

HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

- 1. Please provide a bird's eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).**

The state holds most of the power and responsibilities within the Icelandic healthcare system. However, municipalities are responsible for providing certain social support services for older people and individuals with disabilities, as well as setting tariffs for those services. Additionally, they are responsible for providing day care and nursing home services for older people.

The government is responsible for the financing of the healthcare system and policy-making. Institutions under the Ministry of Health are responsible for ensuring the quality and safety of pharmaceuticals and medical devices; granting licenses to healthcare professionals; ensuring access to health services for all; and promoting the operational and macroeconomic viability of healthcare; among other responsibilities.

The Icelandic health insurance system automatically covers all individuals who have legally resided in Iceland for six months. The public authority Iceland Health administers health insurance and handles negotiations and payments for healthcare services, as well as additional tasks. Iceland Health covers part or all of the cost of those insured. Iceland Health is supervised by the Ministry of Health.

There are four private insurance companies in Iceland. These private insurers generally do not participate in the financing or reimbursement of healthcare services. Instead, they primarily provide benefits in the event of illnesses or accidents, depending on the insurance coverage bought each time. Private insurance is commonly purchased by individuals until the right to public health insurance becomes effective, which provides coverage similar to that of the public system. Private insurance companies in Iceland are supervised by the Central Bank of Iceland.

Patients are generally required to pay a portion of the cost of healthcare services and pharmaceuticals themselves. However, an individual's healthcare expenditure is capped at a monthly limit. Pharmaceuticals are excluded from this cap and the contributions of Iceland Health are determined by another system. Services, pharmaceuticals or medical devices that do not fall under the coverage of Iceland Health are fully self-paid. However, some private insurance companies provide coverage for certain medical devices, such as those needed after an accident. Additionally, foundations and patient organisations often offer counselling.

- 2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.**

Financing and reimbursement are mainly governed by the Act on Health Insurance. The Act aims to ensure assistance to health-insured persons for the protection of their health and equal access to health services irrespective of financial position.

The Act specifies which healthcare services and products must be covered by Iceland Health, as well as the conditions for coverage. The Regulation on copayment for pharmaceutical costs by Iceland Health specifies the contribution of Iceland Health for pharmaceuticals and conditions for coverage. The Regulation on grants for assistive devices defines which medical devices are covered by Iceland Health and the extent and conditions of coverage.

Furthermore, the Act outlines which services may be subject to fees. The Regulation on the participation of health-insured individuals in the cost of healthcare services, as well as relevant tariffs, determines the cost of healthcare services. However, the health insurance system in Iceland ensures that individuals do not pay more than a certain maximum amount each month for healthcare services.

All tariffs are determined by or with the involvement of the state, either the Ministry of Health or institutions acting on its behalf, such as Iceland Health or the Icelandic Medicines Agency (IMA).

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

Iceland Health administers health insurance, handles negotiations and payments for healthcare services, and monitors the quality and results of the work of individuals providing health services under contracts, as well as additional tasks.

The Ministry of Health is responsible for the supervision of Iceland Health. All tariffs are determined by or with the involvement of the state, either the Ministry of Health or institutions acting on its behalf, such as Iceland Health or the IMA. However, municipalities are responsible for determining tariffs for certain social support services for older people and individuals with disabilities.

The IMA is responsible for the supervision of medical devices and matters concerning pharmaceuticals. The Directorate of Health is responsible for granting licenses to healthcare professionals, supervising healthcare services in Iceland, as well as handling a variety of tasks aimed at health promotion and improving public health.

Private insurance companies in Iceland are supervised by the Central Bank of Iceland, which ensures that they operate in accordance with applicable laws and follow good business practices. The premiums charged by private insurance companies are determined by the companies themselves. The Central Bank of Iceland supervises the financial stability of private insurance companies but does not supervise the specific decisions regarding premiums. Furthermore, private insurance companies fall under the supervision of the Competition Authority.

Insured individuals and service providers may appeal administrative decisions to the Welfare Appeals Committee, which can overturn decisions. The Committee's rulings can be appealed to the district courts. Iceland Health may also appeal decisions made by the Welfare Appeals Committee.

4. Has there been a change to healthcare financing and reimbursement as a

consequence of the Covid-19 pandemic?

The pandemic has not changed the system of healthcare financing and reimbursement. However, during the pandemic the government increased its contribution to healthcare by around ISK 62.7bn in 2020–2022. Additionally, the government's contribution to Covid-19 testing in 2020–2022 was approximately ISK 11.4bn. The government's contribution for the purchase of coronavirus vaccines amounted to ISK 3.5bn.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

The Icelandic health insurance system covers, as a rule, all individuals who have legally resided in Iceland for six months (official registration of domicile). Icelandic health insurance ensures equal access to healthcare services, irrespective of financial position. Furthermore, patients have the right to the most advanced healthcare services available at any given time.

All healthcare providers must be authorised by the Directorate of Health before operating in the healthcare sector to ensure the safety of patients. Healthcare providers who want to provide services at the expense of Iceland Health must have an agreement in place with them. To manage costs, Iceland Health limits the number of healthcare providers within each specialty agreement. Services provided at hospitals and primary health clinics are funded by the government.

In order for pharmaceuticals and medical devices to be covered by Iceland Health, they must be included in specific lists. Pharmaceuticals must first be authorised by the IMA, which is responsible for granting marketing authorisation. When applying for marketing authorisation, the authorisation holder submits a request to the IMA for the price and copayment of Iceland Health. The IMA then determines the maximum wholesale and retail prices of pharmaceuticals and the copayments of Iceland Health. The Regulation on grants for assistive devices specifies which medical devices are covered by Iceland Health.

Iceland Health also covers certain treatments abroad. Emergency treatments abroad are covered at least up to the extent that the respective service would be covered in Iceland. Planned treatments abroad are not covered by Iceland Health, unless a health-insured individual urgently requires medical treatment which is not provided in Iceland.

Tourists from the European Economic Area (EEA), Switzerland and the United Kingdom can be treated in Iceland for emergencies if they are in possession of a European insurance card. Tourists from other countries must have travel insurance that covers health costs.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

Iceland Health administers health insurance in Iceland. Healthcare in Iceland is primarily funded by taxation revenue and allocations are made in the national budget for each year. Health insurance in Iceland covers the majority of healthcare costs. However, insured individuals may be required to pay minimal fees for certain services.

Private insurance companies generally do not participate in the financing or reimbursement of healthcare services. Instead, they primarily provide benefits in the event of illnesses or

<p>accidents. Private insurance is commonly purchased by individuals until the right to public health insurance becomes effective, which provides coverage similar to that of the public system. The primary source of income of private insurance companies are the premiums paid by the insured, along with the sale of shares in the company. Premiums are determined by private insurance companies and can differ based on the individual.</p>
<p>7. How is the coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?</p>
<p>The Ministry of Health is responsible for defining the scope of services and medical devices covered by Iceland Health. However, in some cases, Iceland Health is responsible for determining the scope of healthcare services and the level of coverage for them. In making these decisions, they may consider the allocated budget. Furthermore, attempts are to be made to ensure that services are available to insured individuals wherever they live in Iceland.</p> <p>The IMA is responsible for determining which pharmaceuticals are reimbursed by Iceland Health. Reimbursed pharmaceuticals and medical devices are listed in exhaustive positive lists. Pharmaceuticals or medical devices not included in these lists are not reimbursed by Iceland Health.</p> <p>Iceland Health may decide to contribute to the cost of pharmaceuticals that have been granted an exemption from the requirement of marketing authorisation if an insured person needs them for urgent medical reasons.</p> <p>The cost of in-person appointments and telemedicine appointments with general healthcare workers is roughly equivalent. However, the cost of in-person appointments with specialists is slightly higher compared to telemedicine appointments.</p>
<p>HOSPITAL SECTOR</p>
<p>8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?</p>
<p>Outpatient and inpatient treatments that are included in the insurance system are covered by Iceland Health, after the deduction of a contribution by the insured. An individual's healthcare expenditure is capped at a monthly limit and costs exceeding this limit are covered by Iceland Health. The limit is lower for older people, children and individuals with disabilities. For children under the age of two years, there is no fee. Once the maximum payment is reached, the limit for the following month is reduced. Fees for the insured are determined by hospital tariffs that are based on regulations issued by the Minister of Health. The tariffs determine service fees according to specialties.</p> <p>Iceland Health covers hospitalisation on the recommendation of a physician in hospitals run by the state or under contracts with Iceland Health, including maternity hospitals. Hospitalisation is covered for as long as necessary, along with the medical care, pharmaceuticals and other services provided by the hospital.</p>
<p>9. How are the prices of such services determined? How is economic efficiency controlled?</p>
<p>The objective of the Act on Health Insurance is to ensure assistance to health-insured</p>

persons for the protection of their health and equal access to health services, irrespective of their financial position. In order to comply with the provision of the Act, tariffs must be reviewed and adjusted regularly to ensure their fairness.

Hospital tariffs are based on regulations issued by the Minister of Health. The Regulation on the participation of health-insured individuals in the cost of healthcare services sets certain service fees, while other fees are determined by the hospitals based on assessments of necessary operating costs. Tariffs must be decided economically and appropriately.

However, it is to be noted that an individual's healthcare expenditure is capped at a monthly limit and costs exceeding this limit are covered by Iceland Health.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

Iceland Health provides copayments for services provided by private practitioners who have an agreement with Iceland Health. All agreements made by Iceland Health must receive confirmation from the Minister of Health. Healthcare providers are prohibited from charging higher or different fees for health-insured individuals than those stipulated in the relevant agreements.

Iceland Health has entered into several agreements with private practitioners. These agreements are either in the form of framework agreements or contracts between Iceland Health and relevant associations, which private practitioners are allowed to adhere to. Tariffs are outlined in the agreements and apply to the services specified within them. Iceland Health does not provide copayments for services that are excluded from the tariffs.

However, in cases where health service contracts are not established with certain healthcare providers, Iceland Health may, under special circumstances, temporarily reimburse insured individuals for expenses incurred. In such cases, reimbursement is based on the tariffs issued by Iceland Health.

11. How are the prices of such services determined? How is economic efficiency controlled?

The contributions of Iceland Health for services provided by private practitioners are based on tariffs included in the agreements. The tariffs included in contracts between Iceland Health and associations are the result of negotiations between the contracting parties, which private practitioners can enter into. However, the tariffs in framework agreements are determined through a tender process.

If doctors want to introduce a new service that is not included within the contractual tariff, they must apply for copayment from Iceland Health.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

The IMA decides which pharmaceuticals Iceland Health participates in subsidising and consults with Iceland Health before making a decision. Pharmaceuticals can only be approved for the copayment system if they have been granted marketing authorisation by

IMA and are prescribed for use outside healthcare institutions.

The copayment system for purchasing pharmaceuticals is based on a graduated contribution rate, where each individual pays proportionately less as their cost of pharmaceuticals increases within a 12-month period. When the cost of pharmaceuticals has reached a certain amount, the pharmaceuticals are paid in full by Iceland Health for the remainder of the 12-month period. All pharmaceuticals that Iceland Health participates in paying for are included in the payment levels.

Iceland Health contributes to the cost of medical devices that are listed in the Regulation on grants for assistive devices. A grant from Iceland Health is conditional on the medical device being purchased from a specific contracted company. Where Iceland Health has not concluded contracts, bids are sought for individual devices or price surveys are conducted. Grants are awarded based on that price.

Private insurance companies in Iceland generally do not provide insurance for the cost of pharmaceuticals. However, some private insurance companies provide coverage for certain medical devices, such as those needed after an accident.

Licensed pharmaceuticals may only be authorised after approval from the National University Hospital's Pharmacy Committee. They are usually costly or problematic and require professional knowledge or involvement of healthcare professionals for the donation, patient monitoring or use of the product. The National University Hospital's Pharmacy Committee decides on the individual payment participation of licensed pharmaceuticals. If payment participation is approved for licensed pharmaceuticals, it is free of charge and therefore not included in the payment levels.

Iceland Health may decide to contribute to the cost of pharmaceuticals that have been granted an exemption from the requirement of marketing authorisation if an insured person needs them for urgent medical reasons.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

The IMA determines the maximum wholesale and retail prices of pharmaceuticals and the copayments of Iceland Health, except for licensed pharmaceuticals and copayments for pharmaceuticals that have been granted an exemption from the marketing authorisation requirement.

All pharmaceuticals that Iceland Health participates in paying for are included in the payment levels. The copayment of Iceland Health is based on the reference price of the pharmaceutical. The reference price is the lowest maximum price of generic medicines. If the reference price is lower than the price of a medicine that a person buys, the individual pays the difference. These costs are not covered by the payment level.

Pharmacy license holders are required to notify Iceland Health when a pharmacy provides a discount on the copayment price of prescription pharmaceuticals.

The Regulation on grants for assistive devices specifies the level of contribution for medical devices. A grant for a medical device may be paid either in full or in part, depending on the device and the severity of the condition.

LITIGATION INVOLVING HEALTHCARE FINANCING AND

REIMBURSEMENT
14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.
<p>The Court of Appeal, Case No 293/2022</p> <p>The Court of Appeal's judgment concerned the legality of billing an insured person for the use of a CPAP ventilator. The Court ruled that the provision on medical devices should be interpreted as a contribution from Iceland Health and not as a service fee. Furthermore, the Court clarified that the government did not intend to cover all costs associated with medical devices, as the regulation specified that the contribution did not cover the average monthly cost of replaceable accessories, supplies or services beyond a certain amount. As a result, a legal basis for billing was not required. The judgment emphasises that the contribution of Iceland Health for medical devices is provided in the form of a grant.</p>
<p>The Court of Appeal, Case No 16/2020</p> <p>The Court of Appeal ruled that Iceland Health was allowed to refuse access to a framework agreement based on instructions from the Minister of Health to suspend the registration of new doctors due to the financial situation in Iceland Health's budget. However, the Court emphasised that Iceland Health was still required to assess the doctors' applications, taking into account among other factors the available budget. This decision emphasises the broad authority of the Minister of Health and Iceland Health to ensure that agreements stay within budget and to reduce expenses arising from it.</p>
<p>The Supreme Court, Case No 411/2007</p> <p>The Supreme Court ruled that the Competition Act, as a general law, must yield to conflicting provisions of special laws, which grant authority to the Minister of Health to determine the types of services eligible for reimbursement for health-insured individuals. Consequently, the Court ruled that the Competition Authority was not authorised to instruct the Minister of Health to enter into agreements with psychologists, as it would be harmful to competition to negotiate only with psychiatrists. The judgment underscores the broad right of the Minister of Health and institutions acting on his behalf to determine which services are financed or reimbursed by Iceland Health.</p> <p>It is to be noted that most disputes concerning financing and reimbursement of Iceland Health end with a ruling by the Welfare Appeals Committee.</p>
RECENT DEVELOPMENTS AND TRENDS
15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes or trends for healthcare financing and reimbursement, and briefly indicate how these may foreseeably affect the medical sector in the near future.
<p>According to new legislation that entered into force in January 2025, patient insurance for self-employed healthcare professionals has been transferred from private insurance companies to Iceland Health. The value of the premium for self-employed healthcare professionals will be decided by the Minister of Health.</p> <p>In recent years, the framework agreement between Iceland Health and psychologists has</p>

undergone changes, including an increase in the types of services it covers and funding, thus improving access for insured individuals.