

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 healthcare system in Poland operates under a centralised model in which key decisions and resource allocation are within central institutions, notably the Minister of Health and the National Health Fund (NFZ). The Minister of Health is responsible primarily for setting healthcare priorities, regulating the healthcare economy and overseeing the functioning of the healthcare system. The NFZ is financed from healthcare premiums paid by individuals to which public health insurance applies. The regional units of NFZ negotiate and contract with health service providers (both public and private, if they intend to render healthcare services based on such contracts) and pay remunerations for services rendered under relevant contracts.

There is no strict differentiation between the private and public sector in Poland's healthcare market. Currently, the private sector dominates the provision of services in primary care, outpatient care, rehabilitation and long-term care, while hospitals remain the domain of the public sector. However, it is different for highly specialised single-specialty hospitals, eg, hospitals for eye surgery.

For most Polish residents, public health insurance is mandatory. These include, in particular, Polish, European Union, European Free Trade Area and United Kingdom citizens, refugees, asylum seekers who are employees, entrepreneurs, pensioners, students, farmers, pensioners, or public functionaries. Their family members are also entitled to benefits under the public health system. For other Polish, EU, EFTA and UK citizens, refugees and asylum seekers, public health insurance is voluntary. Currently, approximately 34.1 million Polish residents have – either obligatorily or voluntarily – public health insurance.

Besides public health insurance, Polish residents can also subscribe to private insurance or health subscriptions offered by private providers. Those for whom public health insurance is mandatory cannot, however, exempt themselves from paying premiums to the NFZ because of subscribing to private health insurance (opt-out from the public system is not allowed). Polish residents can also access medical services provided individually in private practice. In that case, however, they must bear all the costs associated with the medical services.

Foundations and patient organisations are also involved in financing medical services, which are not funded by the NFZ. Overall, however, their part is minor.

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

The Polish healthcare economy is regulated primarily by the Act on publicly funded healthcare services. It sets out, amongst others, the conditions for providing and procedure of financing of publicly funded healthcare services. It also determines the conditions for compulsory and voluntary public health insurance. Finally, it specifies responsibilities of public authorities with respect to ensuring publicly funded healthcare services.

Enforcement of the Act on publicly funded healthcare services is enabled by several regulations of the Minister of Health on guaranteed healthcare services within specific categories (eg, dental treatment, hospital treatment, primary care, highly specialised services). They contain tables of guaranteed healthcare services and conditions for performing them for each service group. The applicability of the Act is also guaranteed by the orders of the President of the NFZ concerning, in particular, the principles of concluding and performing funding contracts with service providers, under which services are performed. In practice, negotiations between healthcare providers and the regional units of the NFZ are the key element in the process of contracting healthcare services. They concern, in particular, the price per tariff point or inserting provisions foreseeing, eg, higher remuneration for meeting certain quantitative or qualitative criteria.

In terms of reimbursement for medicines and medical devices, the key law is the Act on reimbursement of medicines and medical devices. It regulates the terms and conditions under which such products are publicly funded. Specific lists of reimbursed medicines and medical devices are set out in the Regulation of the Minister of Health on the list of medical devices issued on prescription, and the Announcement of the Minister of Health on the list of reimbursed medicines, which is issued once a quarter.

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

The main body overseeing the functioning of the healthcare economy is the Minister of Health. It has a key role in ensuring that the activities of NFZ comply with the law, the financial plan, and with the Polish healthcare policy. The Minister appoints the President of NFZ, approves its Financial Plan (together with the Minister of Finance) and can issue instructions and guidelines which bind the NFZ. It also considers appeals against administrative decisions issued by the NFZ concerning insured persons, service providers, or payers.

The NFZ (including its regional units), in turn, supervises compliance with the law, the terms and conditions of contracts by healthcare providers, and the performance of tasks financed by public funds. To this end, the Act on publicly funded healthcare services grants the President of the NFZ specific authority to inspect. If irregularities are identified during an inspection and are not corrected within a given time, the Minister of Finance can fine a service provider up to one month's value of the contract with the NFZ.

The draft of tariff plan for healthcare services is prepared each year by the Agency for Health Technology Assessment and Tariffs (AOTMiT) – the national HTA agency. The tariff plan is then approved by the Minister of Health, who may first require it to be amended.

Competition in the healthcare financing system is supervised by the Office of Competition and Consumer Protection (UOKiK). It combats conduct restricting competition or abuse of a dominant position by both NFZ and providers of private health insurance and subscriptions. Decisions of the President of UOKiK can be appealed and are then considered by the Antitrust Court (SOKiK). In the past, the UOKiK has, on several occasions, fined the NFZ and the

private entities for breaching the prohibition on restrictive competition practices (mainly abuse of a dominant position).

Both administrative courts and civil courts are important in disputes between NFZ and service providers concerning financing contracts for the provision of healthcare services. There are two main categories of such disputes: over the granting or refusal of financing and over the performance of contracts. Administrative courts deal with cases concerning the first category and civil courts with the second one (mainly over quotas).

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

To combat the Covid-19 pandemic, the government established and managed a special fund: the Covid-19 Counteracting Fund. The purpose was to streamline disbursements by skipping the standard, time-consuming procedure of contracting services with the NFZ.

The fund was intended to finance or contribute to the implementation of Covid-19 counteracting tasks and to reimburse expenses incurred in the performance of the tasks. The resources collected thereto came, *inter alia*, from contributions from public finance sector entities, funding from the EU, contributions from the national budget, and funds from loans and bonds.

Spending from the Covid-19 Counteracting Fund reached a total of nearly PLN190bn between 2020 and 2022. However, media reports indicate that some of the money was spent incorrectly for purposes unrelated to combating the Covid-19 pandemic.

Currently, some healthcare services are still financed by the Fund (eg, vaccinations and post-Covid rehabilitation), but from 1 April 2022 treatment of patients with Covid-19 is financed by the NFZ.

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?

In principle, all persons insured under the NFZ are guaranteed equal access to the public healthcare system, ie, healthcare providers providing services at the expense of the NFZ cannot refuse a patient as long as the institution has the capacity. As an exception, access to the public healthcare system is also guaranteed to uninsured Polish citizens or refugees with an income below a certain threshold, to certain persons under the age of 18, and to pregnant or postpartum women. In the area of private insurance, there is full contractual freedom, ie, an insurer can refuse to insure an individual and can include reservations in the individual insurance policies.

Pharmaceuticals and medical devices to be reimbursed by the NFZ must be included, respectively, on the list of reimbursed medicines or the list of medical devices issued by prescriptions. All persons who are insured under the NFZ or who are entitled to healthcare services under additional entitlements are eligible to receive medicine or medical devices at a reduced price or for free.

Tourists from the EU/EFTA and the UK can be treated in Poland for emergencies, if they possess a European insurance card (ie, they are insured in their home country). Tourists from other countries must have travel insurance covering health costs.

Planned treatment of residents abroad financed by the NFZ is possible with individual consent granted by the President of the NFZ. The NFZ does not fund treatment outside Poland as part of clinical trials, experimental treatment, or treatment that is not among the guaranteed services in Poland.

To obtain funding from the NFZ, healthcare providers must submit an offer that meets the requirements set out by the NFZ concerning, eg, premises, personnel, types of services to be provided and the conditions for providing them. The selected healthcare provider and the NFZ must then enter into a contract for the provision of healthcare services. To this end, the parties negotiate, *inter alia*, the price per tariff point or inserting provisions foreseeing, eg, higher remuneration for meeting certain quantitative or qualitative criteria.

HEALTH INSURANCE FINANCING AND COVERAGE

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

Public health insurance carriers are financed mainly by premiums. The NFZ Financial Plan for 2025 puts the NFZ budget at around PLN183m, which includes PLN173m from premiums. Insurance carriers also have income from unused previous years' premiums, a subsidy from the state budget, fees for a licence to sell alcohol, fees for marketing products containing sugar, caffeine and taurine, and allocations from targeted funds.

Private health insurance carriers are financed fully by the premiums that are paid by insured persons. As a rule, private insurers are free to determine premiums.

The rate of public health insurance premiums is set in the Act on publicly funded healthcare services. Therefore, revision of it requires an amendment to the Act. In such a case, the parliamentary stage is preceded by, among others, cross-departmental consultation and works in government committees, and then approval by the government. Currently, the health insurance premium is 9 per cent of the assessment base (ie, monthly income minus social insurance contributions). Therefore, the premiums will vary depending on income.

As a rule, the courts do not have the authority to review insurance premium rates set out in the Act on publicly funded healthcare services. Such competence is, however, reserved to the Constitutional Tribunal, which examines whether rates are permitted by the Polish Constitution.

7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?

The Minister of Health determines in several regulations on guaranteed healthcare services within specific categories which healthcare services are financed by the NFZ. The valuation of these services falls under the responsibility of the AOTMiT. Its tariff is then approved by the Minister of Health.

Private insurers and health subscription providers, however, are free to determine the scope of financed healthcare services.

The valuation of online and inpatient primary healthcare appointments in Poland is the same. In 2021, an attempt was made to introduce a premium scheme for physicians who performed

a low number of remote consultations. However, it was abandoned following the intervention of the union of healthcare providers (Porozumienie Zielonogórskie, OZPSP).

In Poland, orphan drugs are subject to the same reimbursement assessment procedure as all other medicines. Still, an upward trend in the reimbursement of orphan drugs should be recognised: in 2024, out of a total of 135 reimbursed molecules of drugs, 36 were for rare diseases and from 1 January 2025, another 12 were reimbursed. There are also suggestions to introduce a fast-track for orphan drug reimbursement.

Medicinal products in Poland can also be reimbursed for indications other than those registered and listed in the summary of product characteristics. The Minister of Health, after consulting the Transparency council and the national consultant in the relevant area of medicine can issue an *ex officio* administrative decision on the reimbursement of a drug with respect to indications for use, dosage or route of application other than those specified in the summary of product characteristics (off-label use). This is done on the basis of criteria discussed in materials prepared by AOTMiT.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

For outpatient treatment, the payment rate is assigned to a specific medical procedure. Inpatient treatment, however, is billed under a system based on a bundle payment per whole treatment (rather than individual medical service) of a patient with a specific condition (diagnosis-related groups system). The draft of a tariff plan for both outpatient and inpatient treatment is prepared each year by AOTMiT and is subsequently approved by the Minister of Health.

Both inpatient and outpatient services are financed from the same pool, divided within the annual financial plan of the NFZ, determined by the President of the NFZ. NFZ revenue comes mostly from premiums. The financial plan for 2025 envisages that the subsidy for NFZ from the state budget will be approximately PLN18.3bn, which is approximately 10 per cent of the NFZ annual budget. However, it might be slightly lower because of the Minister of Finance's objection.

Criticism of the healthcare services valuation system focuses mainly on the fact that it does not keep pace with increasing costs of services mainly because of inflation and wage increases. It has been pointed out that a temporary solution would be to automatically increase the valuation of services by the rate of inflation. It is also noted that the valuation does not take place early enough, as a result of which hospitals do not know, until almost the last minute, how much money they will have to cover their operating costs.

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

The draft of a tariff plan for both outpatient and inpatient treatment is prepared each year by the AOTMiT and is subsequently approved by the Minister of Health.

Each service contracted by the NFZ is assigned a specific number of units of account (point weight). The unit price results from contracts concluded by the NFZ with healthcare providers and is determined individually as a result of negotiations. Likewise, in the course of

negotiations, the so-termed correction factor (a mechanism used in valuation systems that allows the basic value of a service to be changed to reflect its cost or performance conditions more fairly) is determined. The product of the point weight and the unit price constitutes the value of the service.

When contracting with service providers, the NFZ rarely agrees to increase the price per service. Therefore, in practice, negotiations are often focused on the number and not the price of services. However, sometimes actions coordinated by the unions of healthcare providers (eg OZPSP) are undertaken with the aim to collectively negotiate more favourable terms of contracts with the NFZ. They are particularly focused on negotiating higher unit prices for healthcare services.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

Even though the Polish healthcare system is broad (ie, accessible to a wide range of patients), it might also be described as being rather ‘shallow’ – the actual access to services is limited by long waiting periods for services rendered within the public sector and a limited number of modern medical devices. Therefore, an important role is assigned to private practitioners.

However, private practitioners often decide to enter into contracts with the NFZ for the provision of certain services. For services provided under contracts with the NFZ, they are then subject to the same rules as public entities receiving public funding (for more information, see Q8 and Q9). Diversification of income sources by obtaining partial public financing is for them, indeed, a more secure business model than relying solely on profits from individual private appointments.

Also, larger service providers frequently offer health subscriptions. In this model, the patient pays a regular subscription fee and, in return, gains access to selected medical services, often medical appointments, diagnostic tests or minor outpatient procedures. About 5.1 million individuals in Poland are currently benefiting from medical subscriptions.

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

As to the rule, private practitioners are free to determine the prices of provided healthcare services. However, this freedom is limited by antitrust and consumer protection legislation.

The UOKiK guidelines indicate in particular that contractual provisions regarding price should be precise and should not leave the entrepreneur too much room for interpretation: ie, a clause such as ‘The price of the operation may change due to the prolongation of the operation or the need to carry out additional, not previously foreseen actions’ would be prohibited. Similarly, provisions that give the healthcare provider the right to determine or increase the price after entering into the contract, without giving the consumer the right to withdraw from it, are also prohibited.

PHARMACEUTICALS AND MEDICAL DEVICES

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

The public reimbursement of drugs and medical devices depends on whether a patient has public insurance. Otherwise, a medical practitioner can only issue a full-pay prescription. If a patient is insured and the drug or medical device is on the list of reimbursed drugs or the list of commissioned medical devices, the NFZ can pay part of the costs associated with the purchase of it, if the criteria determining the granting and level of reimbursement are fulfilled. It is worth mentioning that the list of reimbursed drugs refers to specific medicinal products available on the market, while the list of medical devices refers to certain types of devices.

For drugs, a medical practitioner will indicate the relevant level of reimbursement on the prescription out of those indicated in the list (100 per cent, 50 per cent or 30 per cent reimbursement, fixed amount of PLN3.20 or full reimbursement). Magistral preparations prepared from pharmaceutical raw materials or ready-made drugs to which reimbursement also applies are also reimbursed. Regarding medical devices, the list of commissioned medical devices provides, as a rule, one level of financing (in some cases it is different for children).

Some orphan drugs are fully or partially reimbursed in Poland. They are subject to the same reimbursement rules as all other drugs. It is, however, postulated to introduce a fast-track reimbursement pathway for them.

Alongside the system of universal reimbursement, Polish law foresees two exceptional, individual (applicable to a specific patient) reimbursement regimes. The first one concerns the financing of medicines, which are not registered in Poland, by means of a direct import procedure. The second mechanism is a so-termed ‘emergency access to drug therapies’ (RDTL). It concerns drugs that have been registered and are available in Poland, but to which universal reimbursement does not apply. Reimbursement under RDTL is possible if there is a justified need, based on current medical knowledge, to use a medicine that in a given indication is not financed from public funds, if this is necessary to save that patient’s life or health. It is also required that all available publicly reimbursed medical technologies for that indication have already been fully exhausted. In both cases individual reimbursement requires the approval of the Minister of Health.

Sometimes, private health insurances also provide for reimbursement of the cost of purchased medicines used to treat an illness, and the extent of the reimbursement is then set out in the contract with the insurer.

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

The assignment for the appropriate level of payment under the reimbursement system and the determination of the funding limit (the level up to which the drug is reimbursed) for products with similar therapeutic effect and similar mechanism of operation is made by the Minister of Health. The classification into payment levels is based on the criteria of the type of disease the medicinal product is intended to treat, the expected duration of its use and the price. When determining the funding limit, the Minister considers the wholesale prices in the relevant group of drugs and the market turnover volume for individual products in the group. Reimbursement lists are updated quarterly by the Minister of Health.

Regarding the mechanisms for controlling the commercial efficiency of the reimbursement, Polish law permits confidential rebate agreements between drug producers and the Ministry of Health. The agreements provide for conditioning the official sales price level on the supply of the drug at a reduced price, agreed in negotiations. It results in lower expenses for the NFZ

and increased availability of drugs. Confidential rebates contracts are incorporated in approximately 63 per cent of applications for reimbursement.

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.

A major litigation topic regarding healthcare financing in Poland is the issue of remuneration to healthcare providers for life-saving or health-saving healthcare services performed above the limit specified in the contract with the NFZ (over quotas). Over several years consistent dicta have been developed in reported cases, recognising the right of hospitals to be paid for such healthcare services. Also, on 19 March 2019, the Supreme Court adopted a resolution stating that if the hospitals have provided life-saving or health-saving healthcare services above a contractual limit, they are entitled to remuneration equal to the contract price for such services. Therefore, it is not necessary for them to demonstrate or verify the costs incurred in providing these services. However, healthcare providers are still struggling to obtain the remuneration due to exceeding quotas.

Administrative courts have recently issued important judgements regarding reimbursement for orphan drugs. In 2017, the Act on reimbursement of medicines and medical devices was supplemented by a provision, under which an application for individual reimbursement of orphan drugs is to be rejected if the President of the NFZ can (theoretically) authorise the foreign language labelling for a set number of packages of orphan drugs (Article 39 (3e)(5)). In practice, it excluded orphan drugs from individual reimbursement by means of direct import. In 2020, the Voivodship Administrative Court in Warsaw overturned the decision of the Minister of Health to reject the application for individual reimbursement of an orphan drug on the basis of Article 39 (3e)(5). The Supreme Administrative Court upheld the judgement. It stated that the ‘automatic’ application of that provision would mean excluding all orphan drugs from reimbursement, which is unacceptable in a democratic state governed by the rule of law, which respects the principles of social justice. It concluded that refusal to grant approval for individual reimbursement of an orphan drug on the basis of Article 39 (3e)(5) is only possible if the Minister of Health proves that the procedure of authorising the foreign language labelling by the President of NFZ has actually been applied.

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.

A specific feature of the Polish healthcare economy is that it is accessible to a wide range of the population, but the challenges refer to the actual access to services which is limited by long waiting periods for services rendered within the public sector and the need to use modern medical technologies. The main trend in terms of the development of the financing and reimbursement system is, therefore, financing the use of up-to-date innovative medical technologies. Funds for further reforms in this regard are expected to be generated from the

reorganisation and rationalisation of the hospital network, with the aim, *inter alia*, of consolidating district hospitals.

The tendency for funding innovative therapies is reflected particularly by the first surgeries carried out using da Vinci robots, which are based on AI, financed by the NFZ. This type of service has been included in the group of guaranteed healthcare services since 2022. Also, there is an upward trend in the reimbursement of orphan drugs: in 2024, out of a total of 135 reimbursed molecules of drugs reimbursed in Poland, 36 were for rare diseases and from 1 January 2025, another 12 were reimbursed. It is worth noting that one of these drugs is Luxturna – the second reimbursed gene therapy in Poland, used in treatment of patients aged 4 to 35 years that have Leber congenital blindness.

There is also an apparent drive to make medicines more accessible to patients while also supporting national drug production. To this end, in August 2023, an amendment to the Act on reimbursement of medicines and medical devices, introducing incentives for Polish drug manufacturers, was adopted. Thanks to this, from 1 April 2024, patients pay 10 per cent less for reimbursed medicines produced in Poland and 15 per cent less if, in addition, ingredients produced in the country were used in producing the medicines. The NFZ pays the differences in prices.

Another objective is to harmonise Polish reimbursement legislation with EU law. In particular, legislative work is underway to adjust the Act on reimbursement of medicines and medical devices to the requirements in Health Technology Regulation 2021/2282. The current draft includes, among others, an exemption from the need to submit evidence of the efficacy of a medical technology already presented at EU level, when applying for reimbursement at the national level.

Efforts are also being made to optimise the rules for calculating health premiums. On 1 January 2025 an amendment to the Act on publicly funded healthcare services came into force that changes the method of calculating the basis for health insurance premiums for entrepreneurs. From now on, the sale of property, plant and equipment will not qualify as income, which will reduce and rationalise premiums for entrepreneurs.