

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 Bulgarian healthcare system is centralised, as the powers and responsibilities lie with the state government in the form of the Council of Ministers, the Minister of Healthcare and the Regional Health Inspectorates. Public health policy is managed and carried out by the Council of Ministers, who, based on the proposals of the Minister of Health, approve the National Health Strategy (adopted by the National Assembly), and adopt national health programmes and national plans.

The overall functioning of the healthcare system and the exercise of control are vested to the Minister of Healthcare. The Regional Health Inspectorates are subordinated to the Ministry of Healthcare and are responsible for public healthcare policy at the regional level. Municipalities can establish healthcare directorates in their administration, which are overseen by the Regional Health Inspectorates.

A number of medical services are guaranteed to patients regardless of their health insurance status, such as emergency treatment, inpatient psychiatric care and organ transplantations, and are covered by state and municipal budgets.

Mandatory health insurance is provided through the separate budget of the National Health Insurance Fund (NHIF), which is a specific governmental body, and Regional Health Insurance Funds (RHIFs). Voluntary health insurance through private insurance companies is also possible on the basis of private medical insurance contracts.

Foundations and patient organisations do not have a designated role in providing funding for health insurance.

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

Legislation for healthcare financing and reimbursement is not contained in a single act but scattered among the Law on Healthcare Insurance (LHI), Law on Health (LH), Law on Medicinal Products in Humane Medicine (LMPHM), Law on Medical Devices (LMD), Law on Medical Institutions (LMI) and numerous ordinances for their implementation.

The key act is the Law on Healthcare Insurance, which provides for the status of the NHIF, mandatory insured persons and their premiums. It outlines the package of medical care covered by mandatory health insurance and the exercise of control over spending for the NHIF's budget. The package of medical activities covered by NHIF's budget is specified in

an ordinance issued by the Minister of Healthcare. The pricing and reimbursement of medicinal products is governed by the LMPHM and ordinances of the Minister of Healthcare. Voluntary insurance is briefly regulated by the LHI and Insurance Code.

The NHIF concludes so-called National Framework Agreements (NFAs) with the Bulgarian Medical Association, and with the Bulgarian Dental Association for dental activities. NFAs specify, among other things, the different types of medical services to be provided in the package covered by the NHIF, volumes, prices, and methodologies for the pricing and purchasing of the said types of medical services. On the basis of NFAs, healthcare providers conclude individual contracts for the provision of medical services with RHIFs.

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

The key supervisory body for mandatory health insurance is the NHIF, where the governor of the NHIF exercises control over mandatory health insurance, and officials from the NHIF and RHIFs oversee the implementation of contracts with medical care providers, as well as contracts for the dispensing of medicinal products, medical devices and dietary foods. The NHIF itself is subject to financial control by the Bulgarian National Audit Office and the Public Financial Inspection Agency, as well as the National Revenue Agency (NRA) in respect of NHIF's revenue from premiums, as the payment of premiums is made through the NRA.

The Financial Supervision Commission exercises control over private insurance companies in the voluntary health insurance sector.

The specialised Medical Supervision Executive Agency oversees the provision of the medical package guaranteed by the NHIF, as well as the provision of the health service by private insurance companies on the basis of voluntary health insurance.

The Commission on Protection of Competition (CPC) has a two-fold role in the system as well. The CPC can initiate so-called competition advocacy proceedings and assesses the compliance of existing or proposed legislation through the Law on Protection of Competition. Apart from that, because state hospitals are obliged to conduct public procurement procedures, the CPC is the competent body for appeals with respect to public procurement procedures.

Potential sanctions imposed on medical care providers from the NHIF or RHIFs can be appealed before the competent administrative courts of law.

4. Has there been a change to healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

During the Covid-19 pandemic the government invested additional financing to secure vaccines against the virus. According to official information provided recently, the Minister of Healthcare Bulgaria spent BGN 145m on Covid vaccines, which were scrapped in the period between 2022 and 2024 due to the expiration of their shelf life.

A new clinical pathway (for a detailed explanation of clinical pathways see question 8) was created for inpatient post-Covid-19 treatment of patients, which includes physical therapy, rehabilitation and specialised aftercare from Covid-19.

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?

Healthcare insurance provided by the NHIF is mandatory for the following categories of individuals: (1) Bulgarian citizens who are not citizens of another country or, in the case of dual citizenship, if they reside permanently in Bulgaria; (2) foreign citizens who are permitted as a permanent or long-term resident in Bulgaria; (3) persons granted refugee status, humanitarian status or the right of asylum; (4) European Union Blue Card holders; and (5) foreign students and PhD candidates, and persons to whom Bulgarian legislation applies under rules for the coordination of social security systems (persons in possession of a European healthcare insurance card). Healthcare insurance rights are considered discontinued if the obliged person does not pay premiums for three months in the last 36 months.

Mandatory health insurance guarantees free access of the insured persons to medical care through a defined package of healthcare activities, as well as the free choice of a healthcare provider, who has concluded a contract with an RHIF. The right of choice is valid for the entire territory of Bulgaria and cannot be limited on geographical and/or administrative grounds.

In the field of voluntary health insurance, the principle of contractual freedom applies, that is, the insured person and private insurance company can negotiate the particular scope of medical activities and the premiums to be paid.

In order for a healthcare provider to have access to public funding by the NHIF, it must conclude a contract with the relevant RHIF for the medical activities that it is going to provide. The conditions that healthcare providers must meet are specified in National Framework Agreements. RHIFs can refuse to conclude a contract with a healthcare provider that does not fulfil them and the criteria for ensuring accessibility and quality of medical care.

In order for private insurance companies to be able to operate at all, they should first receive a license from the Financial Supervision Commission. In order to qualify for a license, such a company should, among other things, meet certain corporate requirements (eg, the amount of registered capital and organisational form).

Certain medical services are guaranteed to uninsured persons, such as emergency treatment, preventive check-ups and examinations, and obstetric care for all uninsured women, inpatient psychiatric care, comprehensive outpatient monitoring of uninsured persons with mental illnesses, as well as persons with dermato-venereal diseases, provision of blood and blood products, organ transplantation, vaccines for mandatory immunisation and reimmunisation. This type of medical care is covered by the state and municipal budgets, and not the NHIF.

Foreigners who are staying in Bulgaria for a short period of time or are in transit through the country are obliged to have health insurance or insurance covering the costs of treatment and a hospital stay for the period of stay in the country.

For a detailed explanation of access to medical goods (medicinal products and medical devices) and their reimbursement, see question 12.

HEALTH INSURANCE FINANCING AND COVERAGE

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

The NHIF's sources of income are regulated by the LHI. The highest income items in the NHIF's budget are premiums paid by the insured persons (approximately BGN 4.3bn for 2023) and transfers from the state budget that are intended to cover premiums for retired persons, children under 18 years of age, students enrolled in full-time studies and so on (approximately BGN 2.5bn for 2023).

Premiums for mandatory health insurance are calculated as a percentage of the insured person's income, with a lower and upper limit according to the minimum wage, which is determined by an act of the Council of Ministers (BGN 1.077 for 2025), and the maximum social security income base, which is determined according to the Law on the Budget of the Public Social Security (BGN 3.750 for 2024, potentially to be increased for 2025). The specific amount of the health insurance premium is determined annually according to the Law on the Budget of the NHIF. In past years, it has remained unchanged at eight per cent.

The determination of premiums in the sector of voluntary healthcare insurance is not regulated. Private insurance companies can set their premiums based on the particular risk assessment they have made according to the age, gender, health and financial status of the insured person.

Courts cannot review the specific amount of premiums because, in the case of mandatory health insurance, they are statutorily determined and, in the case of voluntary health insurance, they are contractually agreed by the respective parties. Administrative courts could only decide on potential conflicts for the non-payment of premiums between the NRA, which is responsible for the collection of premiums, and insured persons.

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?

Medical services falling within mandatory health insurance are covered by the NHIF and defined as a package by an ordinance of the Minister of Healthcare. The package is further specified in NFAs.

The medical insurance contract for voluntary health insurance can provide that the insurer covers the cost of healthcare goods and services arising from illness or as a result of an accident, or other agreed healthcare goods and services, including those relating to prevention, pregnancy and childbirth for the insured person or temporary loss of income as a result of illness or accident, as well as a combination of the above coverages. A medical insurance contract could also cover other goods and services related to the insured person's medical care arising from illness or as a result of an accident, including transport, specialised care and palliative care.

The type, prices, conditions and procedure for the provision of health services falling within voluntary health insurance are determined in the contracts between healthcare providers and insurers.

Currently, there is no difference in coverage depending on whether the appointment is in person or a telemedicine appointment.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and

ambulatory (outpatient) settings financed and reimbursed?

The specific prices of medical services covered by mandatory health insurance are negotiated and fixed in NFAs. Inpatient treatment is generally financed through so-called clinical pathways, which include the steps and treatment that needs to be implemented by the medical specialist for a patient with a certain diagnosis that requires hospitalisation, that is, the group of medical services that are included in a clinical pathway are priced as a whole. This method is criticised as being more relevant for the quality of the medical care itself and not being a fit tool for measuring financing because it does not take into account the specifics in the condition that a certain patient may have and the individual treatment that this may require, which could result in different pricing than the one fixed in NFAs. Individual medical services for ambulatory treatment are agreed in NFAs as fixed flat fees.

Outside coverage provided through mandatory health insurance, patients are obliged to pay user fees for each doctoral visit and for each day of inpatient treatment (up to a maximum of ten days per year). User fees are fixed by the Council of Ministers. Currently the fee for a doctoral visit is BGN 2.90 and each day of inpatient treatment is BGN 5.90.

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

As the prices of medical services covered by mandatory health insurance are agreed in NFAs between the NHIF and respective associations (the Bulgarian Medical Association and Bulgarian Dental Association), the latter have a key role in safeguarding the interests of medical professionals and forming a proper basis for them to conclude their individual contracts with RHIFs. Individual contracts between RHIFs and healthcare providers cannot be concluded on less favourable terms than those laid down in NFAs.

Reimbursement from the NHIF is made based on specific medical documentation describing the medical services provided. Financial control over the NHIF and the supervision of medical services provided by healthcare providers is described in question 3.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

Financing and reimbursement for ambulatory treatment provided by individual medical practitioners is the same as those for hospitals (see question 8).

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

Financing and reimbursement for ambulatory treatment provided by individual medical practitioners is the same as those for hospitals (see question 9).

PHARMACEUTICALS AND MEDICAL DEVICES

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

In order for medicinal products to qualify for reimbursement, they should first be included on the Positive Drug List (PDL) maintained by the National Council on Pricing and Reimbursement of Medicinal Products (NCPRMP). In order to determine the reimbursement value of medicinal products included on the PDL, the NCPRMP calculates a reference value based on the defined daily dose (DDD) or therapeutic course or concentration, or volume by International Non-Proprietary Name (INN), dosage form and concentration per unit volume. The lowest value determined according to these parameters becomes the reference value for all medicinal products with the same INN and the same pharmaceutical form. The level of payment for medicinal products, grouped by INN and pharmaceutical form, included in the PDL is determined in percentages and can be up to 100 per cent. For example, the NHIF fully reimburses medicinal products for diseases with a chronic course, leading to severe impairment of quality of life or disability and requiring prolonged treatment; it reimburses 75 per cent for medicinal products for chronic diseases with a high prevalence of morbidity; and it reimburses up to 50 per cent for other medicinal products. The maximum value at which the medicinal product is reimbursed is formed by multiplying the determined level of payment by the value per package determined on the basis of the reference value. According to surveys in the healthcare sector in the EU, out-of-pocket payments by patients for medicinal products not fully covered by the NHIF are the highest in the EU.

The NHIF annually conducts a centralised procedure for the negotiation of rebates of medicinal products provided by marketing authorisation holders (MAHs) or their authorised representatives. The main type of rebate is set in a total amount of not less than ten per cent of the NHIF's expenditure on medicinal products for the relevant quarter.

Medical devices can also be reimbursed by the NHIF or the state budget if they are included on a list maintained by the Bulgarian Drug Agency (BDA). The NHIF conducts an annual procedure for determining the reimbursement level for various groups of medical devices that are covered by its budget. The procedure is carried out by an expert commission that examines applications submitted by the medical device manufacturers/suppliers with their price suggestions. Applicants whose price suggestions fall within the scope of the estimated value of payment determined by the NHIF are admitted to the next stage of negotiations where they have to propose rebates. The expert commission evaluates the proposals and suggests to the NHIF the values up to which it will reimburse the different groups of medical devices.

The Ministry of Healthcare can conduct public procurement procedures for ensuring medical devices that are covered by the state budget.

To guarantee the predictability and sustainability of the budget of the NHIF, the Supervisory Board of the NHIF adopts two mechanisms annually (one for medicinal products and one for medical devices) and methodologies for their implementation. The goal of the mechanism is to secure the budget of the NHIF in the case of an excess of the amounts fixed by the Law on the Budget of the NHIF for the respective year. In the case of medicinal products, MAHs are obliged to pay back the received reimbursement up to the exceeded amount and, in the case of medical devices, manufacturers/suppliers receive a reduced reimbursement price.

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

The prices of the medicinal products are determined by the NCPMP at the request of the respective MAH or its authorised representative. The price of all medicinal products is subject to regulation by the NCPMP, regardless of whether they are listed on the PDL, prescribed ('Rx drugs') or for sale over-the-counter ('OTC drugs'). Once established, the medicinal products cannot be sold at a price exceeding that set by the NCPMP.

All Rx drugs (reimbursed or not) are subject to an external reference pricing system. The states taken into account for reference purposes are Belgium, Greece, Spain, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia and France. The maximum price of an Rx drug is formed on the basis of the price of the manufacturer (based on the reference states), mark-ups for wholesalers and retailers, and VAT.

The maximum price of an OTC drug is subject only to registration (the price is stated in the application form when initiating the procedure). The price should include VAT.

The prices of medical devices that are not reimbursed by the NHIF or the state budget are not regulated. The LMD provides for a definition of the selling price of a medical device, and that such a price shall include VAT and any additional taxes and charges, at which the medical device is offered to the consumer.

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.

Decision No 6 from 11 April 2024 of the Constitutional Court

Although not a judgement on a specific case, this decision has a major role for all healthcare providers as the Constitutional Court declared that the LHI article that provides that the NHIF will not reimburse medical and dental care services provided by the medical institutions in violation of the volumes and values negotiated in their individual contracts with RHIFs is contrary to the Constitution of Bulgaria. In essence, the rationale behind the provision is that individual contracts set the limit of medical care that is going to be reimbursed by the NHIF and, if exceeded, care would not be covered by the NHIF, even if such care is actually provided to a patient. The Constitutional Court concluded that said the provision is contrary to patients' constitutional right of free access to medical care as it would force patients to comply with conditions that they cannot foresee, that is, whether the healthcare provider that they have chosen has exceeded its limit. According to the Constitutional Court, potentially exceeding the negotiated limit is an issue for the NHIF, which is responsible for the proper planning and ensuring of necessary medical care for patients, and cannot be transferred to healthcare providers, which ultimately leads to violation of the right of accessible medical care for patients.

Ruling No 9630 from 30.08.2024 on administrative case No 8096 from 2024 of the Supreme Administrative Court

The subject of appeal was the provision of an NFA between the NHIF and Bulgarian Medical Association that pertains to the reimbursement of medical care exceeding the limits agreed in individual contracts of healthcare providers. The case was initiated by the National Association of Private Hospitals seeking that the application of these provisions is suspended. The Supreme Administrative Court stated that the decision of the Constitutional

Court (described above) is binding upon the courts and declared the suspension of the provisions of the NFA that prohibit the NHIF from reimbursing medical services provided by healthcare providers above the agreed limits.

Decision No 4439 from 10.04.2024 on administrative case No 8742 from 2023 of the Supreme Administrative Court

The case was initiated by several pharmaceutical companies that sought the cancellation of the Mechanism Assuring Predictability and sustainability of the budget of the NHIF for medicinal products for 2021. The Supreme Administrative Court confirmed the annulment by the first instance court. Its reasoning was that there were procedural violations during the adoption of the mechanism and that it is unlawful as:

'formally, the NHIF budget is balanced, but in reality it has a hidden deficit, which has been transferred to the private entities that supply the country with medicines included in the PDL, and these entities are charged with covering the difference between the earmarked revenue and the actual spending. The overspending of the NHIF budget that MAHs should cover according to the Mechanism is not an exception, but a regular occurrence in each quarter...!'

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.

Currently, the procedure for the adoption of the budget of the NHIF for 2025 is taking place. The draft budget is set at BGN 9.5bn, which is a 16.5 per cent increase compared to the budget from 2024. Again, the largest item in the budget is set for inpatient treatment, which was met with some criticism, with the argument that more emphasis should be placed on the prevention of diseases, that is, a larger budget for outpatient treatment. The mandatory health insurance premium is set to remain unchanged at eight per cent.

Considering the recent decision of the Constitutional Court, the reimbursement of medical care services after the limits set in the individual contracts of healthcare providers has been exceeded would be a topic of discussion in the sector in the future.