

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 the Czech Republic is structured around a universal public healthcare model, primarily funded through mandatory health insurance contributions. The private sector plays a supportive and supplementary role, typically offering additional options.

Main features of the public healthcare system

Mandatory health insurance contributions

Healthcare is financed through compulsory health insurance, with contributions from employers, employees, self-employed individuals and the government, which covers the insurance costs for certain vulnerable groups, such as children, students, pensioners and the unemployed. Seven health insurance funds function as healthcare payers, engaging in annual negotiations with healthcare providers to determine the pricing and volume of healthcare services.

Ownership

Most hospitals are owned and operated by the state, regions or municipalities, providing a broad range of services to the population. Some hospitals are privately owned, but they are usually located in smaller towns and tend to be smaller. Primary care and secondary care facilities are largely operated by private healthcare providers.

Central government

The Ministry of Health of the Czech Republic plays a central role in shaping and overseeing the country's healthcare system. It is responsible for setting and enforcing standards for healthcare services, including the quality of care, safety and medical practices. It also supervises the public health insurance system.

Regional authorities

The enforcement of regulations regarding the provision of healthcare services is decentralised. Regional authorities in the Czech Republic grant authorisations for the provision of healthcare services. They also play a significant role in organising the provision of healthcare in regions or within municipalities and ensure that healthcare remains accessible.

Main features of health insurance in the Czech Republic

Solidarity

In the Czech Republic, the healthcare system is based on the principle of solidarity, whereby all economically active residents are required to contribute to the funds of one of the licensed health insurance companies. In the case of the other individuals (eg, retired people or children), the state assumes the responsibility for the payment of insurance premiums.

Health insurance companies

The largest national insurer is Všeobecná zdravotní pojišťovna (General Health Insurance Company), which is state-owned and provides coverage for the majority of the population. There are six other smaller health insurance companies that operate independently but are regulated by the Ministry of Health. They are not private companies, but semi-autonomous bodies funded by compulsory contributions.

Premiums

The premiums collected by health insurance companies are used to pay for the provision of healthcare services, pharmaceuticals and medical devices. In certain cases, patients may be required to contribute financially towards the cost of their treatment.

Private healthcare system

No supplementary or private health insurance system

The Czech Republic currently has no supplementary or private health insurance system in place that would, for example, cover additional care. However, the Czech Parliament is currently debating a draft amendment to the Public Health Insurance Act that would enable the provision of supplementary programmes (see the answer to question 15).

General practitioners, specialists and dentists

Many general practitioners, specialists and dentists operate privately, but their fees are reimbursed by public insurance, to a large extent. In certain instances, patients may be required to make additional payments for services or pharmaceuticals that are not fully covered by public health insurance. This is usually related to supplementary pharmaceuticals, dental services or medical devices.

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

Pertinent law

- The main acts governing health insurance are Act No 48/1997 Coll. on public health insurance and Act No 592/1992 Coll on public health insurance premiums. This is the primary law governing the system of public health insurance in the Czech Republic. It establishes the framework for mandatory health insurance for all residents and details the responsibilities of health insurance funds, as well as the rights and obligations of insured individuals and healthcare providers.
- Act No 372/2011 Coll on Healthcare Services: This act governs the conditions for the provision of healthcare services in the Czech Republic.
- Act No 378/2007 Coll on Pharmaceuticals: This act governs the regulation of pharmaceuticals, including their production and distribution.

Regulator's guidelines

The State Institute for Drug Control (Státního ústavu pro kontrolu léčiv or SÚKL) has issued

several guidelines and methodology opinions related to the pricing and reimbursement of pharmaceuticals. The SÚKL guidelines concern the determination of prices and reimbursements for pharmaceuticals and food for special medical purposes in the Czech Republic. These include detailed instructions on submitting applications, methodologies for pricing and reimbursement evaluations, and processes for appeals or updates to pricing and reimbursement decisions.

Industry codes

Association of Health Insurance Funds of the Czech Republic

The Association of Health Insurance Funds of the Czech Republic (Svaz zdravotních pojišťoven ČR or 'SZP ČR') provides guidelines on recommendations for the pricing, evaluation and categorisation of pharmaceuticals for reimbursement purposes. These guidelines also include standards for collaboration between health insurance funds and healthcare providers to ensure the cost-effective and efficient use of pharmaceuticals. The Pharmaceuticals Committee has issued methodologies concerning the procedures and principles for negotiations between the SZP ČR and market authorisation holders (MAHs) regarding the inclusion of pharmaceuticals in the reimbursement system. The Medical Devices Committee has similarly issued methodologies on the assessment and categorisation of pharmaceuticals for determining reimbursement levels and conditions within the Czech healthcare system.

Association of the Innovative Pharmaceutical Industry in the Czech Republic

The Association of the Innovative Pharmaceutical Industry in the Czech Republic (Asociace inovativního farmaceutického průmyslu or AIFP), a member of the European Federation of Pharmaceutical Industry and Associations (EFPIA), has issued a Code of Conduct for its members. While the Code of Conduct itself does not regulate pricing or reimbursement processes, it promotes transparency in the relationships between pharmaceutical companies and healthcare organisations. This indirectly affects discussions around the value and financing of pharmaceuticals.

Negotiations

Contracts

In order to guarantee the effective delivery of covered healthcare services to insured individuals, health insurance companies enter into contractual agreements with healthcare providers for the provision and reimbursement of covered services. These contracts specify the conditions for reimbursement, including the amounts and regulatory limitations on reimbursement. In certain instances, health insurance companies may provide coverage for health services that are not typically covered by insurance. In such cases, the health insurance companies assess on a case-by-case basis whether the statutory conditions for patient eligibility are met.

MAHs

Once the SÚKL has set the maximum price for a pharmaceutical, MAHs can negotiate with health insurance companies to establish the actual reimbursement rate. These negotiations often focus on factors such as the cost-effectiveness of the pharmaceuticals, the clinical benefits compared to existing treatments and the financial sustainability of the healthcare system. The SZP ČR also plays a key role in these negotiations as it coordinates the position

of the health insurance funds in discussions with pharmaceutical companies.
3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?
<p>Central government agencies and public authorities</p> <ul style="list-style-type: none">• Ministry of Health: This is the primary regulator responsible for setting national healthcare policy, overseeing the operation of health insurance companies, and establishing reimbursement rules and tariffs.• Ministry of Finance: The state budget is prepared annually by the Ministry of Finance. It includes the government's funding for the health insurance system for specific groups, such as children and pensioners.• Supreme Audit Office: It is an independent body responsible for auditing the management of public funds and property, including those allocated to healthcare. Thus, it plays a role in healthcare financing, although its involvement is indirect and focused on oversight and accountability.• Czech Competition Authority (Úřad pro ochranu hospodářské soutěže or ÚOHS): It ensures fair competition among health insurance funds and prevents anti-competitive practices in healthcare services and the pharmaceutical and medical devices markets. <p>Specialised bodies and industry organisations</p> <ul style="list-style-type: none">• SÚKL: It regulates pharmaceuticals and medical devices, including their pricing and reimbursement status within the public health insurance system.• Czech Medical Chamber: It is an autonomous, professional organisation that represents all doctors in the Czech Republic. Membership in the Chamber is compulsory. Among its significant powers is the right to engage in negotiations on the development of healthcare services tariffs, as well as the ability to establish conditions for the private practice of its members. <p>Courts</p> <p>The judicial system plays an important role in healthcare governance in the Czech Republic. Disputes between healthcare providers and health insurance funds are addressed in administrative proceedings, while civil proceedings are reserved for resolving private disputes in the healthcare sector, such as disputes between private healthcare providers and insurers, or between patients and healthcare providers.</p> <p>The Supreme Administrative Court reviews final decisions in administrative healthcare disputes, ensuring compliance with national and European Union laws.</p> <p>The Constitutional Court is responsible for reviewing challenges to healthcare laws or policies that may infringe on constitutional rights, including the right to healthcare.</p>
4. Has there been a change to healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?
<p>The efforts to address the Covid-19 pandemic led the Czech Government to increase its direct involvement and public spending to manage pandemic-related healthcare needs, allocating substantial funds for testing, vaccination, personal protective equipment and hospital capacity expansion. These efforts included reallocating existing healthcare budgets</p>

and introducing emergency financing measures. Additional funding was directed to support overburdened hospitals, ensure healthcare worker availability and compensate healthcare providers for pandemic-related losses or increased workloads. Health insurance companies also adapted their reimbursement schemes to cover pandemic-specific care, such as testing and some types of telemedicine services. However, no significant permanent changes with healthcare financing and reimbursement have been made.

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?

Access for patients

All Czech citizens and foreigners with residence permits in the Czech Republic who pay contributions to the public health insurance system are entitled to access healthcare services, which include coverage for a wide range of healthcare services, hospital stays and specialist care. Children, pensioners, students and the unemployed are entitled to public healthcare, as the state covers their contributions. Non-residents are not automatically covered by the public healthcare system, but they may get access to healthcare in emergency situations under the principle of reciprocity or with their own funds.

Access for healthcare providers

Healthcare providers (hospitals, doctors etc) must be accredited and meet specific criteria set by the Ministry of Health to be reimbursed by the public health insurance system. To access reimbursement, providers enter into contracts with one or more of the public health insurance companies. In order to provide healthcare services in the Czech Republic, healthcare providers must obtain a special permission.

Some healthcare providers, including private clinics and specialists, may offer services to insured patients which are outside the scope of standard public insurance coverage. These may include more immediate or specialised treatment, often at an additional cost to the patient.

Access for suppliers of medical goods

Suppliers of pharmaceuticals must obtain a distribution authorisation from the SÚKL. Suppliers of medical devices need to notify their activity with the SÚKL.

For pharmaceuticals or medical devices to be reimbursed from health insurance in the Czech Republic, they must be included in the reimbursement list maintained by the SÚKL. This involves submitting an application, demonstrating the product's clinical efficacy, cost-effectiveness and added therapeutic value compared to existing alternatives. Pricing negotiations are involved to determine the maximum reimbursement amount and patient co-payment, if any.

HEALTH INSURANCE FINANCING AND COVERAGE

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

Mandatory or optional insurance

Health insurance in the Czech Republic is mandatory for all residents and administered through public health insurance funds that are financed by the contributions of insured

individuals (premiums).

Governmental involvement in determination of premiums

The government plays a significant role in regulating the health insurance system. Premiums are based on a fixed percentage of income, as stipulated by law. For non-earning individuals covered by the state, the government contributes a set amount to the health insurance funds.

Judicial review of premiums

Premium rates are determined by law, minimising the need for judicial review. However, any disputes or challenges related to the system are addressed through the legal and judicial framework of the Czech Republic.

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?

Public health insurance companies

Public health insurance companies in the Czech Republic have limited autonomy to define the range of the coverage they provide. In general, health insurance pays for health services that are intended to improve or maintain the insured person's health or alleviate suffering. These include diagnostic and therapeutic healthcare (outpatient and inpatient) emergency and rescue services. The Ministry of Health publishes a List of Health Procedures, which is amended annually to include newly approved procedures. Health insurance companies cannot arbitrarily exclude certain healthcare services from coverage. However, they do have some leeway in deciding which healthcare providers will provide these services.

Telemedicine

Telemedicine services have been increasingly recognised and partly reimbursed under the public health insurance system as a result of the Covid-19 pandemic. The coverage framework is still evolving, and differences in reimbursement rates or conditions for telemedicine and in-person consultations may exist due to various approaches of different health insurance companies.

Orphan drugs

Orphan drugs and other high-cost treatments often require special approval processes. Their inclusion in coverage typically depends on specific assessments by the SÚKL and Ministry of Health.

HOSPITAL SECTOR

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

For inpatient healthcare services in hospitals payments are made using a diagnosis-related group (DRG) system. This means hospitals receive a set amount based on the patient's diagnosis and treatment type, regardless of the actual costs. For outpatient services (ambulatory doctor visits or minor procedures), payments are made based on a fee-for-service model. Each service is reimbursed individually according to a tariff schedule set by the government.

The government is partly involved in financing hospital services, particularly through

contributions to health insurance funds for specific population groups (eg, children and pensioners), and funding and support for infrastructure, technology and other capital expenditure of state-owned hospitals.
9. How are the prices of such services determined? How is economic efficiency controlled?
<p>As noted, in the Czech Republic, prices for healthcare services are regulated rather than freely determined. Inpatient services are reimbursed using the DRG system, where standardised prices are set by the government based on diagnosis and treatment type. Outpatient services follow a government-regulated tariff schedule that specifies reimbursement rates for individual procedures.</p> <p>Negotiations between health insurance companies and healthcare providers influence the financial framework, though within the limits established by government regulations. The Ministry of Health plays a key role in defining tariffs, ensuring uniformity and predictability in pricing. The government monitors expenditure through audits and enforces cost-control measures while using the DRG system to incentivise hospitals to operate within predefined costs. These mechanisms ensure cost-effectiveness and minimise inefficiencies in the healthcare system.</p>
HEALTHCARE PROVIDERS IN PRIVATE PRACTICE
10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?
<p>Healthcare services provided by physicians, therapists, laboratories and other healthcare providers are primarily financed and reimbursed through the public health insurance system. For most of these healthcare services, reimbursement follows a fee-for-service model, where each procedure or consultation is reimbursed based on a predefined list from the Ministry of Health.</p> <p>As noted, the government contributes to healthcare financing by paying health insurance contributions for certain population groups, such as children, pensioners and the unemployed, ensuring broad access to these services.</p> <p>In addition, certain services which are not covered by the public health insurance may be provided to patients at their own expense.</p>
11. How are the prices of such services determined? How is economic efficiency controlled?
<p>For most services, the Ministry of Health defines a fixed price list that specifies reimbursement rates for individual procedures, tests and treatments. This ensures consistency in pricing across providers and aligns with the public health insurance system's framework.</p> <p>Professional associations, such as the Czech Medical Chamber, advocate for fair reimbursement rates and may propose adjustments to tariffs during negotiations. These discussions, however, occur within the boundaries of legal and regulatory guidelines set by the government. Moreover, the Association of Health Insurance Companies (Svaz zdravotních pojišťoven or SZP) plays a significant role in the negotiation process on the other side. It acts as a key player representing health insurance companies' interests within</p>

the broader healthcare financing system in the Czech Republic.

For services that fall outside the coverage of public health insurance, the fees are determined by medical practitioners.

PHARMACEUTICALS AND MEDICAL DEVICES

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

Health insurance companies provide coverage for the majority of necessary pharmaceuticals and devices available on prescription by healthcare providers. In cases where pharmaceuticals are excluded from the reimbursement list, such as non-essential medical devices, patients are charged at their own expense, or, if a pharmaceutical is only partially covered by the health insurance, patients pay supplemental fees.

Orphan drugs, which are used to treat rare diseases, are subject to special provisions under Czech law. These pharmaceuticals are often very expensive and may not be included in the regular reimbursement list. The Ministry of Health can approve additional funding or reimbursement for orphan drugs under specific conditions. These pharmaceuticals are usually provided through special funding programmes, which are available to patients with rare diseases, ensuring that they can access treatments that would otherwise be unaffordable.

Early access to drugs that are not officially authorised but show promising results may be granted under certain circumstances, such as compassionate use or for patients with life-threatening conditions. The Ministry of Health may approve early access to these treatments, often in partnership with pharmaceutical companies. These products may be reimbursed by public health insurance on a case-by-case basis or patients may be required to pay for them, depending on the specific regulatory conditions.

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

In the Czech Republic, the prices of pharmaceuticals and medical devices are primarily determined through a combination of government regulations, negotiations between the SÚKL and manufacturers, and external factors, such as international price comparisons. The process ensures that prices are set in a way that balances the availability of new and effective treatments with the financial sustainability of the public healthcare system.

Pricing mechanisms

The maximum price per pharmaceutical product is determined by the SÚKL based on a request in an administrative proceeding. Three main rules apply for setting the manufacturer's maximum price, which is the price that the manufacturer cannot exceed when introducing a pharmaceutical product to the market:

1. The first rule sets the maximum price as the average of the three lowest manufacturer prices from countries in the reference basket (EU countries excluding Bulgaria, the Czech Republic, Estonia, Luxembourg, Austria, Romania, Greece, Cyprus and Malta).
2. The second rule applies when the pharmaceutical is not available in three reference countries, and results in setting the maximum price based on the manufacturer's price in a written agreement with health insurance companies (maximum price agreement).

3. The third rule applies if the pharmaceutical is not available in three reference countries and no agreement on the maximum price exists, in which case the maximum price is determined based on the manufacturer's price of the nearest therapeutically comparable product.

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.

Key case law in the health insurance context has focused primarily on the inconsistent approach to the reimbursement of otherwise unreimbursed healthcare services, as outlined in section 16 of the Public Health Insurance Act. The courts often review, on a case-by-case basis, whether health insurance companies should cover treatments not covered under standard health insurance if they are necessary and cannot be replaced with alternatives.

Under Czech law such exceptional insurance coverage is justified when the following conditions are fulfilled simultaneously: (1) the treatment is not covered under standard health insurance; (2) it is an exceptional case; and (3) the treatment is the only viable option for the patient. The second and third conditions remain contentious due to the lack of clear legal definition of the terms 'exceptional case' and 'viable option'. Recent case law, however, appears to be developing consistently, leading to the following conclusions of the Supreme Administrative Court:

- The third condition must be interpreted with reference to the right to health protection under the Charter of Fundamental Rights and Freedoms, which includes the right to free healthcare on the basis of public health insurance. In this regard, the condition of 'the only viable option' must be considered fulfilled even if the insured individual has another covered medical treatment option available to them, provided that such an option is demonstrably significantly less effective and does not realistically represent a comparable treatment alternative.¹
- The second condition, that is, the exceptional case condition, cannot be limited to the insured's health alone. It can also result from previous treatment decisions, which may be influenced by the health insurance company. The Court has stated that exceptional circumstances may be determined by various situations, such as rapid disease progression and the risks of delaying treatment. It is also acknowledged that the exceptional case condition does not imply that the patient's case is unique, meaning that multiple patients may encounter similar circumstances.²

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.

The lower chamber of the Czech Parliament is currently debating a major draft amendment

¹ Judgment of the Supreme Administrative Court, case no 5 Ads 228/2019-81.

² *Ibid.*

to the Public Health Insurance Act, which is aimed at addressing rising healthcare costs and current system needs by revising the pricing and reimbursement mechanisms for pharmaceuticals and medical devices. The topic of supplementary health insurance has been widely discussed in relation to this draft amendment. While the draft amendment does not explicitly specify supplementary insurance, the Minister of Health has suggested that they would be enabled through bonus programmes that the health insurance companies may implement.

The draft amendment aims to provide health insurance companies with greater scope to create rewards for individuals demonstrating good healthcare, thereby contributing to the promotion of prevention.

The proposed key changes include:

- enhanced prevention measures: the draft amendment increases funding for preventive benefits, the conditions these benefits may have on proper healthcare practices and allows health insurance companies to create their own motivational programmes, such as initiatives in stomatology;
- facilitation of cross-border care: the draft amendment aims to simplify the reimbursement of medical services provided abroad, including long-term treatment cases, and introduces the possibility for insurers to enter into agreements with foreign healthcare providers;
- efficient use of financial resources: the draft amendment involves reallocating part of the reserve fund into the basic fund and allows a part of insurance contributions to be used for supporting medical education and patient organisations, and improving care quality.
- new rules for pharmaceutical reimbursement: the draft amendment further adjusts reference pricing for pharmaceuticals and establishes improved conditions for innovative pharmaceuticals and food for special medical purposes, aiming to accelerate their availability while ensuring cost sustainability; and
- changes in dentistry and non-medical care: the draft amendment emphasises prevention, introduces flexible reimbursement for modern treatment methods, and expands the competencies of psychologists and other non-medical professionals.