



## VELFERÐARRÁÐUNEYTIÐ

*Ministry of Welfare*

### **Act on Patient Insurance, No. 111/2000, as amended by Act No. 176/2000, Act No. 160/2007, Act No. 112/2008, Act No. 162/2010, Act No. 126/2011 and Act No. 85/2015.**

*Patients covered by the Act.*

#### Article 1

Patients, as defined in Article 2 of the Act on Patients' Rights, who suffer physical or mental damage in Iceland in connection with examination or medical treatment in a hospital, health-care centre or other health institution, during medical transport, or in the care of a self-employed health-service worker certified as such by [the Medical Director of Health],<sup>1)</sup> are entitled to compensation pursuant to this Act. The same applies to those who lose their principal provider upon the death of such patients.

Patients who urgently require hospitalisation in a foreign hospital or other health institution abroad, *cf.* [Article 23 of Act on Health Insurance],<sup>1)</sup> and suffer physical or mental damage as a result of examination or medical treatment in the institution in question are entitled to compensation under this Act, following deduction of any compensation to which they may be entitled in the foreign state.

People participating in medical experiments that are not part of the diagnosis or treatment of the illness of the party concerned shall have the same rights as patients under this Act, unless otherwise specified.

Donors of tissue, organs, blood or other body fluids shall have the same rights as patients under this Act, unless otherwise specified.

<sup>1)</sup> Act No. 112/2008, Article 61.

*Incidents of damage covered by the Act.*

#### Article 2

Compensation shall be paid irrespective of whether anyone may be liable for damages according to rules of tort, provided that the damage suffered can in all probability be traced to any of the following incidents:

1. It may be assumed that damage could have been avoided if the examination or treatment under the circumstances in question had been conducted in the best possible manner and based on existing knowledge and experience in the relevant field.
2. Damage results from a malfunction or defect in instruments, tools or other equipment used during examination or medical treatment.
3. Subsequent evaluation reveals that damage could have been avoided by employing a different available treatment method or technique, which would from a medical point of view have been equally useful in the treatment of the patient.
4. Damage results from treatment or examination, including operations conducted for diagnostic purposes, and the damage is suffered from infections or other side effects which are more extensive than the patient should reasonably be expected to endure without compensation. On the one hand, account shall be taken of the extent of the damage, and on the other hand the illness and general health of the patient. It shall also be taken into consideration whether it is common for damage to result from treatment of the type received by the patient, and whether or to what extent the risk of such damage could have been anticipated.

### Article 3

Compensation shall be paid for damage resulting from incorrect diagnosis in instances described in items 1 and 2 of Article 2. However, this does not apply to instances falling under items 3 and 4 of Article 2.

In the event that a patient is injured from causes other than those described in item 2 of Article 2, compensation shall be paid only if the patient was undergoing examination or treatment at the hands of an institution or other party covered by this Act, and if the accident occurred in such a manner that such institution or other party must be regarded as liable for damages pursuant to the general rules of tort.

Compensation under this Act shall not be paid if the damage can be traced to the characteristics of a medical product used in examination or medical treatment.

### Article 4

Compensation shall be paid to individuals referred to in paragraphs 3 and 4 of Article 1 if they suffer damage as a possible result of a medical experiment, removal of tissue, etc., unless all the indications are that the damage can be traced to another cause.

The provisions of paragraph 1 do not apply to damage that can be traced to the characteristics of a medical product used in examination or treatment, *cf.* paragraph 3 of Article 3.

### *Determination of the amount of compensation.*

#### Article 5

The determination of the amount of compensation under this Act shall be conducted in accordance with the law of tort, *cf.* however paragraph 2 of Article 10.

Compensation pursuant to paragraph 1 shall be paid if the damage suffered is assessed at ISK 50,000 or more. However, the maximum amount of compensation accorded for a single incident of damage shall be ISK 5,000,000. These amounts shall be adjusted as of 1 January each year according to [the consumer price index].<sup>1)</sup>

The provisions of paragraph 2 do not apply to damage described in paragraph 1 of Article 4, *cf.* paragraphs 3 and 4 of Article 1.

Compensation shall not be paid pursuant to this Act for the satisfaction of reimbursement claims.

<sup>1)</sup> Act No. 176/2000, Article 1.

### *Own fault.*

#### Article 6

Compensation may be reduced or cancelled if a patient is involved in causing the damage, intentionally or as a result of gross negligence.

### *Law of Tort pursuant to general rules.*

#### Article 7

No claim for damages shall be made on any party subject to liability under the rules of tort, unless the damage in question has not been fully compensated in accordance with Article 5, and then only for the residual amount due.

### *Reimbursement claims.*

#### Article 8

In the event that a liable party pursuant to Article 9, or an employee or former employee of such party, is liable to pay damages to a patient pursuant to the rules of tort, no reimbursement claims shall be made against the liable party for payment pursuant to Article 5, unless the damage in question was caused intentionally.

*Liabile parties.*

Article 9

All providers of health service, in institutions and otherwise, are liable for damage by this Act. These are:

- a. health care centres, whether run by the state, municipalities or other parties,
- b. hospitals, whether run by the state, municipalities or other parties,
- c. other health institutions, regardless of the parties responsible for their operation,
- d. self-employed health service workers who have been certified for such work by [the Medical Director of Health],<sup>1)</sup> regardless of whether the health care service they provide is paid for in full by the patient or by sickness insurance in accordance with an agreement [based on [the Act on Health Insurance]<sup>1)</sup>],<sup>2)</sup>
- e. [the Icelandic Health Insurance],<sup>1)</sup> in respect of patients who urgently require hospitalisation in a foreign hospital or other health institution abroad, *cf.* paragraph 2 of Article 1, and
- f. parties operating medical transport.

<sup>1)</sup> Act No. 112/2008, Article 61. <sup>2)</sup> Act No. 160/2007, Article 13.

*Insurance obligation.*

Article 10

Liabile parties pursuant to Article 9 shall be insured (patient insurance) with an insurance company holding an operating licence in Iceland, subject, however, to Article 11.

[The Minister]<sup>1)</sup> shall issue a regulation<sup>2)</sup> regarding, e.g., the minimum insurance amount in each insurance year and the implementation of the obligation to carry insurance. The Minister may subject the operating licenses of health institutions not covered by Article 11 and work permits of self-employed health service workers to the condition of full compliance with the insurance obligations pursuant to this Act.

<sup>1)</sup> Act No. 126/2011, Article 313. <sup>2)</sup> Regulation No. 763/2000, *cf.* No. 40/2001.

*Own risk.*

Article 11

Health-care centres, hospitals and other health institutions owned or partly owned by the State are exempted from the insurance obligation pursuant to Article 10. The same applies to [the Icelandic Health Insurance]<sup>1)</sup> and parties operating medical transport for the state. However, such parties may take out insurance pursuant to Article 10.

<sup>1)</sup> Act No. 112/2008, Article 61.

*Insurance company processing of compensation cases.*

Article 12

Claims for compensation under this Act in respect of damage suffered by parties other than the parties listed in Article 11 shall be addressed to the insurance company of the liable party.

Employees of insurance companies responsible for the cases of patients or other injured parties shall maintain full confidentiality regarding all personal data which may come to their knowledge in the course of their work or in connection therewith.

*Processing of compensation claims in cases where the liable party is exempted from insurance obligation.*

Article 13

Claims for compensation under this Act in respect of damage suffered by parties that have exercised their right not to purchase insurance, *cf.* Article 11, shall be addressed to [the Icelandic Health Insurance].<sup>1)</sup>

<sup>1)</sup> Act No. 112/2008, Article 61.

*Patient insurance of the Icelandic Health Insurance.*

Article 14

[The Icelandic Health Insurance, cf. the Act on Health Insurance],<sup>1)</sup> shall provide patient insurance in respect of parties that have exercised their right not to purchase insurance, cf. Article 11.

The Minister shall issue a regulation regarding operation and processing of patient insurance cases within [the Icelandic Health Insurance].<sup>1)</sup>

<sup>1)</sup> Act No. 112/2008, Article 61.

*Process within the Icelandic Health Insurance.*

Article 15

[The Icelandic Health Insurance]<sup>1)</sup> shall gather data as necessary and may, e.g., obtain depositions before the District Court where the deponent is resident. The Institute may require health care centres, hospitals, other health institutions, self-employed health service workers certified by [the Medical Director of Health],<sup>1)</sup> and parties operating medical transport, to surrender documents of any kind, including clinical records that the Institute regards as relevant to the processing of a case pursuant to this Act.

Following data gathering, [the Icelandic Health Insurance]<sup>1)</sup> shall decide on liability and establish the amount of compensation.

Employees of the Institute responsible for the cases of patients or other injured parties shall maintain full confidentiality regarding all personal data which may come to their knowledge in the course of their work or in connection therewith

<sup>1)</sup> Act No. 112/2008, Article 61.

Article 16

[The Icelandic Health Insurance]<sup>1)</sup> shall notify all parties concerned of its conclusion in each case. The Institute's findings may be referred to [the Welfare Appeals Committee]<sup>2)</sup> in accordance with the [the Welfare Appeals Committee]<sup>2)</sup> Act.

<sup>1)</sup> Act No. 112/2008, Article 61. <sup>2)</sup> Act No. 85/2015, Article 13.

*Annual report on patient insurance.*

Article 17

[The Icelandic Health Insurance]<sup>1)</sup> shall annually prepare a report for [the Minister]<sup>2)</sup> describing activities in respect of patient insurance and the cases processed by the Institute. The Institute's annual report shall furthermore describe, to the extent possible, the processing by insurance companies of cases of compensation claims based on patient insurance. The annual report shall be accessible to the general public.

<sup>1)</sup> Act No. 112/2008, Article 61. <sup>2)</sup> Act No. 162/2010, Article 71.

*Obligation of the Icelandic Health Insurance to provide information.*

Article 18

[The Icelandic Health Insurance]<sup>1)</sup> is under obligation to inform the general public of the provisions of this Act on Patient Insurance. Such information shall reveal, inter alia, that in cases involving self-employed health service workers, claims shall be addressed to insurance companies.

<sup>1)</sup> Act No. 112/2008, Article 61.

*Miscellaneous provisions.*

Article 19

Claims for compensation pursuant to this Act shall lapse when four years have elapsed from the time that the injured party was informed of or could have been informed of his/her damage.

However, in any case, claims shall lapse when ten years have elapsed from the incident resulting in the damage.

#### Article 20

Violations of paragraph 1 of Article 10, *cf.* however Article 11, are punishable by fine.

Violations of paragraph 2 of Article 12 and paragraph 3 of Article 15 are punishable by fine or imprisonment.

In the event that a punishable offence is committed in the course of employment with a company, institution, or other non-natural entity, such entity shall be held responsible for payment of the consequent fine.

#### Article 21

[The Minister]<sup>1)</sup> may issue a regulation<sup>2)</sup> for the further implementation of this Act. Such regulation shall include further definition of what shall constitute medical treatment, *cf.* Article 1, and what shall constitute a medical experiment, *cf.* paragraph 3 of the same Article.

<sup>1)</sup> Act No. 162/2010, Article 71. <sup>2)</sup> Regulation No. 763/2000, *cf.* No. 40/2001.

#### Article 22

This Act shall enter into force on 1 January 2001, and shall apply to instances of damage occurring subsequent to that date. This Act shall be reviewed within four years of its entry into force.

#### *Amendments to other Acts.*

#### Article 23

...

#### Article 24

...

#### **[Temporary Provisions.**

...]<sup>1)2)</sup>

<sup>1)</sup> Act No. 112/2008, Article 61. <sup>2)</sup> Act No. 160/2007, Article 15.

*[This translation is published for information only.*

*The original Icelandic text is published in the Law Gazette.*

*In case of a possible discrepancy, the original Icelandic text applies.]*