

Act on Health Insurance No. 112/2008

as amended by Act No. 173/2008, 55/2009, 121/2009, 131/2009, 147/2010, 162/2010, 126/2011, 155/2011, 45/2012, 105/2012, 130/2012, 131/2012, 125/2014, 11/2015, 85/2015, 115/2015, 130/2015, 13/2016, 77/2016, 80/2016, 80/2018, 90/2018, 126/2018, 52/2019, 71/2019, 92/2020, 93/2020, 99/2020 and 100/2020.

Where mention is made in this Act of 'the minister' or 'the ministry' without further definition, the reference intended is to the Minister of Health or to the Ministry of Welfare, which is responsible for the implementation of this Act. Information on the division of responsibilities between ministries according to a presidential decree may be found <u>here</u>.

CHAPTER I

Objective, scope and definitions.

Article 1 *Objective*.

The objective of this Act is to ensure assistance to health insured persons for the protection of their health and equal access to health service, irrespective of financial position, as further provided in this Act and in accordance with the Health Service Act, the Patients' Rights Act and other legislation, as applicable.

Furthermore, it is the objective of this Act to promote the efficiency and economic viability of health service and maximise its quality to the extent possible at any time. It is also the objective of this Act to strengthen the role of the State as a buyer of health services and to analyse the cost of the health service.

Article 2

Scope and policy making.

This Act provides for social security health insurance, contracts on health services and consideration paid by the State for health services. [The Minister]¹⁾ is responsible for policy making within the framework of this Act, the Health Service Act and other legislation. The Minister is authorised to take necessary measures to implement this policy, *inter alia* as regards the organisation of the health service, prioritisation within the service, the efficiency, quality and safety of the service and accessibility.

1) Act No. 126/2011, Article 496.

Definitions.

In this Act, the following terms shall have the following meanings:

- 1. Health insured person: A person entitled to assistance and payments pursuant to this Act.
- 2. *Benefits*: Benefits paid in cash, such as per diem benefits, reimbursement of outlays, grants and other payments, and assistance to the sick and injured provided in another form pursuant to this Act.
- 3. *Health service*: All forms of primary healthcare, medical care, nursing, general and specialised hospital care, transport of patients, medical-aids service, and service from health personnel within and outside healthcare facilities, provided in order to promote health, to prevent, diagnose or treat illness, and to rehabilitate patients.
- 4. *Healthcare practitioner*: Person working in health services, licensed by the Medical Director of Health to use to the professional title of an authorised health profession.
- 5. *Consideration*: Payments to health service providers under contract.
- [6. *Internationally recognised medical treatment*: Medical treatment that is considered to have been sufficiently tried and tested, *cf.* Article 44, in the light of the circumstances in any given case, and that is based on medical research, recognised methods and experience.]¹⁾

In other respects the definitions in the Health Service Act shall apply, as appropriate.

¹⁾ Act No. 13/2016, Article 1.

CHAPTER II Administration.

Article 4

Central administration.

[The Minister]¹⁾ is responsible for the central administration of health insurance and contracting for health services and other assistance under this Act, and the administration of the Health Insurance Administration.

1) Act No. 126/2011, Article 496.

Article 5

Health Insurance Administration.

A Health Insurance Administration is hereby established. Its main offices shall be in Reykjavík, and as circumstances permit the Health Insurance Administration and the Social Insurance Administration shall operate joint reception facilities to provide services and information to users of the service. Outside Reykjavík, the Health Insurance Administration may contract with other parties providing public services for the operation of an agency; location and arrangements shall be subject to the decision of the Administration.

The Health Insurance Administration is responsible for the implementation of health insurance and will contract and pay a consideration for health services under this Act in accordance with the Minister's policy at any time.

The functions of the Health Insurance Administration are the following:

- 1. To assume responsibility for the implementation of health insurance pursuant to Chapter III;
- 2. To contract for health services pursuant to Chapter IV;
- 3. To assume responsibility for the procurement of the goods and services that it is required to provide pursuant to Chapter III;
- 4. To disburse consideration for health services to be provided under the Health Service Act or contracted for in accordance with Chapter IV:
- 5. To monitor the quality and results of the work of persons providing health service under contracts pursuant to Chapter IV;
- 6. To undertake other tasks entrusted to the Administration pursuant to law, administrative instructions or decisions of the Minister.

The Health Insurance Administration shall regularly publish concise information on all its activities. Furthermore, the Administration shall disseminate information to the public concerning their rights under this Act.

Article 6

Board of governors.

The Minister shall appoint five members to the board of governors of the Health Insurance Administration; one member shall be appointed as chairman and another as vice-chairman. An equal number of alternate members shall be appointed. The chairman shall call meetings of the board and preside at the meetings; the Director General of the Administration shall attend meetings of the board with the right to participate in discussions and submit proposals. The Minister shall establish terms of reference for the board and decide on the remuneration to be paid to members out of the operating funds of the Administration.

The board of governors of the Health Insurance Administration shall approve the organisation chart of the Administration, its annual programme of operation and budget, and shall establish its long-term strategy. The board shall supervise the work of the Administration and the maintenance of its operations within the framework of the State Budget at any time.

The chairman of the board of the Health Insurance Administration shall report regularly to the Minister on the work of the Administration and notify the Minister if its activities and services are not in compliance with the provisions of law and if its operation is not in compliance with the State Budget.

Article 7 Director General.

The Minister of Health shall appoint the Director General of the Health Insurance Administration for a term of five years ...¹⁾. The Director General shall have completed university training and possess experience of management and administration which is of practical use for his or her work. The Director General shall appoint other staff of the Administration and take charge of its day-to-day operation.

The Minister of Health shall issue a letter of appointment for the Director General stating the principal goals of the services and operation of the Administration and its tasks for the long and short term. The letter of appointment shall also provide for the relations between the Director General and the board of governors of the Health Insurance Administration.

The Director General is responsible for ensuring that the operation of the Health Insurance Administration is in compliance with statutory law, administrative instructions and the letter of appointment provided for in the second paragraph. The Director General is responsible for the activities of the Administration and for ensuring that the expenditures and financial performance of the Administration comply with the State Budget and that its funds are used in an effective manner.

1) Act No. 92/2020, Article 1.

Article 8

Working groups and experts.

The Health Insurance Administration is permitted to appoint working groups and call upon experts to assist the Administration, e.g. in contract negotiations, use of evidence-based knowledge in the field of health services, performance evaluation, quality evaluation, monitoring and assessment of whether medical treatment can be provided in Iceland, *cf.* Article 23.

CHAPTER III

Health Insurance. A. General provisions.

Article 9

Health insurance.

Health insurance covers health service and other assistance to be provided at the expense of the State or with the cost participation of the State in accordance with this Act, regulations under the Act or contracts. In addition, health insurance cover benefits under this Act which are paid out in cash. Health insured persons are entitled to assistance, as further provided in this Act.

Article 10

Health insured persons under this Act.

A health insured person is a person who is resident in Iceland and has been resident in Iceland for a minimum of six months before health insurance benefits are requested, subject to fulfilment of other conditions of this Act, except as otherwise provided in international agreements. Residence refers to legal domicile in the understanding of [the Domicile and Residence Act].¹⁾

Children under the age of 18 who are resident in Iceland are covered by health insurance with their parents. The same applies to stepchildren and foster children.

Health insurance coverage shall lapse at the time that a health insured person moves his or her residence from Iceland, subject to the provisions of Articles 11, 12 and 15, except as otherwise provided in international agreements. Also, international agreements to which Iceland is a party may entail exceptions and restrictions with regard to the implementation of provisions of this Act.

The Health Insurance Administrations shall determine whether a person shall be regarded as covered by health insurance in Iceland under this Act.

The Minister of Health shall issue a regulation on the further implementation of this Article, e.g. as regards registration of the rights of health insured persons. The regulation may provide for exemptions from the requirement of six months' residence.

1) Act No. 80/2018, Article 20.

Article 11

Health insurance coverage notwithstanding stay, studies or employment abroad.

The Health Insurance Administration may decide, following an application to such effect, that a person covered by health insurance pursuant to this Act should continue to enjoy coverage, even where such person does not meet the conditions of Article 10, provided that such person is working abroad in the employ of a person having its residence and operations in Iceland, and provided that payroll taxes pursuant to the Payroll Tax Act are paid on his or her wages in Iceland. The same shall apply to a spouse and children under 18 years of age residing with such person.

The Health Insurance Administration is permitted to decide, following an application to such effect, that a person covered by health insurance pursuant to this Act should continue to enjoy coverage even where such person does not meet the conditions of Article 10, provided that such person is resident abroad as a student and not covered by health insurance under social security in the country of study. The same shall apply to a spouse who was covered by health insurance in Iceland at the start of studies and the student's children under 18 years of age residing with him or her.

The Health Insurance Administration is permitted to decide, following an application to such effect, that a person covered by health insurance pursuant to this Act should continue to enjoy coverage up to one year from departure from Iceland, even if such person does not meet the conditions of the first or second paragraph or Article 10, provided that no international agreement dictates otherwise. This is subject to the condition that the person in question was resident in Iceland for a minimum of five years prior to departure and that the reason for departure is not to seek medical treatment.

The Minister of Health shall issue a regulation on the further implementation of this Article, e.g. as regards what constitute recognised studies abroad.

Employees of Icelandic embassies, permanent delegations and consulates.

Icelandic citizens employed by the State abroad in embassies, permanent delegations or consulates and receiving their salaries from the State Treasury shall enjoy health insurance coverage under this Act.

The same applies to spouses and children residing with them, provided that they do not acquire independent rights in the country in question.

Icelandic citizens employed in embassies, permanent delegations or consulates, or in the service of diplomatic agents, who are not posted for work in the interest of the State, do not enjoy health insurance coverage under this Act, except as otherwise dictated by international agreements, subject to the provisions of Article 11. It is permitted to decide that such individuals should enjoy health insurance coverage pursuant to application, on the recommendation of [the Ministry in charge of the affairs of embassies, permanent delegations and Icelandic consulates abroad]¹⁾, in the case of work which is important for Icelandic interests abroad and if they do not enjoy insurance coverage in the host state.

The Minister may issue a regulation²⁾ on the further implementation of this Article.

¹⁾ Act No. 126/2011, Article 496. ²⁾ Regulation No. 1025/2008.

Article 13

Employees of foreign embassies, permanent delegations and consulates.

Diplomatic agents of foreign states in Iceland do not enjoy health insurance coverage under this Act.

The same applies to their spouses and children residing with them who are not Icelandic citizens, provided that they do not acquire independent rights in Iceland on the basis of employment in Iceland.

Personal servants who are foreign nationals, work exclusively in the service of diplomatic agents and are not permanently resident in Iceland do not enjoy health insurance coverage under this Act, provided that they enjoy health insurance coverage in the sending state.

The Minister may issue a regulation¹⁾ on the further implementation of this Article.

¹⁾ Regulation No. 1025/2008, cf. 1546/2021.

Article 14

Employees of international organisations.

Icelandic citizens employed abroad in international organisations, whose salaries are paid by the international organisations, do not enjoy health insurance coverage under this Act. It is permitted to decide, following an application to such effect that an individual should enjoy health insurance coverage in the case of organisations to which Iceland is a party when the work is regarded as serving Iceland's interests abroad. The conditions for such an exception is that the person in question was health insured pursuant to this Act at the start of employment and cannot enjoy health insurance coverage by virtue of his or her employment or employer.

The Minister may issue a regulation on the further implementation of this Article.

Article 15

Members of the Iceland Crisis Response Unit.

Members of the Icelandic Crisis Response Unit who are on peacekeeping missions abroad for [the Ministry in charge of the affairs of peacekeeping missions]¹⁾, and who are paid salaries out of the State Treasury pursuant to the Act on the Icelandic Crisis Response Unit, shall be covered by health insurance under this Act.

The Minister may issue a regulation on the further implementation of this Article.

1) Act No. 126/2011, Article 496.

[Refugees and individuals who possess a residence permit on humanitarian grounds.]¹⁾

[Refugees granted [international protection]²⁾ by the State government and individuals who possess a residence permit on humanitarian grounds enjoy health insurance coverage under this Act, provided that they have arrived to Iceland and that confirmation has been obtained from the Directorate of Immigration that the person in question has been granted refugee status or has residence permit on humanitarian grounds under the Act on Foreigners.]¹⁾

The Minister may issue a regulation on the further implementation of this Article.

¹⁾ Act No. 11/2015, Article 1. ²⁾ Act No. 80/2016, Article 124.

B. Assistance.

Article 17

Primary healthcare.

Health insurance covers primary healthcare pursuant to the Health Service Act, i.e. general medical treatment, nursing, health protection and preventive care, emergency and casualty treatment and other health care services provided by health care centres operated by the State or under contracts pursuant to Chapter IV.

Furthermore, health insurance covers general medical treatment and nursing provided outside health care centres under contract pursuant to Chapter IV.

The Minister may issue a regulation¹⁾ on the further implementation of this Article.

Article 18

Hospital services.

[Health insurance covers free hospitalisation, on the recommendation of a physician, in hospitals run by the State or under contract pursuant to Chapter IV, including maternal wards, subject to Article 23 ...¹⁾ or the provisions of special legislation.]²⁾ Hospitalisation shall be covered for as long as necessary, together with medical assistance and pharmaceuticals and other services provided by the hospital.

Furthermore, health insurance covers general and specialised services provided in outpatient wards, daytime wards, casualty wards and emergency wards of hospitals, even in the absence of need for hospitalisation.

The Minister may issue a regulation³⁾ on the further implementation of this Article.

¹⁾ Act No. 45/2012, Article 1. ²⁾ Act No. 173/2008, Article 16. ³⁾ Regulation No. 722/2009. Regulation No. 1551/2022.

Article 19

Service provided by medical specialists.

Health insurance covers necessary laboratory testing and treatment by medical specialists under contract pursuant to Chapter IV.

The Minister may issue a regulation¹⁾ on the further implementation of this Article, which may include provisions where cost participation by health insurance is subject to the condition of a reference by a primary care practitioner or a general practitioner.

¹⁾ Regulation No. 722/2009. Regulation No. 1239/2018, cf. 508/2019, 1138/2019, 1242/2020, 1458/2021, 2/2023 and 731/2023. Regulation No. 1551/2022. Regulation No. 898/2023.

Article 20

Service provided by dentists.

Health insurance covers necessary dental treatment for the elderly, disabled persons and children under the age of 18, other than orthodontic treatment, under contract pursuant to Chapter IV. Furthermore, health insurance covers necessary dental and orthodontic treatment under contract pursuant to Chapter IV made necessary by the serious consequences of congenital defects, accidents and disease.

¹⁾ Regulation No. 722/2009. Regulation No. 1551/2022.

The Minister shall issue a regulation¹⁾ on the further implementation of this Article, which may include provisions on further conditions and limits on cost participation by health insurance as regards dental and orthodontic treatment. The regulation may furthermore provide that health insurance should cover partial costs of orthodontic treatment which does not fall within the scope of the second sentence of the first paragraph.

¹⁾ Regulation No. 451/2013, cf. 331/2014, 281/2015, 706/2015, 1243/2016, 1254/2018, 1149/2019, 1413/2020, 829/2021, 1011/2021, 1627/2021, 1481/2022 and 899/2023.

Article 21

Services provided by physiotherapists, occupational therapists and speech therapists.

Health insurance covers necessary physiotherapy, occupational therapy and speech therapy under contract pursuant to Chapter IV. The Health Insurance Administration may require a medical certificate confirming the need for therapy.

The Minister shall issue a regulation¹⁾ on the further implementation of this Article, which may include provisions on further conditions and limits on cost participation by health insurance as regards therapy.

1) Regulation No. 1364/2019, cf. 281/2020, 834/2020, 1052/2020, 1453/2020, 471/2021, 767/2021, 984/2021, 1218/2021, 106/2022, 496/2022, 780/2022, 1176/2022, 48/2023 and 452/2023. Regulation No. 1551/2022.

[Article 21 a

Psychological therapy and other evidence-based talk therapy.

Health insurance covers the necessary psychological therapy and other evidence-based talk therapy by healthcare professionals under contract pursuant to Chapter IV. The Health Insurance Administration may require a medical certificate from a general practitioner, a primary care physician or a medical specialist about the necessity for treatment.

The Minister shall issue a regulation on further implementation of this Article, which may include provisions on further conditions and limits on cost participation by health insurance as regards psychological therapy.]¹⁾

1) Act No. 93/2020, Article 1.

Article 22

Other specialised health services.

Health insurance covers other specialised health services than provided for in Articles 17–21 [and Article 21 a]¹⁾ under contract pursuant to Chapter IV in accordance with the Health Minister's policy, e.g. as regards midwife assistance in childbirth in the home and specialised treatment of serious skin disorders.

The Minister shall issue a regulation²⁾ on the further implementation of this Article, which may include provisions on further conditions and limits on cost participation by health insurance as regards specialised health services pursuant to the first paragraph.

¹⁾ Act No. 93/2020, Article 2. ²⁾ Regulation No. 1185/2014, cf. 453/2015. Regulation No. 1238/2018, cf. 615/2019 and 1247/2019. Regulation No. 1551/2022.

Article 23

[Medical treatment abroad that cannot be provided in Iceland.]¹⁾

If a health insured person urgently requires internationally recognised medical treatment abroad, ...¹⁾ when it is not possible to provide the necessary assistance in Iceland, health insurance will pay the cost of the treatment. The same applies to the cost of the stay, pharmaceuticals and medical assistance needed abroad in connection with the treatment. Also, health insurance will pay a travel grant to the health insured person and an escort in special circumstances.

Instead of the recourse provided for in the first paragraph, and under the same conditions as in that paragraph, the Health Insurance Administration may decide that medical specialists working abroad should provide treatment to the patient in a hospital in Iceland.

The Health Insurance Administration will determine whether the conditions provided for in this Article are present and where the health insured person should undergo treatment abroad. If a health insured person opts for treatment in another and more expensive location abroad than decided by the Administration, health insurance will pay only the cost that would have been paid in the location decided by the Administration. Authorisation for payment shall be obtained from the Health Insurance Administration beforehand.

The Minister shall issue a regulation²⁾ on the further implementation of this Article and other medical treatment abroad which does not fall within the scope of Article 33, e.g. when international agreements to which Iceland is a party apply.

¹⁾ Act No. 13/2016, Article 2. 2) Regulation No. 712/2010, cf. 918/2011.

[Article 23 a

Medical treatment abroad that can be provided in Iceland.

If a health-insured person chooses to avail himself or herself of health services in another Member State of the EEA Agreement, the Health Insurance Administration will reimburse the cost of the treatment as if it were a health service within Iceland providing that the service provided corresponds to services the cost of which the administration participates in paying in Iceland.

Reimbursement of costs as provided for in the first paragraph may be refused if:

- 1. The health service can be provided in Iceland within a time period that can be justified on medical grounds, taking account of the patient's state of health and the likely progress of the disease.
- 2. The safety of the patient or the public is jeopardised by a health service provided under the first paragraph.
- 3. There is reason to doubt that the provider of the health service complies with the quality and safety requirement.

The provisions of the first paragraph shall not apply to services provided in connection with the activities of daily life, the disposal of organs and access to organs for purposes of organ transplants and vaccinations against infectious diseases.

The Minister shall issue regulations¹⁾ setting further provisions on the application of this Article, including when it is necessary to apply for approval in advance for reimbursement under the first paragraph.]²⁾

1) Regulation No. 484/2016. 2) Act No. 13/2016, Article 3.

Article 24

[Service in nursing home, residential home and day-care centres.

Health insurance covers service provided in nursing home, residential home and day-care centres under contract pursuant to Chapter IV. This is subject to the condition that the need of the health insured person for service must have been conducted pursuant to the Act on the Affairs of the Elderly.]¹⁾ *Act No. 126/2018, Article 7.*

Article 25

Pharmaceuticals.

[Health insurance covers necessary pharmaceuticals which have marketing authorisation in Iceland, have been prescribed for use outside healthcare facilities, including ...¹⁾ medicinal products subject to licence, *cf.* the Medicinal Products Act.¹²⁾

The Minister may issue a regulation³⁾ on the further implementation of this Article, which may, *inter alia*, provide for partial health insurance payments in exceptional cases for the purchase of pharmaceuticals which do not have a marketing authorisation in Iceland, *cf.* the Medicinal Products Act.

1) Act No. 100/2020, Article 112. 2) Act No. 125/2014, Article 17. 3) Regulation No. 1143/2019, *cf.* 1454/2020, 314/2022 and 318/2023.

Assistive technology.

Health insurance will participate in the cost of obtaining necessary assistive technology that need to be used for over three months, with limitations and pursuant to the further provisions of a regulation¹⁾ issued by the Minister. The regulation shall provide, *inter alia*, for the kinds of medical aids that health insurance will participate in paying for and to what extent.

Assistive technology refers to device intended to reduce a disability, to assist [disabled people]²⁾ in coping with their environment, increasing or maintaining their capabilities and self-sufficiency, or to facilitate caregiving. The medical aid must also constitute a necessary and suitable device to facilitate the functions of daily life.

Authorisation for payment shall be obtained from the Health Insurance Administration beforehand. The Health Insurance Administration may require a certificate from a specialist confirming the need for the medical aid

¹⁾ Regulation No. 969/2015, cf. 871/2017 and 615/2022. Regulation No. 760/2021, cf. 1178/2021, 1628/2021, 238/2022 and 1553/2022. ²⁾ Act No. 115/2015, Article 14.

Article 27

Nutrients and special dietary foods.

Health insurance will participate in the cost of purchasing vital nutrients and special dietary foods with limitations and pursuant to the further provisions of a regulation¹⁾ issued by the Minister. The regulation shall provide, *inter alia*, for the kinds of nutrients and dietary foods that health insurance will participate in paying for and to what extent.

Authorisation for payment shall be obtained from the Health Insurance Administration beforehand. The Health Insurance Administration may require a certificate from a specialist confirming the need for a nutrient or dietary food.

¹⁾ Regulation No. 55/2009, cf. 1039/2010, 1063/2012, 1154/2013, 371/2019, 1411/2020, 660/2021 and 1047/2022.

Article 28

Medical transport.

Health insurance covers the cost of unavoidable medical transport of a health insured person to a hospital in Iceland under contracts pursuant to Chapter IV, provided that the need for transport is so urgent, and the condition of the health insured person is such, that normal passenger transport is precluded. The same applies to the transport of a health insured person from a hospital to the person's home or place of residence, provided that normal passenger transport is precluded.

If an escort is necessary, health insurance will participate in the cost of the fare of the escort, even in the case of a regular scheduled route. If there is need for escort by a health professional, the fare of the escort and remuneration shall be paid. The Minister will issue a regulation concerning health insurance participation under this paragraph.

The cost of transport between hospitals shall be paid in full by the hospital sending the patient, except in the case of transport between hospitals in the same municipality and if the health condition of the patient will permit the use of normal passenger transport. The same shall apply to transport between hospitals and nursing homes.

The Minister may establish further provisions on the implementation of this Article in a regulation.

Article 29

Fees.

A fee may be charged based on regulations¹⁾ issued by the Minister for the following health services and assistance that health insured persons are entitled to pursuant to law or contracts:

1. Primary healthcare provided by health care centres and visits by primary care practitioners, as provided for in the first paragraph of Article 17. The fee covers, *inter alia*, the cost of admission and facilities and the cost of medical service, and services provided by other health care

practitioners. Also, a fee may be charged for vaccination, tests, cancer screening and parent counselling. However, no fee may be charged for maternal and infant health care, primary healthcare in schools and nursing in the home. The service fees shall be reduced for the elderly, disabled persons and children, and fees for services outside normal working hours may be higher than for services during normal working hours. [It may be decided that the service fee is to be higher if the health-insured person receives the service at a health clinic, or from a general practitioner, other than those with which he or she is registered.]²⁾

- 2. ...³⁾ [General]³⁾ and specialised health services in outpatient wards, daytime wards, casualty wards and emergency wards of hospitals which are provided without hospitalisation, *cf.* the second paragraph of Article 18. The fee covers, *inter alia* the cost of admission and facilities and the cost of medical service and services provided by other health care practitioners. However, no fee may be charged for admission to a maternity ward and for infant health care. The service fees shall be reduced for the elderly, disabled persons and children. The fee for services by specialised physicians may be a proportional fee, and its maximum amount may be prescribed by regulations. [It may be decided that the fee for services by specialised physicians is to be lower if the health-insured person receives the service under a referral from his or her primary health clinic or general practitioner.]²⁾
- 3. Services of self-employed health service professionals and their undertakings, as provided for the second paragraph of Article 17 and Articles 19–22, which have been contracted pursuant to the provisions of Chapter IV. However, no fee may be charged for nursing in the home, maternal and infant health care and midwife assistance on childbirth in the home. The fee for services may be a proportional fee, and its maximum amount may be prescribed by regulations. The fees shall be reduced for the elderly, disabled persons and children, and fees for services pursuant to the second paragraph of Article 17 outside normal working hours may be higher than for services during normal working hours. [It may be decided that the fee for services is to be lower if the health-insured person receives the service under a referral from his or her primary health clinic or general practitioner. It may also be decided that the fee for services to children is to be lower, or to be waived, if the service is received under a referral from the patient's primary health clinic or general practitioner.]²⁾
- 4. Tests, diagnostic radiology conducted at hospitals or on the premises of self-employed health service professionals or their undertakings, which have been contracted pursuant to the provisions of Chapter IV, as provided for in the second paragraph of Article 18 and Article 19. The fee may be a proportional fee, and its maximum amount may be prescribed by regulations. The fees for the services shall be reduced for the elderly, disabled persons and children.
- 5. Issue of medical certificates in a health care centre and in hospitals.
- 6. [Pharmaceuticals, cf. Article 25. Fees for pharmaceuticals (medicinal products) shall be proportions of the cost and shall be divided into steps according to the accumulated pharmaceutical costs incurred by the person insured over a specific period; the proportion, period and steps shall be stated in regulations. The monetary amounts in the steps shall be reviewed each year with the aim that the overall portion of the cost to be paid by persons insured shall remain for the most part unchanged from one year to the next. The proportion may, however, be raised when new classes of pharmaceuticals are added into the system in the interests of the persons insured. The period shall be 12 months from the first dispensing of pharmaceutical products. When the payments borne by the insured person reach a certain sum, which shall be determined in regulations, it shall be possible, subject to conditions laid down in regulations, to issue a pharmaceutical certificate which shall grant the insured person full cost participation by health insurance for the remainder of the 12-month period. If the accumulated pharmaceutical costs incurred by the insured person do not amount to a specific minimum during the period, he/she shall bear them in full. Fees for pharmaceuticals shall be lower for elderly persons, disabled persons, children and young people aged 18-21 years, and shall not be higher than 2/3 of the amount of the cost steps applying to other insured persons. [Full cost participation may be granted

for prescription medicinal products in accordance with decisions by the Icelandic Medicines Agency.]⁴⁾ Full cost participation by health insurance in the case of medicinal products that are subject to licences may be made subject to the further conditions, e.g. as regards the special circumstances of the person insured, or a particular medical specialist field. Amongst other things, it shall be permitted, in regulations, to state the maximum number of units in prescriptions and the cost participation price, i.e. the price on which the health insurance is to base its cost participation, *cf.* the Medicinal Products Act. In addition it shall be permitted to limit payment participation by health insurance in particular categories of products to the most economical packaging, as defined in further detail in regulations. It shall be permitted, in regulations, to limit the issue of pharmaceutical certificates to a specific number of pharmaceuticals.]³⁾

- 7. Medical transport, as provided for in Article 28.
- [8. Stay at a patient hotel. Health insured persons shall pay fee for a stay at a patient hotel corresponding to the maximum 20% of the cost of board and lodging, and the fee shall be in accordance with regulations⁵⁾ issued by the Minister.]⁶⁾

[Payments made by health-insured persons for healthcare services under Articles 17-19 and 21-22 shall form a discount base. The discount base shall be used when determining payments to be made by health-insured persons when purchasing healthcare services. The discount base may never be greater than the maximum amount to be paid by health-insured persons in one calendar month, *cf.* the third paragraph. The discount base shall be transferred between months, less 1/6 of maximum payments at the end of each month, irrespective of the amount paid by the health-insured person.

The Minister shall decide, in regulations, the maximum amount to be paid by health-insured persons for healthcare services in each calendar month under Articles 17-19 and 21-22. It may be decided that the costs of a specific service are to fall outside the maximum paid by health-insured persons and are not to be included in the discount base, e.g. the costs of courses or workshops and health examinations in connection with the granting of licences. Maximum sums to be paid shall be lower in the case of elderly persons, disabled persons and children, and shall not exceed 2/3 of payments by other health-insured persons.

When the share of the costs of healthcare services to be borne by health-insured persons, cf. Articles 17-19 and 21-22, is determined, the discount base and the payments made by the health-insured person when purchasing healthcare services shall be added together. If the combined payments come to less than the maximum payment, cf. the third paragraph, the health-insured person shall pay costs up to the maximum payment according to the regulation, cf. the first paragraph. Costs in excess of the maximum payment to be made by the health-insured person shall be paid by the Health Insurance Administration in the case of services the cost of which the administration participates in paying; otherwise, they shall be paid by the healthcare institution involved.]²⁾

Persons who are not covered by health insurance in Iceland pursuant to this Act shall pay a fee corresponding to the cost of the health services provided in accordance with regulations⁷⁾ issued by the Minister, unless an agreement is in effect concerning the service with their state of origin.

[Persons who are not covered by health insurance in Iceland pursuant to this Act shall pay a fee for a stay at a patient hotel corresponding to all the cost due to stay at the patient hotel in accordance with regulations⁵⁾ issued by the Minister, unless an agreement is in effect concerning the service with their state of origin.]⁶⁾

Health establishments which have been authorised by the Minister to provide health services to persons not covered by health insurance on a private basis pursuant to the Health Service Act are permitted to charge a higher fee for their service than the cost of its provision. This shall apply except as otherwise provided in agreements in effect concerning the services with the state of origin of the uninsured person.

In other respects fees for health services shall be subject to the provisions of special laws, as applicable. [On fees from a resident for service in residential or nursing home, as well as in day-care, is subject to the Act on the Affairs of the Elderly.]⁸⁾

¹⁾ Regulation No. 451/2013, cf. 331/2014, 281/2015, 706/2015, 1243/2016, 1254/2018, 1149/2019, 1413/2020, 8/2021, 1011/2021, 1627/2021, 1481/2022 and 899/2023. Regulation No. 1145/2015. Regulation No. 313/2017.

Regulation No. 1143/2019, cf. 1454/2020, 314/2022 and 318/2023. Regulation No. 800/2020, cf. 893/2020. Regulation No. 1551/2022. ²⁾ Act No. 77/2016, Article 1. On commencement of that Act, the discount base shall be based on payments made by the health-insured person for services under items 1-4 of the first paragraph during the last five months preceding commencement, cf. the interim provisions in that Act. ³⁾ Act No. 45/2012. ⁴⁾ Act No. 100/2020, Article 112. ⁵⁾ Regulation No. 429/2019, cf. 1136/2019, 1244/2020, 1543/2021, 664/2022, 951/2022 and 1389/2022. ⁶⁾ Act No. 131/2009, Article 1. ⁷⁾ Regulation No. 817/2012, cf. 581/2020, 640/2020, 299/2021 and 718/2021. Regulation No. 1552/2022. ⁸⁾ Act No. 130/2015, Article 11.

[Article 29 a

Central pharmaceutical cost payment database.

The Icelandic Health Insurance shall be responsible for, and shall operate, a database containing the data necessary to calculate the cost participation by health insurance and fees paid by insured persons when purchasing pharmaceuticals, *cf.* item 6 of the first paragraph of Article 29. Information on the cost of pharmaceuticals borne by the person insured, and no other information about his use of pharmaceuticals, shall be registered in the database.

In addition, the information necessary to operate a special payment system for the purchase of pharmaceuticals and information which pharmacies use for calculating participation in the payment of the cost of pharmaceuticals under this Act shall be registered in the database.

Pharmacies shall be obliged to connect to the database, use information from the database when calculating participation in the payment of costs and submit information to it. [Healthcare facilities may connect to the database, utilise the information of the database and provide information in it, provided that the conditions of the Act on Data Protections and the Processing of Personal Data are met. The purpose of the processing shall be to ensure quality and safety of health service, with the aim of working towards secure and rational handling of medicinal products and to fulfil legal obligations according to Medicinal Products Act and Health Service Act.]¹⁾

The Minister shall issue regulations on the operation of the database. This shall include, *inter alia*, provisions on:

- 1. what information is to be registered in the database,
- 2. the deletion of registered information,
- 3. access by pharmacies, physicians and other parties to information in the database,
- 4. the obligation of pharmacies to connect to the database and to make use of information from the database when calculating participation in the payment of costs and
- 5. the obligation of pharmacies to submit information to the database. [2]

[Article 29 b

Central health service database.

The Health Insurance Administration shall be responsible for, and shall operate, a database containing the information on payments by health-insured persons that is necessary to calculate their payments and the share of payments borne by the administration in the purchase of healthcare services. Information on each health-insured person's payments for healthcare services, the type of service and the person's standing in the system shall be recorded.

Healthcare institutions and healthcare workers who collect fees for healthcare services subject to maximum payments by health-insures persons, *cf.* the third paragraph of Article 29, shall be obliged to connect with the database, use information from the database when calculating the payment of shares of the cost and to supply information to the database.

The Minister shall issue regulations on the operation of the database. Amongst other things, these shall specify:

- 1. what information is to be recorded in the database,
- 2. the deletion of recorded information,
- 3. access by healthcare institutions and healthcare workers to information in the database,

¹⁾ Act No. 99/2020, Article 14. ²⁾ Act No. 45/2012, Article 3.

- 4. the obligation of healthcare institutions and healthcare workers to connect with the database and to use information from the database when calculating shares of the cost, and
- 5. the obligation of healthcare institutions and healthcare workers to supply information to the database.]

1) Act No. 77/2016, Article 2.

C. Payments in cash.

Article 30

Travel costs.

Health insurance shall participate in unavoidable travel costs, with restrictions and in accordance with the provisions of regulations¹⁾ issued by the Minister for health insured persons who need repeated treatment by a physician or in a hospital, with or without hospitalisation.

The Minister may, in regulations¹⁾, decide on further cost participation of health insurance in travel costs than prescribed in the first paragraph.

¹⁾ Regulation No. 1140/2019, cf. 296/2020, 46/2021, 1345/2021, 464/2022 and 63/2023.

Article 31

Subsistence expenses.

Health insurance will participate in the unavoidable subsistence expenses of one parent on the hospitalisation of a child under the age of 18 in a hospital which is distant from the home, with restrictions and in accordance with the provisions of regulations¹⁾ issued by the Minister. In the case of difficult treatment of a life-threatening illness it may be decided that the cost participation should extend to both parents of a child under the age of 18.

¹⁾ Regulation No. 1105/2022.

Article 32

Per diem sickness benefits.

Health insurance shall pay per diem sickness benefits if a health insured person who has reached the age of 18 and is not receiving an old-age or invalidity pension or disability grant becomes totally incapable of work, provided that all work is ceased and wage payments, if any, cease. Per diem sickness benefits shall not be paid for the same period as occupational injury benefits from Social Security, nor over the same period as payments under the Act on maternity/paternity leave and parental leave.

Health insured persons shall be entitled to per diem sickness benefits as of the 15th day of sickness if they are incapable of work for a minimum of 21 days. The start of the waiting period shall be based on the day that incapacity for work is confirmed by a physician. Per diem sickness benefits shall not be paid for more than a total of 52 weeks in any 24-month period.

Full per diem benefits shall amount to ISK 1,040 for an individual and ISK 285 for each dependent child under the age of 18, including children outside the home in respect of which the applicant verifiably pays child support according to a confirmed agreement, court settlement, administrative ruling or court judgment.

Persons who have to give up full-time gainful employment shall receive full per diem benefits. Those who give up gainful employment amounting to less than full-time but at least half-time employment shall receive half per diem benefits. If gainful employment amounting to less than half-time employment is given up, per diem benefits shall amount to three quarters of the wages lost, up to a limit of half per diem benefits. Gainful employment under this Article means all employment for the purpose of earning an income by employers as well as employees.

Per diem benefits on account of housework in one's own home which, because of illness, has to be entirely given up shall amount to one half of full per diem benefits. Furthermore, up to one half additional per diem benefits may be paid for expenses from household assistance. An applicant taking per diem benefits as a result of giving up gainful employment shall not receive half per diem benefits for household work that has been given up, but may be entitled to a supplement for expenses from household assistance.

Students may be entitled to per diem benefits owing to absence from studies to the extent that the absence causes a delay in passing a level of studies.

If an applicant is taking an old age pension, disability pension or disability grant from Social Security which is lower in amount than the per diem sickness benefits the applicant would otherwise have been entitled to, per diem benefits shall be paid in an amount corresponding to the difference.

In the determination of per diem benefits, account should normally be taken of the situation of the applicant's employment in the last two months preceding the incapacity for work.

Per diem benefits shall not be paid to a person on strike unless such person was entitled to the benefits before the strike commenced.

Per diem benefits are not paid to persons in prison.

Health insurance shall pay full per diem sickness benefits, together with a supplement for children, where applicable, to a mother who has given birth in the home for 10 days from the childbirth.

The Minister shall issue regulations on the further implementation of this Article, which may provide for extension of the maximum payment period, exemptions from the age requirement in the first paragraph for 16 and 17-year-old children, restrictions on payments of per diem benefits amounting to less than full per diem benefits, per diem benefits for housework in one's own home and per diem benefits to students.

Benefits pursuant to this Act shall be adjusted annually in accordance with the State Budget at any time. The Minister shall issue regulations¹⁾ on increases in benefits.

¹⁾ Regulation No. 1025/2008, cf. 1141/2015, 1242/2016, 1173/2017, 1163/2018, 1129/2019, 1243/2020, 1546/2021, 1482/2022 and 64/2023. Regulation No. 1606/2023 (on the amount of benefits of occupational injury benefits from Social Security for the year 2024).

Article 33

Medical costs resulting from sickness and accidents abroad.

If a health insured person located abroad requires local medical assistance health insurance shall pay the cost in the same manner as in the case of medical assistance in Iceland. However, in the case of persons who, under an international agreement, acquire the right to medical assistance as a result of their stay, this shall not apply as regards to the assistance covered by the agreement.

If a health insured person located abroad in a member state of the EEA Agreement requires local medical assistance, health insurance shall pay the cost of the assistance pursuant to the rules of the EEA Agreement relating to social security.

Health insurance shall also pay the cost that results if a health insured person needs to seek medical treatment when located in a member state of the Convention establishing the European Free Trade Association.

The Minister shall issue regulations on the implementation of this Article, e.g. as regards the extent to which health insurance is permitted to reimburse a health insured person for cost resulting from sickness or accident abroad which such person would not otherwise obtain reimbursement for from health insurance.

D. Applications for benefits, procedure etc.

Article 34

Applications for benefits.

All benefits under this Act shall be applied for to the Health Insurance Administration. However, the Administration may decide that no application is needed for certain benefits. Applications for benefits should be made in a form decided by the Health Insurance Administration.

Applicants are required to provide the Health Insurance Administration with all the information necessary to arrive at a decision concerning entitlement to benefits, the amount and payment of benefits and their revision.

The Health Insurance Administration is authorised ...¹⁾ to collect any information it needs concerning the income of the applicant from tax authorities, concerning payments to the applicant from the Social Insurance Administration, the Unemployment Insurance Fund, the Directorate of Labour and comparable

agencies abroad, where applicable, electronically or by other means. Furthermore, information may be collected concerning disability assessment from the Social Insurance Administration. If an applicant believes that information from these parties is incorrect the applicant shall submit documentation in confirmation thereof.

An applicant is required to notify the Health Insurance Administration of any changes in income or other circumstances which may affect payments. If incorrect information is submitted the provisions of Article 37 shall apply.

In the event that it proves impossible to decide on benefit entitlements, amounts and payment of benefits and their revision owing to a lack of necessary information which may be attributed to the applicant, the Social Insurance Administration may defer its decision and payment of benefits until the situation has been rectified. The Administration shall immediately notify the individual in question in the event of deferment and call for submission of the necessary information.

[The Health Insurance Administration is required to inform the applicant about the intended collection of information according to the third paragraph, in accordance with the second paragraph of Article 17 of the Act on Data Protections and the Processing of Personal Data, No. 90/2018 *cf.* Article 14 of Regulation (EU) 2016/679 of the European Parliament and the Council.]¹⁾

1) Act No. 52/2019, Article 1.

Article 35

Decisions on benefits.

All applications shall be processed as promptly as possible, and benefits shall be calculated from the date that an applicant has fulfilled the conditions for the benefits.

Benefits shall not be awarded retroactively for a longer period than two years from the time that an application and/or other documents necessary for the determination of rights to benefits and their amount are received by the Administration. Notwithstanding the above, per diem sickness benefits shall normally not be awarded retroactively for a longer period than two months; however, the Health Insurance Administration may extend this period for up to six months in cases where the right to benefits is in other respects clear.

Wage-earners covered by international agreements who give up gainful employment and go abroad may retain their rights to per diem sickness benefits, subject to fulfilment of other conditions, for up to two months after discontinuation of employment in Iceland. This is subject to the condition that they have not taken up employment in another state with which Iceland has concluded an agreement.

Awarded benefits shall be cancelled if they are not claimed within twelve months; however, benefits may be awarded again if a new reasoned application is received.

The basis for entitlement to benefits may be reviewed at any time and benefits may be adjusted to any changes that have occurred.

Article 36

Administrative appeals.

In the event of any dispute regarding the basis, conditions or amount of benefits under this Chapter, decisions of the Health Insurance Administration may be appealed to [the Welfare Appeals Committee]¹⁾ pursuant to the Social Security Act.

An appeal to [the Welfare Appeals Committee]¹⁾ shall be in writing and submitted within three months from the date that the party in question was notified of a decision. The offices of the Health Insurance Administration shall make available forms for this purpose, and the staff of the Administration shall provide the necessary assistance in filling them in.

The Health Insurance Administration shall supply the Committee with all documents of the case, including any information and clarifications that the Committee considers necessary.

The Health Insurance Administration may initiate legal proceedings to obtain an overturning of a ruling of [the Welfare Appeals Committee.]¹⁾

¹⁾ Act No. 85/2015, Article 13.

Overpayment and underpayment of benefits.

If the Health Insurance Administration has overpaid benefits pursuant to this Act, the Administration shall deduct overpaid benefits from any benefits to which the recipient may subsequently become entitled to. Also, the Administration has the right to recover funds from the recipient in accordance with general rules. If overpayment is a result of fraudulent action by the recipient, the recipient shall pay default interest on the amount, to be calculated from the time that the right to recovery was established.

If the Health Insurance Administration has underpaid benefits, the Administration shall pay to the recipient the amount underpaid.

The Minister may issue regulations on the further implementation of this Article, *inter alia* as regards collection of overpaid benefits, exemptions from collection of overpaid benefits and writing off claims.

Article 38

Contracts on health services not available.

If no contract is available on a health service, *cf.* Chapter IV, the Health Insurance Administration is authorised in special cases to reimburse for a limited period the outlays of a health insured person resulting from health service temporarily on the basis of a tariff issued by the Administration. [If no contract is available on service in [nursing home, residential home and day-care centres]¹⁾, *cf.* Chapter IV, it is also authorised in special cases to pay agencies for a limited period costs on the basis of a tariff issued by the Health Insurance Administration.]²⁾

The Minister shall issue regulations³⁾ on the further implementation of this Article, *inter alia* as regards the duration of the authorisation and the conditions for reimbursement.

¹⁾ Act No. 126/2018, Article 8. ²⁾ Act No. 130/2015, Article 12. ³⁾ Regulation No. 1023/2011, cf. 178/2012, 776/2012 and 1229/2013. Regulation No. 451/2013, cf. 331/2014, 281/2015, 706/2015, 1243/2016, 1254/2018, 1149/2019, 1413/2020, 829/2021, 1011/2021, 1627/2021, 1481/2022 and 899/2023. Regulation No. 1184/2014, cf. 475/2015. Regulation No. 1245/2016, cf. 1174/2017, 1134/2018, 1139/2019, 1247/2020, 1542/2021, 1414/2022 and 1512/2022. Regulation No. 1238/2018, cf. 615/2019 and 1247/2019. Regulation No. 1239/2018, cf. 508/2019, 1138/2019, 1242/2020. 1458/2021, 2/2023 and 731/2023. Regulation No. 1364/2019, cf. 281/2020, 834/2020, 1052/2020, 1453/2020, 471/2021, 767/2021, 984/2021, 1218/2021, 106/2022, 496/2022, 780/2022, 1176/2022, 48/2023 and 452/2023. Regulation No. 1040/2021, cf. 1117/2021, 1510/2021 and 255/2022. Regulation No. 898/2023.

CHAPTER IV

Contracts on health services.

Article 39

Authority to conclude contracts.

The Health Insurance Administration is responsible for negotiating contracts on the provision of health services and assistance under this Act, the Health Service Act and other laws, and on the consideration to be paid by the State. [The Administration is also responsible for negotiating contracts on granting service in [nursing home, residential home and day-care centres]¹⁾ and on the consideration to be paid by the State due to the service.]²⁾

The Health Insurance Administration shall conclude contracts with health establishments, as provided for in the Health Service Act, as well as municipalities, foundations, undertakings and individuals, on the provision of health services, and shall pay a consideration in accordance with the provisions of the respective contracts.

[The Minister is authorised to set further provisions in regulation³⁾ on contract negotiations according to the second paragraph. This shall include provisions on type and extent of the health services that the Administration contracts on, *inter alia* of the health services in health establishments owned by the State.]⁴⁾

¹⁾ Act No. 126/2018, Article 8. ²⁾ Act No. 130/2015, Article 13. ³⁾ Regulation No. 190/2022, cf. 801/2022 and 664/2023. ⁴⁾ Act No. 131/2012, Article 1.

Contracts on health services.

Contracts on health services shall be concluded in accordance with the policy formulated under Article 2, *inter alia* on the organisation of health services, prioritisation of tasks within the service, and the efficiency, quality and accessibility of the service. Contract negotiations shall be guided by the interests of health insured persons. Contracts may only be concluded following confirmation by the Medical Director of Health that the operation or prospective operation of a health service meets professional standards and other conditions of health legislation, *cf.* the Health Service Act and the Medical Director of Health Act.

Contracts shall, *inter alia*, provide for the quantity, type and quality of the service, where it is to be provided and by whom, in addition to the consideration to be paid to the provider and supervision of contract performance. Contracts shall state the requirements that service providers must meet, e.g. as regards competence, service area and level of service. When negotiating a contract, the availability of the health service for which the contract is made for all health insured persons shall be ensured, irrespective of financial position. Moreover, efforts shall be made to ensure the availability of services to all health insured persons, irrespective of where in Iceland they live, and that the service providers ensure equal treatment of health insured persons.

The selection of contractors shall be made on the basis of non-discriminatory and objective criteria. The selection shall take into account the policy formulated under Article 2, the provisions of the Health Service Act, competence, quality, efficiency, cost, safety, maintenance of necessary knowledge and equality. The Health Insurance Administration shall determine the weight of individual factors. When negotiating contracts on health services, care shall be taken to ensure that services to be provided under the Health Service Act are not disrupted.

Should the supply of a specific health service exceed needs, or exceed the amount for which contracts can be made in view of available funding, it is permitted, on the basis of non-discriminatory and objective considerations, e.g. with respect to the cost-effectiveness and quality of the service, to restrict contracts to only some of the parties capable of providing the service.

A party intending to start an independent health service undertaking on the assumption that the State will pay part or all of the patients' costs shall have concluded a contract with the Health Insurance Administration prior to commencing operations, unless the Minister has made a unilateral decision on cost participation based on authorisation in other legislation.

The Minister may establish further provisions in regulations¹⁾ on conditions for contracts on the consideration to be paid by the State for health services provided outside State-run health establishments, in accordance with the policy formulated under Article 2, and for such consideration to be restricted to evidence-based treatment in the field of health services.

1) Regulation No. 510/2010.

Article 41

Contracts on development or operation.

The Minister may instruct the Health Insurance Administration to contract with municipalities, or parties other than those responsible for operating health services under the Health Service Act, concerning the development and operation of certain aspects of the health services to be provided under that Act. The Health Insurance Administration shall also conclude work contracts and contracts on operational projects as provided in the Government Financial Reporting Act.

Article 42

Authority to issue calls for tenders.

The Health Insurance Administration may tender the operation of health services and the purchase of a health services in accordance with the Health Service Act and this Act.

Consideration for health services.

Consideration for health services pursuant to this Chapter may be in the form of fixed payments, payments for each service recipient, per diem payments, contractor payments, payments based on output and performance-related payments. It is also possible to combine two or more of the above payment methods.

The fee to be paid by a health insured person for the service is subject to the provisions of Article 29; service providers are prohibited from charging an additional fee.

Health establishments and other health service providers shall itemise the cost of their services using internationally recognised methods. The itemisation of costs shall take all economic costs into account, including housing, financing and depreciation costs.

The Minister shall issue regulations on nursing need assessment in connection with payment for health services provided in [nursing home, residential home and day-care centres]. 1) *Act No. 126/2018, Article 8.*

Article 44

Evidence-based knowledge in the field of health services.

Providers of health services shall generally base their operations on evidence-based knowledge in the field of health services, follow the professional instructions of the Medical Director of Health and utilise, as appropriate, the Director's clinical guidelines, *cf.* the Medical Director of Health Act.

When making decisions and concluding contracts on new methods, services, pharmaceuticals and products, the Health Insurance Administration shall take account of the results of professional and economic assessment in compliance with internationally recognised methods.

Article 45

Quality and monitoring.

[The Health Insurance Administration shall monitor the activities of contracting parties and their service providers who receive payments on the basis of a tariff issued by the Administration, *cf.* Article 38. The goal of the monitoring is to ensure that the type, quantity, quality, cost and effectiveness of the service are in compliance with contracts made or, as the case may be, that invoicing is in compliance with the service provided and Administration's tariff.]¹⁾ The Administration shall consult with the Medical Director of Health on the arrangement and implementation of the monitoring.

The Health Insurance Administration shall include in contracts provisions designed to improve the quality and effectiveness of the service, including provisions on quality management systems and their certification, accreditation, performance measurements, and disclosure and reporting, *cf.* the Medical Director of Health Act.

The Health Insurance Administration may require contracting parties to make use of harmonised information systems, including coordinated registration of waiting lists, and to supply the Administration with information on the provided services and activities in a standardised electronic form. In connection with its monitoring responsibilities the Administration is also permitted access to non-personally identifiable data from medical records kept by the Medical Director of Health under the Medical Director of Health Act, as appropriate.

Medical doctors or, as the case may be, the appropriate healthcare practitioners of the Health Insurance Administration, are authorised to seek information from service users as necessary for the fulfilment of the Administration's monitoring responsibilities.

¹⁾ Act No. 92/2020, Article 2.

Obligation of healthcare practitioners to provide information.

Healthcare practitioners who are responsible for the safeguarding of medical records [cf. the Medical Records Act], are required to provide medical doctors or, as the case may be, the appropriate healthcare practitioners of the Health Insurance Administration, with the information and data that the Administration needs to be able to perform its monitoring role, cf. also Article 45. Medical doctors or, as the case may be, the appropriate healthcare practitioners of the Health Insurance Administration, are furthermore authorised to inspect [or request for those]²⁾ parts of a medical record which are necessary for monitoring contract performance and invoices issued to the Administration. ...²⁾

¹⁾ Act No. 55/2009, Article 26. ²⁾ Act No. 92/2020, Article 3.

Article 47

Contracts for the purchase of goods and services.

The Health Insurance Administration is authorised under the Public Procurement Act to negotiate contracts with institutions, undertakings or individuals on the goods and general services it is required to provide that are not covered by contracts for health services.

The Health Insurance Administration is required to seek the best possible terms on the goods and services for which it pays in whole or in part under this Act, taking account of quality.

Article 48

Default and default remedies.

Contracts shall contain provisions on what constitutes a default and on default remedies. In addition, the general rules on default and default remedies apply. In the event of verified default, the measures taken by the Health Insurance Administration in response to such default shall be based on objective considerations and may involve:

- 1. Instructions on altered performance, e.g. with respect to services, registration or charging of fees.
- 2. Warnings.
- 3. Imposition of restrictions on the quantity and types of service for which a consideration is paid.
- 4. Termination of contracts with or without notice.
- 5. Claims for reimbursement or damages.
- 6. Notification of the Medical Director of Health or the Icelandic Medicines Control Agency in their capacity as monitoring bodies.
- 7. Reporting alleged violations of law to the police.

Article 49

Disputes.

Contracts shall contain provisions on the process for handling disputes. Disputes over contract performance and the selection of counterparties are not subject to ministerial review.

Disputes in connection with calls for tenders are subject to the Public Procurement Act.

Disputes over the professional competence of health service providers, service quality and evidence-based treatment in the field of health services shall be referred to the Medical Director of Health.

Complaints by members of the public and others regarding services and the competence of contracting parties shall be referred to the Medical Director of Health. The Medical Director of Health shall inform the Health Insurance Administration of such complaints in a mutually agreed form.

CHAPTER V

Miscellaneous provisions.

Article 50

Handling of personal data.

[The Health Insurance Administration is authorised to process personal information, including sensitive personal data concerning health, use of medicinal products and health service of individuals, in order to carry out its legal obligations, including monitoring according to this Act and in compliance with the Act on Data Protection and the Processing of Personal Data. During that processing, the provisions of the Patients' Rights Act shall also be observed, as appropriate. The sharing of such data occurs through a secure web portal of the Health Insurance Administration, which has access controls, traceability and encryption.]¹⁾

1) Act No. 92/2020, Article 4.

Article 51

Confidentiality.

[Employees of the Health Insurance Administration and its agencies are subject to confidentiality in accordance to Chapter X of the Administrative Procedures Act.]¹⁾ The same applies to non-employees who perform tasks for the Health Insurance Administration.

1) Act No. 71/2019, Article 5.

Article 52

Information on patient movements.

Hospitals, health care facilities and institutions for the elderly shall provide the Health Insurance Administration with information on patient movements, i.e. admissions and discharges. The information shall be submitted on a regular basis as often as necessary and no less frequently than once a month.

Article 53

International agreements on health insurance.

In cases where an international agreement to which Iceland is party provides for mutual rights to health insurance, the persons to be covered by Icelandic law under the provisions of the agreement shall acquire rights pursuant to this Act.

The Health Insurance Administration shall pay the cost of providing assistance to those who enjoy rights under the agreement and are staying in Iceland on a temporary basis.

The Minister shall issue regulations¹⁾ on the further implementation of this Article, *inter alia* regarding authorisation to deduct benefits under foreign legislation from benefits provided under this Act over the same period.

¹⁾ Regulation No. 860/2012. Regulation No. 617/2013. Regulation No. 1098/2013. Regulation No. 961/2015. Regulation No. 50/2017. Regulation No. 410/2019. Regulation No. 781/2019. Regulation No. 1552/2022.

Article 54

Cost of health insurance.

Cost of health insurance shall be paid out of the State Treasury to the extent provided for in this Act or special legislation or regulations issued on the basis thereof. The annual total cost of health insurance shall be consistent with the decision of the Althing as stated in the Budget Act and Supplementary Budget Act for each year.

Article 55 [Regulations.

The Minister may establish further provisions on the implementation of this Act in regulations.¹⁾ These may include provisions for more extensive participation by the Health Insurance Administration in the cost of health services than prescribed in Chapter III.¹²⁾

¹⁾ Regulation No. 1023/2011, cf. 178/2012, 776/2012 and 1229/2013. Regulation No. 1175/2011, cf. 63/2012. Regulation No. 860/2012. Regulation No. 451/2013, cf. 331/2014, 281/2015, 706/2015, 1243/2016, 1254/2018, 1149/2019, 1413/2020, 829/2021, 1011/2021, 1627/2021, 1481/2022 and 899/2023. Regulation No. 1098/2013. Regulation No. 1184/2014, cf. 475/2015. Regulation No. 1185/2014, cf. 453/2015. Regulation No. 969/2015, cf. 871/2017 and 615/2022. Regulation No. 1245/2016, cf. 1174/2017, 1134/2018, 1139/2019, 1247/2020, 1542/2021, 1414/2022 and 1512/2022. Regulation No. 50/2017. Regulation No. 313/2017. Regulation No. 1238/2018, cf. 615/2019 and 1247/2019. Regulation No. 1239/2018, cf. 508/2019, 1138/2019, 1242/2020, 1458/2021, 2/2023 and 731/2023. Regulation No. 410/2019. Regulation No. 781/2019. Regulation No. 1140/2019, cf. 296/2020, 46/2021, 1345/2021, 464/2022 and 63/2023. Regulation No. 1143/2019, cf. 1454/2020, 314/2022 and 318/2023. Regulation No. 1364/2019, cf. 281/2020, 834/2020, 1052/2020, 1453/2020, 471/2021, 767/2021, 984/2021, 1218/2021, 106/2022, 496/2022, 780/2022, 1176/2022, 48/2023 and 452/2023. Regulation No. 1040/2021, cf. 1117/2021, 1510/2021 and 255/2022. Regulation No. 190/2022, cf. 801/2022 and 664/2023. Regulation No. 1515/2022. Regulation No. 1552/2022. Regulation No. 898/2023. ²⁾ Act No. 13/2016, Article 4.

[Article 55 a Implementation of EEA acts.

The Minister may issue a regulation¹⁾ adopting the European Union's rules on social security systems as incorporated in Annex VI to the Agreement on the European Economic Area, *cf.* Act No. 2/1993, with subsequent amendments, and also the Decision of the EEA Joint Committee, No. 76/2011, of 1 July 2011, incorporating into the Agreement Regulations (EC) No 883/2004 on the coordination of social security systems, with subsequent amendments and No. 987/2009, on its implementation.

This Act constitutes the implementation in Icelandic law of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, as it was incorporated in Annex X of the EEA Agreement, *cf.* Act No. 2/1993, with subsequent amendments, and also the Decision of the EEA Joint Committee, No. 153/2014 of 9 July 2014.

EU Regulations that may be adopted into the EEA Agreement and that may entail amendments or additions to the regulations referred to in this Article may also be implemented by means of regulations. The same applies to the social security rules of the Convention Establishing the European Free Trade Association.1²⁾

¹⁾ Regulation No. 617/2013. Regulation No. 961/2015. ²⁾ Act No. 13/2016, Article 5.

CHAPTER VI Entry into force.

Article 56 *Entry into force*.

This Act shall enter into force on 1 October 2008.

Notwithstanding the provision of the first paragraph, the provisions of Chapter IV as regards contracts made by [the Ministry]¹⁾ shall enter in force no later than 1 July 2009. [Moreover, the provisions of Chapter IV shall take effect no later than 1 January 2015 as regards contracts with municipalities and other entities which operate nursing homes.]²⁾

Notwithstanding the provision of the first paragraph, item 12 of Article 59 is effective immediately. ¹⁾ Act No. 162/2010, Article 81. ²⁾ Act No. 131/2012, Article 2.

CHAPTER VII Amendments to other Acts.

Articles 57–73

...

Temporary provisions.

I.

Social Insurance Administration employees who have been employed in tasks falling within the scope of this Act, Chapter IV of the Social Security Act No. 100/2007 and/or Act No. 111/2000 on patient insurance, and who are employed by the Administration on the entry into force of this Act, shall be offered a new position at the Health Insurance Administration on the same employment terms as they previously enjoyed. The same applies to those employees of the Ministry of Health, primary health care centres and Landspítali University Hospital who have been responsible for contract negotiations and other tasks that will fall within the scope of the functions of the Health Insurance Administration pursuant to this Act. The provisions of Article 7 of the Government Employees Act No. 70/1996 shall not apply to positions which are filled under this provision.

II.

Notwithstanding the provision of the first paragraph of Article 56, the Director of the Health Insurance Administration, *cf.* the Interim Provisions of the Health Service Act No. 40/2007, is granted the authority to make preparations for the entry into force of this Act, including the authority to offer employees of the Social Insurance Administration, the Ministry of Health, primary health care centres and Landspítali University Hospital posts with the Health Insurance Administration as of 1 October 2008, *cf.* Interim Provision I.

III.

The Health Insurance Administration will take over the assets, rights and obligations of the Social Insurance Administration as regards the implementation of health insurance and occupational injury insurance pursuant to Social Security Act No. 100/2007, and patient insurance pursuant to Act No. 111/2000 on patient insurance.

IV.

[Until [1 January 2015],¹⁾ *cf.* the second sentence of the second paragraph of Article 56, the Minister may determine with regulations²⁾ the per diem rates for health services provided in the nursing facilities of hospitals, the nursing facilities of geriatric institutions and nursing homes.]³⁾ Per diem rates shall be decided on the basis of a nursing weight assessment, *cf.* the fourth paragraph of Article 43.

¹⁾ Act No. 131/2012, Article 3. ²⁾ Regulation No. 99/2014. ³⁾ Act No. 147/2010, Article 2.

[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.]