaws and other acts for its implementation.

The contents, features and the number of data collections are also conditioned by the fact that data and data collections in the field of health are fed into a large information system of statistical research as a single information system in the field of health care. These data collections serve as the basis of statistical data for the implementation of the Statistical Research Programme in the Field of Health Care. This implies that they need to provide an appropriate number, type and structure of data. Furthermore, when laying down legal solutions in the Bill on Data Collections in the Field of Health Care, positive practical experiences were used for the most part, because by doing so the effect of better maintenance of data collections in the operative sense was achieved.

### V ASSETS NEEDED FOR LAW IMPLEMENTATION

For implementation of this law, it is necessary to provide assets for salaries of the newly employed, for the purpose of keeping registries at the Institute of Public Health.