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health care and rehabilitation (hereinafter: the patient) has the rights established by this law.

1) medical documentation means basic medical documentation determined by a special law;

CONTACT

HOME

tests;

interventions.

FREE

Article 1

Article 4

THIS REGULATION IS UPDATED ON 31.3.2021. YEARS.

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I. BASIC PROVISIONS

In exercising the rights established by this law, respect for human dignity, physical and mental integrity and protection of those rights shall be ensured. **Article 2**

Any person, sick or healthy, who requests or is provided with a health service in a health institution in order to preserve and improve health, prevent disease, treat and

The equal right to quality and continuous health care is guaranteed to every patient in accordance with his health condition, generally accepted professional standards and

ethical principles, with the right to alleviate suffering and pain at every stage of illness and condition, at all levels of health care.

Article 3 This law also applies to foreigners who receive health care in health care institutions in Montenegro, in accordance with the law and concluded international agreements.

This law accordingly applies to all entities that perform health care activities in accordance with the Health Care Act.

Article 5 The terms used in this law have the following meaning:

3) diagnostic procedure means all medical procedures that are performed in order to determine the health condition of the patient; 4) diagnosis is the recognition of a particular disease, which is set by the doctor on the basis of anamnesis, symptoms and signs of the disease, as well as the results of various morphological and functional

5) **therapeutic procedure** means all procedures performed in order to improve the health condition and cure the patient; 6) medical intervention is a medical procedure that is applied to the patient for the purpose of prevention, diagnosis and therapy.

2) scientific examination and research is examination and research undertaken for the purpose of acquiring new knowledge that can be applied for the improvement of health and treatment of sick persons;

II. PATIENTS 'RIGHTS 1. The right to freely choose a doctor of medicine or a dentist

Article 6 The patient has the right to choose a doctor of medicine, ie a dentist, in the health institution in the place of residence, in accordance with the law.

2. The right to information and notification

Article 7

Article 9

In the health institution at the secondary and tertiary level of health care to which the patient is referred by the chosen doctor of medicine, ie doctor of dentistry, the patient has the right to choose a doctor as a specialist in medicine, ie dentistry, in accordance with the staffing possibilities of the institution.

For a minor patient, ie a patient deprived of legal capacity, the choice of a doctor from para. 1 and 2 of this Article shall be performed by the legal representative, ie guardian. The patient has the right to request a change of doctor or dentist during the treatment in writing.

The patient has the right to timely access to all types of information about his health condition and illness, the manner of providing health services and their use, as well as to all information that is, based on scientific research and research, known and available. The health institution is obliged to provide the patient with information on the content of the medical documentation.

Article 8 The patient has the right to information about the network of health care institutions and the types of health care services that are provided in them.

The patient has the right to be acquainted with the name and surname of the health worker who provides him with the health service and his professional title.

Healthcare workers are obliged to carry an identification card in which the data referred to in paragraph 1 of this Article are entered.

Identification cards are issued in accordance with the statute of the health institution.

The notification referred to in paragraph 1 of this Article shall include:

1) diagnosis and prognosis of disease outcome;

directly endangers the life and health of others.

notice significantly harm the health of the patient.

saves or sustains his life.

if non-intervention would endanger the patient's life.

conditions, to consent to the proposed medical intervention.

The patient can revoke the consent to the proposed medical intervention until the beginning of its performance.

At the request of the patient, the health institution is obliged to provide insight and copying of his medical documentation.

competent guardianship authority.

effects of testing and research.

The patient has the right to seek another expert opinion on his health condition.

certain medical intervention with previously provided conditions for privacy.

The right referred to in paragraph 1 of this Article shall be provided at all levels of health care.

by a regulation of the state administration body responsible for health affairs (hereinafter: the Ministry).

may file an objection with the procedure of a health care or other employee of a health care institution.

The health institution is obliged to organize the work of the protector of patients' rights.

The director of the health institution appoints a protector of patients' rights.

The health institution is obliged to keep records of submitted patient complaints.

A fine of EUR 1,500 to EUR 20,000 shall be imposed on a legal entity for a misdemeanor if:

12) does not organize the work of the Protector of Patients' Rights (Article 31, paragraph 3);

13) does not keep records of submitted patient complaints (Article 33, paragraph 1).

1) does not provide the patient with information on the content of medical documentation (Article 7, paragraph 2);

6) at the request of the patient, does not enable insight and copying of his medical documentation (Article 21);

2) health workers do not carry an identification card with name and surname and professional title (Article 9, paragraph 2);

5) does not provide a translator or interpreter to a patient who does not know the official language or is deaf-mute (Article 11, paragraph 4);

7) fails to insure the patient in case of damage to his health before the beginning of scientific examination and research (Article 24, paragraph 2);

compensation for damages, in accordance with the law.

by law.

urgent (Article 30, paragraph 4);

behavior in that institution.

The patient has the right to timely health care.

changes in his health.

6) the effect of drugs and possible side effects of that effect.

Article 10 The health institution is obliged to determine the dates and make them available to the patient and his family members for a conversation with the doctor who provides him with the health service. **Article 11**

2) a brief description and purpose of the proposed medical intervention, duration and possible consequences of undertaking or not undertaking the proposed medical intervention;

The patient has the right to receive in due time from the healthcare professional the notification he / she needs in order to make a decision on accepting or rejecting the proposed medical

3) type and assessment of possible risks, pain, permanent or other side effects; 4) alternative methods of treatment; 5) possible changes in the patient's condition after undertaking the proposed medical intervention, as well as possible changes in the patient's lifestyle;

Notice from para. 1 and 2 of this Article is provided by a health professional with a university degree who provides the patient with a certain type of health service (hereinafter: the competent health worker)

The competent health worker enters in the medical documentation the information that he gave the patient, ie the family member, the notification from para. 1 and 2 of this article. Article 12

The patient may waive the right to notification, unless the proposed medical intervention is necessary, ie it is risky not to take it, as well as in cases where it is

and if the patient does not require it, orally in a way that is understandable to the patient, taking into account his age, education and emotional state.

If the patient does not know the official language or is deaf, the health institution is obliged to provide an interpreter or interpreter.

In the case referred to in paragraph 2 of this Article, the notification may be given to a member of the patient's family.

During the provision of health care, after each examination and medical intervention, the patient has the right to be informed about the results of the examination or medical intervention, as well as about reasons for the possible difference of these results from the expected ones.

Article 13

Article 14

Article 15

Article 16

The competent healthcare professional who considers that the patient's legal representative or guardian is not acting in the best interest of the patient referred to in paragraph 1 of this Article shall immediately notify the patient.

Article 19

3. The right to self-determination (free choice)

Exceptionally, the competent healthcare professional may withhold the diagnosis, the course of the proposed medical intervention and its risks or notification, if there is a serious risk that the

The patient has the right to freely decide on everything that concerns his life and health, except in cases when it directly endangers the life and health of others. The patient is free to decide between several possible forms of medical interventions offered by a doctor of medicine, ie a doctor of dentistry, and may refuse examination and treatment, surgical and other medical intervention.

is kept in medical records. If the patient refuses to give a written statement referred to in paragraph 2 of this Article, the competent healthcare professional shall make an official note.

The patient has the right to refuse the proposed medical intervention, if he is aware and oriented in time and space and if he is able to reason, even in the case when he

In an emergency, if the patient is unconscious or otherwise unable to give his or her consent, medical intervention may be undertaken when required by such condition and

The consent referred to in paragraph 1 of this Article is not obligatory in the case of providing health care to a mentally ill patient or a patient suffering from a contagious disease.

Article 17 Medical intervention on a minor or incapacitated patient may be undertaken with the consent of his or her legal representative or guardian. The patient referred to in paragraph 1 of this Article may, in relation to medical intervention, make a statement, which is assessed and taken into account in accordance with age and level of understanding of health

The competent healthcare professional is obliged to point out to the patient the consequences of his decision to reject the proposed medical intervention and to request a written statement from the patient

Article 18 The patient consents to the proposed medical intervention orally or in writing.

Medical intervention against the will of the patient, ie the representative of a minor patient or the guardian of a patient deprived of legal capacity may be undertaken only in exceptional cases. cases established by law and in accordance with medical standards and ethics. **Article 20**

4. The right to inspect medical documentation

5. The patient's right to refuse to be the subject of scientific examination and research

Article 21

Article 23

6. The right to another expert opinion

Article 25

7. The right to privacy and confidentiality

Article 27

Article 28

Article 29

The examination of the patient, undertaking medical interventions over him and during the provision of personal care may be attended only by health care workers, ie health care associates, who perform

During the stay in the health institution, the patient has the right to receive visits and communicate with other persons, in accordance with the law and general acts of the institution on the conditions of stay and

8. The right to timely health care

Health care institutions are obliged to determine the time, ie the deadline within which certain health services must be provided, depending on the urgency of the case and the criteria established.

The health care institution is obliged to inform the person designated by the patient to receive the notification about the admission of the patient to the health care institution, as well as to regularly inform them about

Article 30

Article 31

Article 32

Article 33

Article 34

Article 35

III. SUPERVISION

Article 36

Article 37 *

IV. PENAL PROVISIONS

9) the person designated by the patient to receive the notification does not inform about the admission of the patient to the health institution and does not regularly inform them about the changes in his health condition

Article 38 *

2) does not enter in the medical documentation the information that he has given the patient, ie a family member a notification that includes the elements prescribed by Article 11, paragraph 2 of this Law, and which

3) does not determine the time (terms) and does not make them available to the patient and members of his family for a conversation with the doctor who provides him with health care (Article 10);

4) notification containing the elements prescribed in Article 11, paragraph 2 of this Law, which the patient needs to make a decision on accepting or rejecting the proposed medical

interventions, not by a health professional with a university degree who provides a certain type of health service to the patient and if the patient does not require it (Article 11, paragraph 3);

10. Right to compensation

11. The right to leave the health care institution arbitrarily

The patient has the right to voluntarily leave the medical institution where he is treated, except in cases where this would harm the health and safety of others and the safety of the patient, in accordance with

The right to copy the medical documentation of the person referred to in para. 1 and 2 of this Article shall be realized on the basis of a written request and at their own expense. A family member has the right to inspect medical records, in accordance with a special law.

In the event that the patient is a minor or a person deprived of legal capacity, the right referred to in paragraph 1 of this Article has a legal representative or guardian.

In the medical documentation, the competent health worker enters the data on the patient's consent, ie the rejection of the proposed medical intervention.

Article 22 Scientific examination and research may be undertaken on an adult and able-bodied patient, only with his consent, which he may revoke at any time. The patient gives his consent in writing, after being sufficiently informed about the purpose, course of the procedure, expected results, possible risks, as well as possible unwanted

side effects of testing and research. **Article 24** A healthcare worker who conducts scientific examination and research is obliged to take care that the protection of the life and health of the patient always has an advantage over the interest of society and science.

The health institution is obliged to, before the beginning of scientific examination and research, insure the patient in case of damage to health, in accordance with the law.

The patient has the right to participate in the clinical trial of drugs and medical devices, in accordance with the law governing the field of drugs and medical devices.

The health institution is obliged to publish and regularly update the list of organizational units and doctors who provide appropriate health services in a visible place.

Personal data and information provided by the patient to the competent healthcare professional, including those related to his health condition and potential diagnostic and

During the visit to the doctor, conducting diagnostic tests and / or therapeutic procedures, the patient has the right to protection of his privacy.

therapeutic procedures, as well as data from medical records, are a professional secret and are kept in accordance with a special law.

Exceptionally, scientific examination and research may be undertaken both against a minor patient and a patient deprived of legal capacity, only for his immediate benefit and in writing.

the consent of the legal representative, ie the guardian who has been previously informed about the purpose, goal, course of the procedure, expected results, possible risks, as well as possible

The second professional opinion referred to in paragraph 1 of this Article shall, at the oral or written request, be given to the patient by every health worker with a university degree and appropriate specialization who did not participate in the direct provision of a particular form of health care to the patient. **Article 26**

The patient has the right to designate persons to whom notification may be given, as well as persons who may be excluded or who may be partially informed of his illness and the expected outcome. The patient has the right to designate persons who can be informed about his admission to the health institution and the health condition, as well as persons to whom this information cannot be announced.

The patient may consent to the presence of other persons during the examination and undertaking medical interventions over him in accordance with medical standards and practice.

The health care institution is obliged to inform the patient, at his request, about the order and possible changes in the waiting list for the planned medical intervention, at the medical interventions that are not urgent. 9. Right to object

For a minor patient, ie a patient deprived of legal capacity, the complaint referred to in paragraph 1 of this Article shall be submitted by his / her legal representative, ie guardian.

A patient who has been denied the right to health care or a certain right determined by this Law, or a patient who is not satisfied with the provided health service or

The complaint is submitted to the director of the health institution or an authorized person (hereinafter: the Protector of Patients' Rights).

Two or more healthcare institutions that perform healthcare activities in a certain area may appoint a common protector of patients' rights.

A patient who is dissatisfied with the findings of the complaint may contact the health inspectorate, in accordance with the law.

The director of the health institution submits to the Ministry a quarterly and annual report on the submitted patient complaints.

The Protector of Patients' Rights is a person with a college or university degree in health, psychology, sociology or law.

The objection shall be submitted orally or in writing. Upon the patient's complaint, the director or the protector of patients' rights shall immediately, and no later than within three days from the day of filing the complaint, determine all circumstances and important facts related to allegations set out in the complaint and informs the complainant accordingly.

In the case of voluntary departure from a health care institution, the patient, ie legal representative for a minor patient or guardian for a patient deprived of legal capacity, is obliged to to sign a statement of abandonment, which is kept in medical records. If the patient, ie legal representative for a minor patient or guardian for a patient deprived of legal capacity refuses to sign the statement referred to in paragraph 2 of this Article, the competent the healthcare professional will make an official note of this which is kept in the medical records.

Supervision over the implementation of this law and regulations adopted on the basis of this law is performed by the Ministry, through the health inspection.

A patient who deteriorates his health due to unprofessional and conscientious conduct of a healthcare professional or healthcare associate has the right to appropriate

A patient who suffers damage to his body or health due to scientific examination and research is entitled to compensation for damage, regardless of guilt, in accordance with the law.

(Article 29, paragraph 3); 10) does not determine the time, ie the deadline within which certain health services must be provided (Article 30, paragraph 3); 11) does not inform the patient, at his request, about the order and possible changes on the waiting list for the planned medical intervention, in the case of medical interventions that are not

For the misdemeanor referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from EUR 500 to EUR 2,000.

A fine of EUR 250 to EUR 2,000 shall be imposed on a healthcare worker, responsible person or natural person for a misdemeanor if:

4) does not indicate to the patient the consequences of his decision to reject the proposed medical intervention (Article 15, paragraph 2);

8) does not publish and regularly does not update in a visible place the list of organizational units and doctors who provide appropriate health services (Article 26);

he needs to make a decision on accepting or rejecting the proposed medical intervention (Article 11, paragraph 5); 3) communicate the diagnosis, the course of the proposed medical intervention and its risks or do not limit the notification, if there is a serious danger that the notification will significantly harm the health patient (Article 12, paragraph 2);

5) does not request and does not keep in the medical documentation a written statement of the patient who refuses the proposed medical intervention (Article 15, paragraph 2);

proposed medical interventions, in a way that is not understandable, without taking into account his age, education and emotional state (Article 11, paragraph 3);

1) provide the patient with an oral notification that includes the elements prescribed by Article 11, paragraph 2 of this Law, which he needs to make a decision on acceptance or rejection

7) does not immediately inform the competent guardianship authority, if he / she considers that the legal representative of the minor patient or the guardian of the patient deprived of legal capacity does not act in his best interests (Article 17, paragraph 3); 8) does not enter the data in the medical documentation on the consent, ie refusal of the patient to the proposed medical intervention (Article 20);

6) does not make an official note, if the patient refuses to give a written statement rejecting the proposed medical intervention (Article 15, paragraph 3);

(Article 25, paragraph 2);

filing an objection (Article 32 paragraph 2);

V. TRANSITIONAL AND FINAL PROVISION

13) fails to submit to the Ministry a quarterly or annual report on submitted patient complaints (Article 33, paragraph 2); 14) does not sign the statement on the patient's decision to voluntarily leave the health institution where he is being treated (Article 35, paragraph 2). **Article 39**

Article 40

9) does not take into account that the protection of the life and health of the patient always has priority over the interest of society and science when conducting scientific examination and research (Article 24, paragraph 1); 10) does not give another expert opinion on the health condition of the patient when he did not participate in the direct provision of a certain form of health service, at his oral or written request 11) fails to appoint a protector of patients' rights (Article 31, paragraph 3);

12) fails to establish all the circumstances and essential facts related to the allegations set forth in the complaint and fails to notify the complainant immediately, and no later than within three days from the day

The regulation referred to in Article 30 of this Law shall be adopted within six months from the day this Law enters into force.

This Law shall enter into force on the eighth day from the day of its publication in the "Official Gazette of Montenegro".