

Based on Article 95, item 3 of the Constitution of Montenegro, I enact

DECREE  
ON THE PROMULGATION OF THE LAW ON DATA COLLECTIONS IN THE FIELD OF HEALTHCARE

I hereby promulgate the Law on Data Collections in the Field of Health, adopted by the Parliament of Montenegro 23rd convocation, at the seventh session of the second regular session in 2008, on December 17, 2008 years.

Number: 01-2101/2  
Podgorica, December 22, 2008

The President of Montenegro,  
Filip Vujanović, sc

THE LAW  
ON HEALTH DATA COLLECTIONS

I. BASIC PROVISIONS

Article 1

This law regulates the types, content and manner of keeping data collections in the field of health care elements of unique health statistics, as well as the method of collection, processing, use, protection and storage data from collections.

Article 2

Health data collections (hereinafter: data collections) are data sets with precise definitions, which serve for monitoring and studying the health status of the population; planning and health care programming; conducting statistical and scientific research; fulfillment of obligations all subjects in the field of health and as an aid to state bodies in conducting health policy.

Article 3

Keeping data collections provides conditions for obtaining quantitative and qualitative information on the health condition and health protection of the population; the scope and quality of work of the health service and other relevant information necessary for health policy management and standardization of reporting relevant national and international institutions.

Article 4

The data collection manager is the Institute of Public Health (hereinafter: the manager).  
Notwithstanding paragraph 1 of this Article, the tuberculosis registry, as a collection of data, shall be managed by the Special hospital for pulmonary diseases Bilećko.  
The controller collects the data and is responsible for their processing, storage and publication, within determined competences and authorities.

Article 5

The management of databases is based on the principles of relevance, impartiality, reliability, timeliness, rationality, consistency and confidentiality, which imply that:  
- each defined data must meet clearly set conditions relating to providing a purpose of importance to the health of citizens and the health system;  
- definitions and methods of data collection, processing and use are determined in an objective manner, independent of any kind of influence;  
- determination of methods and procedures related to data collection, processing and use is performed on the basis of professional standards, scientific methods and principles, so that the results obtained by managing the collections data fully reflect the health status of the population;  
- data collections are managed within the prescribed deadlines;  
- all resources are used optimally, taking into account the scope of work and costs for keeping records.

Article 6

On the issues of collecting, processing and providing personal data contained in data collections, the provisions of the law governing the protection of personal data and the law governing it shall apply statistical research.

Article 7

Certain terms used in this law have the following meaning:  
1) the **register** is a longitudinal and continuous collection of data, which is defined by organized system for collection, storage, processing, analysis and use of data on a particular disease, a group of diseases and other health-related conditions at the level of the entire population or a collection system, storage, processing, analysis and use of data from the health system on personnel and others health care facilities;  
2) the **data set** is a part of the data collection that contains demographic, socio-economic, medical or other data related to the health of the population;  
3) the **medical documentation** is a group of means for harmonized recording and collection data on events and activities in the health care system;  
4) the **report** presents grouped data, according to a predetermined methodology, on the established one disease or condition and implemented activities in the field of health care;  
5) **health care providers** are health care institutions that are registered to perform health care activities;  
6) **contact** between the user and the health care provider is a direct or indirect way collecting data on the set of registered health problems, performed activities, use responsibility, the subject's health status, health care providers, etc;  
7) **health personal data** are personal data on the health condition of an individual and related personal data with provision of health care for the population and individuals.

II. TYPES, CONTENT AND MANNER OF KEEPING DATA COLLECTIONS

Article 8

In the field of health, the following data collections and registers must be kept as a special type of collection data, namely:  
1) registers of diseases of greater socio-medical significance, infectious diseases and other conditions related to population health;  
2) registers of resources in the health system;  
3) databases:  
- outpatient health care;  
- hospital health care;  
- in the field of health care of employees;  
- on laboratory services;  
- on radiological services;  
- on transfusiology;  
- on physiotherapeutic and rehabilitation;  
- on the work of pharmacies;  
- on the organizational structure and personnel in health care;  
- on the impact of the environment on human life and health;  
- other data collections for which the state administration body responsible for health affairs (hereinafter text: Ministry) determines that they are of interest to the health of the population.

Article 9

Registers of diseases of greater socio-medical significance, infectious diseases and other conditions related to population health registers are:  
- infectious diseases;  
- immunization;  
- tuberculosis;  
- HIV / AIDS;  
- malignant neoplasms;  
- drug addiction;  
- diabetes;  
- cerebrovascular diseases;  
- ischemic heart disease / acute coronary syndrome;  
- psychosis;  
- trauma;  
- occupational diseases;

on health care of children and youth with psychophysical and psychosocial disabilities

- growth and development of children and youth;

- other registers that the Ministry determines to be important for the health of the population.

Article 10

The registers referred to in Article 9 of this Law must contain personal data on the individual: name and surname, date and place of birth, sex, place and address of residence, marital status, education, occupation, employment, use immunization (IMBG), health insurance, name, parent's name and surname, place of residence, marital status, education, employment, job position, health status, contact details as well as donor details

The registers referred to in paragraph 1 of this Article shall also contain specific health data, which shall be regulated by an act Ministries.

Article 11

Registers of resources in the health system are:  
1) register of personnel in health care;  
2) register of health institutions.  
The form, content and manner of keeping the registers referred to in paragraph 1 of this Article shall be regulated by an act of the Ministry.

Article 12

Outpatient health care data collections are:  
1) database of preventive health care;  
2) collection of curative health care data (at the primary level);  
3) specialist health care data collection;  
4) collection of data on health - educational work;  
5) collection of data on emergency medical care.

Article 13

The basic set of outpatient health care data contains: user identification (IMBG), health insurance, name, parent's name and surname, place of residence, marital status, education, employment, job position, health status, contact details as well as donor details

Contacts referred to in paragraph 1 of this Article are classified according to: gender, age group, ICD-10 or diagnostic group and activities undertaken in favor of the health care of the individual.

Article 14

The database of preventive health care contains a set of data:  
1) preventive health care for children;  
2) preventive adult health care;  
3) preventive health care for women;  
4) preventive health care of employees;  
5) preventive dental care.

The basic set of data on preventive health care, in addition to the data referred to in Article 13 of this Law, it also contains data on: the type of preventive activity, the content of the preventive examination and the result of the preventive views.

Article 15

The curative health care database contains a set of data:  
1) curative health care of children;  
2) curative adult health care;  
3) curative health care for women;  
4) curative health care of employees;  
5) curative dental care.

Article 16

The basic set of curative health care data, in addition to the data referred to in Article 13 of this Law, also contains data on: type of curative examination, health status, working diagnosis, final diagnosis, referral to other health care units for the purpose of analysis, referral to other levels of health care protection for treatment, therapy and treatment outcome.

Article 17

The data collection of specialist health care, in addition to the data referred to in Article 13 of this Law, also contains data on: type of specialist examination, performed activity, diagnostic procedure, diagnosis, therapy and treatment outcome.

Article 18

The collection of data on health-educational work contains data on: type, time, place of the contractor and the content of the activity, the population covered, the duration of the activity, the applied strategies and the provider health care.

Article 19

The collection of data on emergency medical care, in addition to the data referred to in Article 13 of this Law, also contains data on: performed examinations, determined disease or condition, outcome, performed resuscitation and transport and health care provider.

Article 20

Hospital health care data collections are:  
1) collection of data on the organization and work of hospitals;  
2) collection of data on hospitalizations (hospitalized patients);  
3) birth data collection;  
4) collection of data on performed abortions.

Article 21

The collection of data on the organization and work of hospitals contains data on: organizational units, health workers, health associates and other employees, bed capacity, days of treatment and movement of treated patients.

Article 22

Basic set of hospital health care data for data collections from Article 20, item 2, 3 and 4 of this of the law contains data on: user identification (IMBG), health insurance, name, name, parent's name and surname, place and address of residence, marital status, education, employment, work place, name of the health institution, health care provider's type, admission, ordinal number of enrollment and date of admission to the hospital.

Article 23

Collection of data on hospitalizations (hospitalized patients), in addition to the data from Article 22 of this law, also contains data on: the date of the beginning of the episode, the ordinal number of the episode, the main diagnosis, accompanying diagnosis, date of onset of the episode, date of admission, date of daily treatment, date of conclusion episode, outcome, date of death of the patient, underlying cause of death, immediate cause of death, and date discharge from the hospital.

Article 24

The collection of data on births, in addition to the data referred to in Article 22 of this Law, also contains data on: anamnesis of the mother, during pregnancy, possible pathological condition in pregnancy, diagnosis of childbirth, the vital status of the newborn, the pathological condition of the newborn at birth and the underlying cause of death, if the newborn died.

Article 25

The collection of data on performed abortions, in addition to the data referred to in Article 22 of this Law, also contains data on: history, type of abortion, age of pregnancy, status, method of performing and outcome of abortion.

Article 26

Databases in the field of employee health care are:  
1) collection of data on injuries at work;  
2) a collection of data on absenteeism.

Article 27

The basic data set for databases in the field of employee health care contains:  
Beneficiary identification (IMBG), health insurance, name, parent's name and surname, place of residence, marital or health status, health care provider's type, job description, diagnosis, as well as date of admission to health care providers.

Article 28

The collection of data on injuries at work, in addition to the data referred to in Article 27 of this Law, also contains data on: type of injury, place and time of injury, cause of injury and further medical procedure.

The collection of data on absenteeism, in addition to the data referred to in Article 27 of this Law, also contains data on: length duration of absence from work, reasons for absence from work, further procedure of absence from work and possible disability.

Article 29

The collection of data on laboratory services contains data on: type of laboratory, headquarters, type tests and the number of samples tested.

Article 30

The collection of data on radiological services contains data on: place of service provided, type of radiological services and number of services.

Article 31

The collection of data on transfusiology contains data on: number of blood samples, amount of blood taken, blood products and blood donor status.

Article 32

The data collection on physical medicine and rehabilitation contains data on: performed physical therapy and rehabilitation, contacts, diagnosis, treatment status, type of rehabilitation and health care providers.

Article 33

The collection of data on the work of pharmacies contains data on: the amount of medicines dispensed, the type of medicines and the method dispensing the drug.

Article 34

The collection of data on the organizational structure and personnel in health care contains data on: the provider health care, health workers and health associates, professional profile of staff, status, as well as types of specialties.

Article 35

Databases on the impact of the environment on human life and health are:  
1) collection of data on hygienic safety of drinking water;  
2) collection of data on air pollution and the impact on the health status of the population;  
3) health care (diagnosis, date of contact, planned contacts, doctor identification, therapy, referral, reason for temporary incapacity for work, cause of death, reason for processing, social family history, health care plan);  
4) other data on other associated activities (care, nutrition, etc.);  
5) other data on health care (findings, statements, opinions and other documents).

Basic medical documentation is a group of means for harmonized recording and collection data on events and activities in the health care system, which is the primary source of data for databases.  
The medical documentation referred to in paragraph 1 of this Article shall be kept in written and electronic form.  
The detailed content and manner of keeping medical documentation shall be regulated by an act of the Ministry.

Article 36

The basic set of data for data collections on the impact of the environment on human life and health contains information on: place, time, type of test and test results.  
In addition to the data referred to in paragraph 1 of this Article, the data collections referred to in Article 35, item 1 and 2 of this law contain and data on physico-chemical characteristics of the tested water or air sample.  
For the data referred to in paragraph 1 of this Article, the collection of data referred to in Article 35, item 3 of this Law shall also contain data on: type of food, its object of general use under examination.

Article 37

The detailed content, form and manner of keeping data collections referred to in Article 8 of this Law shall be regulated by an act Ministries.

Article 38

Data collections are kept in written and electronic form.  
Unique methodological principles, unique ones, must be used for managing data collections standards and standard procedures for formatting and sending reports, prescribed by the Institute, upon proposal Institute of Public Health.

In order to manage and establish an information system in the field of health, the Ministry of Public Health:  
- harmonizes content definitions of data terms;  
- introduces and abolishes data concepts;

III. MANNER OF DATA COLLECTION AND ENTRY

Article 39

Entry of data into medical documentation, of which the basic medical documentation is an integral part and documentation-reporting forms (applications and reports), must be performed by health care providers.  
Basic medical documentation contains information on:  
- individual (IMBG, surname, name, parent's name, marital status, education, occupation, address permanent residence, municipality, employment, insurance, date of death);  
- health care (diagnosis, date of contact, planned contacts, doctor identification, therapy, referral, reason for temporary incapacity for work, cause of death, reason for processing, social family history, health care plan);  
- other data on other associated activities (care, nutrition, etc.);  
- other data on health care (findings, statements, opinions and other documents).

Basic medical documentation is a group of means for harmonized recording and collection data on events and activities in the health care system, which is the primary source of data for databases.  
The medical documentation referred to in paragraph 1 of this Article shall be kept in written and electronic form.  
The detailed content and manner of keeping medical documentation shall be regulated by an act of the Ministry.

Article 40

The entry of data in the medical documentation referred to in Article 39 of this Law shall be performed on the basis of the results examination, public and other documents or statements of the person whose data are entered in the medical documentation.  
In case the data cannot be entered in the medical documentation in the manner prescribed in paragraph 1 of this article, the entry is made on the basis of a signed statement of the person from whom the data is taken.

Article 41

Healthcare professionals and healthcare associates confirm the allegations and results of the examination with their signatures, or other services.  
The health care provider is responsible for the accuracy and completeness of the data entered in the medical documentation a worker and a health associate who performs data entry.  
The person who gave the statement is responsible for the accuracy of the data given in the statement.

Article 42

Healthcare providers are obliged to submit data from data collection managers medical documentation-reporting forms (applications and reports), in written and electronic form.  
The data referred to in paragraph 1 of this Article shall be submitted by health care providers in electronic form to the Center for exchange of data of the Fund (hereinafter: the Center).  
The center is obliged to enable electronic exchange of data between health care providers and data collection manager to develop and maintain information and communication infrastructure and to provide protection and storage of data, in accordance with the law.  
The conditions, manner and procedure of access to data in the Center are regulated by an act of the Ministry.

Article 43

The accuracy and completeness of the data stated in the reports referred to in Article 42, paragraph 1 of this Law shall be confirmed responsible person of the health care provider who submits the data, and for the accuracy and completeness of the data health care provider is the responsibility of the health worker or health associate who enters the data in application.

Article 44

The applications and reports referred to in Article 42 of this Law are:  
1) Report on mandatory immunization against infectious diseases;  
2) Report on a case and epidemic of an infectious disease;  
3) HIV / AIDS reporting;  
4) Report on tuberculosis;  
5) Report on hospitalized patients;  
6) Report on abortions;  
7) Report on births;  
8) Report on treated addicts of psychoactive substances;  
9) Report of malignant neoplasms;  
10) Diabetes report;  
11) Report of ischemic heart disease (acute coronary syndrome);

IV. PROCESSING, USE AND EXCHANGE OF DATA

Article 45

The person authorized to keep the data collections in the controller is responsible for the accuracy and completeness of the data entered data.  
If there is any doubt about the correctness of the submitted data, the manager informs the provider health care.  
The health care provider is obliged to check the correctness of the data referred to in paragraph 2 of this Article and correct it possible error.  
Modification of each data should be carried out in a way that allows insight into the previous data, when and from whom the data was changed.  
The change of data in the data collection is performed by an authorized person in the controller.

Article 46

In order to ensure data processing and preparation of appropriate reports, in accordance with the needs of and reporting standards to national and international entities, the Institute of Public Health is obliged to develop, improve and maintain its own information and statistical infrastructure in accordance with technical standards in that area.

Article 47

To ensure the quality and uniqueness of data, for scientific and statistical research, the manager may exchange data between individuals from data collections containing health personal data data collections.  
The manager is obliged to regulate the manner of providing the data referred to in paragraph 1 of this Article.

Article 48

The manager is obliged to provide health care providers who perform screening tests for the purpose of early disease detection to obtain and link data from data collections.  
The Institute of Public Health may, for the purposes of epidemiological and other research, collect and data related to the health care of individuals.  
In the case referred to in paragraph 2 of this Article, health care providers are obliged to, at the request of the Institute for Public Health submit other data, in addition to the data determined by this law.

Article 49

Medical records are kept for 15 years from the last data entry, except for dental ones, caribound that is kept permanently and health card and medical history that are kept after the death of the patient.  
Health care providers keep medical documentation in written and electronic form, in accordance with this law and regulations on archival material.

VI. SUPERVISION

Article 51

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

VII. PENAL PROVISIONS

Article 52

A fine of thirty to two hundred times the amount of the minimum wage in Montenegro, a legal entity of data will be punished for a misdemeanor, if it does not lead or does not lead according to the prescribed methodological guidelines principles of the data collection (Articles 8 and 39).

For the misdemeanor referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from ten to twenty times the minimum wage in Montenegro.

Article 53

A fine of thirty to two hundred times the minimum wage in Montenegro a legal entity shall be punished for a misdemeanor if:  
1) does not submit applications, reports and other data or does not submit them in the prescribed manner and in prescribed deadlines (Articles 42 and 44);  
2) does not keep medical documentation (Article 50, paragraphs 1 and 2);  
For the misdemeanor referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from ten to twenty times the minimum wage in Montenegro.

Article 54

A fine of one to twenty times the minimum wage in Montenegro a natural person and a responsible person in a legal entity shall be punished if:  
1) incorrectly or incompletely enters data into medical documentation (Article 41, paragraph 2);  
2) incompletely and incorrectly enters data into reports (Article 41, paragraph 1).

Article 55

A fine of one to twenty times the minimum wage in Montenegro a natural person who provided incomplete or inaccurate information with a statement signed by him shall be punished (Article 41, paragraph 3).

VIII. TRANSITIONAL AND FINAL PROVISIONS

Article 56

By laws for the implementation of this law shall be adopted within one year from the date of entry into force to the force of this law.  
Until the adoption of the acts referred to in paragraph 1 of this Article, the current regulations shall apply, if they are not in contrary to this law.

Article 57

On the day this law enters into force, the Law on Health Records shall cease to be valid ("Official Gazette of the SRG of Montenegro", No. 15/79) and application of the Law on Records in the Field of Health (Official Gazette of FRG ", No. 12/98 and 37/02).

Article 58

This Law shall enter into force on the eighth day from the day of its publication in the "Official Gazette of Montenegro".  
St./SK No. 01/10347/7  
Podgorica, December 17, 2008

Parliament of Montenegro  
President,  
Ranko Krivokapić, sc