This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

*Civil law*

**National law database**

<table>
<thead>
<tr>
<th><strong>Language:</strong></th>
<th>Czech</th>
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<tr>
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<td><a href="http://www.portal.gov.cz">www.portal.gov.cz</a></td>
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<tr>
<td><strong>Nature:</strong></td>
<td>Official law database</td>
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<td><strong>Organisation responsible for the website:</strong></td>
<td>The government of Czech Republic</td>
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**Legal UHC start date**

1991

**Source:**


**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
Search list of contents:

Regulation

Overview and publication details .................................................. 2
Regulation Czech Republic .............................................................. 3
Regulation

Czech Republic
HSPM Members:
HSPM Contributors:
Czech Republic: Regulation

2.8 Regulation

The Czech health system is based on compulsory SHI, and the organizational relationship between health insurance funds and health care providers is based on long-term contracts. In terms of regulation, the three main actors in the health system are the health insurance funds, the central government and the regional authorities. The health insurance funds collect SHI contributions and purchase health services; the largest health insurance fund, the VZP, also manages a special central account used for reallocating SHI contributions among the health insurance funds according to a risk-adjustment scheme. The central government plays an important role in the regulation and governance of the health insurance funds; to a lesser degree it also participates in their managerial decisions through the funds' boards of trustees. Finally, the regional authorities play an important role in the health system by registering and supervising all health care providers other than the teaching hospitals and specialized health care centres that are directly subordinate to the Ministry of Health or other ministries. The Ministry of Health is also responsible for licensing health professionals. At the same time the regions own a considerable number of inpatient health care facilities.

2.8.1 Regulation and governance of third-party payers

The health insurance funds in the Czech Republic are quasi-public, self-governing bodies that operate primarily under public law. The funds are not permitted to make profits and are open to any applicant who is legally entitled to health insurance in the Czech Republic; any kind of risk selection or cream-skimming is not permitted. Although all of the health insurance funds serve fundamentally the same purpose, the VZP as the largest one differs from the others in terms of its role and, to a certain extent, its organizational structure and governance.

Two important features distinguish the role of the VZP from that of the other funds. First, its solvency is explicitly guaranteed by the state; as such, it functions as a safety net for members of health insurance funds that close or go bankrupt. Second, the VZP manages the special central account used for reallocating SHI contributions according to a risk-adjustment scheme (see section 3.3.3).

The VZP also differs from the other health insurance funds in terms of its organizational structure. Because of its size, it has 14 regional branches as organizational units, one in each region of the Czech Republic. In contrast, some of the other health insurance funds are relatively small and do not operate on a nationwide basis, although they are free to expand if they so choose. An example of one of the smaller funds is the Škoda Employee Insurance Company (Zdravotní pojišťovna Škoda), which had nearly 140,000 members in 2012 (Chamber of Deputies, 2013).

In terms of governance, the VZP and the other health insurance funds are managed by a director, who is appointed by a board of trustees (správní rada). The board provides oversight of the director's decisions, and the decisions for which explicit agreement by the board is required are defined by law. In the case of the VZP, the board of trustees has 30 members, 10 of whom are nominated by the Ministry of Health and appointed by the government; the other 20 are elected by the Chamber of Deputies in proportion to the numerical strength of the political parties in the Chamber. The members of the board of trustees are not personally liable for decisions made by the board as a whole or for the performance of the health insurance fund.

In other health insurance funds the composition of the board is based on a system of tripartite representation. Like their counterparts at the VZP, the members of the board have no personal liability for decisions made by the board as a whole or for the performance of the health insurance fund. One third of the members are appointed by the government; another third consists of elected representatives of the largest payers of employer contributions (usually from industry, but in some cases also from civil service); and the remaining third are elected representatives of trade unions. Voting procedures for the latter two groups are defined in a directive. Altogether, there are usually 15 trustees represented on the board.

All of the health insurance funds also have a supervisory board (dozorčí rada) at the highest level of
governance. The narrow scope of its regulatory oversight means, however, that its role is rather limited. Its main tasks are to ensure that the health insurance fund follows its own internal rules, as well as its financial and operating plan (zdravotně-pojišťný plán). The supervisory board of the VZP consists of 13 members, three of whom are nominated by the Ministry of Health, the Ministry of Finance and the Ministry of Labour and Social Affairs and appointed by the government, and 10 of whom are elected by the Chamber of Deputies, again using a proportional method. The supervisory board of the other health insurance funds usually consists of nine members and is based on a system of tripartite representation similar to that used to constitute the board of trustees. The three members appointed by the government are nominated by the Ministry of Health, the Ministry of Finance and the Ministry of Labour and Social Affairs.

To help ensure that the health insurance funds are held accountable for their performance, they are obliged every autumn to submit their financial and operating plan for the next year (zdravotně-pojišťný plán). This serves as a business plan per se, and also contains information concerning contracting and purchasing policies, the use of resources and planned investments in the organizational structure and information systems. After the financial and operating plan has been approved by a health insurance fund’s board of trustees, it is submitted to the Ministry of Health, which reviews the document in joint collaboration with the Ministry of Finance. Subsequently, the plan is sent to the central government, which submits it for final approval to the Chamber of Deputies. If the plan is not approved by the Chamber before the start of the subsequent year, a provisional arrangement is sought. A similar procedure is used for approving the final accounts and annual reports of the health insurance funds. However, the Chamber rarely refuses to approve or amends plans so the main oversight and de facto approval lies with the Ministry of Health and the Ministry of Finance.

On a quarterly basis, the health insurance funds submit their financial results and other requested information to the Ministry of Health and the Ministry of Finance, which review these reports and carry out regular inspections and spot checks. If irregularities or errors are identified, the Ministry of Health may call for correction. In more serious cases the Ministry can place a health insurance fund under forced administration or, as a measure of last resort, can revoke its operating licence. This may happen, for example, in cases of poor economic performance, if a fund is in serious debt or cannot meet its liabilities, or as a result of failure to comply with the public interest. Members of a health insurance fund whose licence has been revoked are automatically insured with the VZP. So far there has been only one example of forced administration of a health insurance fund by the Ministry of Health. In 2005 the VZP was put under forced administration for almost six months due to poor economic performance and large debts. With regard to the health insurance funds’ internal accounting systems, the Ministry of Finance publishes a directive that (a) specifies the different accounts that health insurance funds must create, and (b) limits transfers between these accounts so that, for instance, only a certain percentage of revenues can be spent on operating expenses. Examples of internal accounts include a reserve account; an account for financing health promotion programmes; an account for financing investments; an account to cover operating expenses; and, of course, an account for reimbursing providers for health services.

Finally, to start a new health insurance fund, applicants must apply for a licence from the Ministry of Health. Applicants are required to set aside a financial reserve (in the reserve account described earlier) before permission to start the new fund may be granted; after the fund has been established, the reserve should function as a financial buffer in case of a temporary lack of liquidity. Within one year after foundation, a new fund must furnish proof that it has at least 50 000 insured individuals.

During the licensing process the application is reviewed by the Ministry of Health and the Ministry of Finance. Both ministries can request to review additional information or supporting documents. The Ministry of Health must decide on the application within 180 days of receiving it. If all conditions are fulfilled, the applicant is legally entitled to a licence, but only legal entities residing in the Czech Republic may submit an application. Mergers of health insurance funds have to be approved by the Ministry of Health, which assesses whether the merger is not disadvantageous to the system of health insurance. Health insurance funds typically have merged in the past if one of the funds faced financial difficulties or in order to benefit from shared structures and increased efficiency.

2.8.2 Regulation and governance of providers

The regional authorities are responsible for registering hospitals and other health care facilities that are not
owned or operated by the state (that is, the private practices of nearly all providers of ambulatory care, as well as the majority of inpatient care providers and balneological care). A variety of laws and directives define the technical, staffing and hygienic requirements that all providers must fulfill in order to be permitted to supply health care services. Non-state providers may offer health services only after they have been registered by the relevant regional authority.

As part of the registration process, the type and scale of services that a provider is permitted to offer are defined. If there are any major changes in a provider’s services or technical equipment, they must report these changes to the regional authority. Upon successful registration, the provider usually concludes a contract with the health insurance funds. In theory, the provider could refrain from signing a contract and receive direct reimbursement from patients for any services provided. With the exception of dental services, however, this does not occur very often.

Regarding the quality of health care delivery, the Ministry of Health sets minimum criteria for material and technical equipment and qualifications of medical staff. These criteria have to be fulfilled and continuously maintained, otherwise a health care facility is not allowed to register or has to cease to provide health care services. In the case of private providers, monitoring is the responsibility of regional authorities and professional medical chambers. Apart from the requirements concerning personnel and equipment, there is no system-wide compulsory accreditation system for quality standards. The Ministry of Health is currently developing a set of quality indicators to assess inpatient care. The first pilot collection of data took place between April and June 2013. At the time of writing, the results are not yet available.

Since 2012 minimum requirements for staffing of health services have been set up by a Decree of the Ministry of Health. Before 2012 the minimum requirements for staffing of various types of ward and provider were usually specifically determined by the contracts with health insurance funds. The Decree regulates most health providers. Prior to 2012 the providers were obliged to ensure the safety of provision of services by employing adequate numbers of personnel, but the legal requirements were not specific.

The regions manage, directly or indirectly, a large share of hospitals. Some regions, such as Středočeský kraj, have sold several smaller hospitals to private owners; other regions have outsourced hospital management, a common practice in other European countries. Nevertheless, the vast majority of regional hospitals still remain in public ownership, despite their commercial legal status (see section 2.4).

Almost all primary and specialized ambulatory care physicians in the Czech Republic run private practices, which in principle are small businesses under private law.

### 2.8.3 Registration and planning of human resources

In accordance with EU legislation, physicians graduating from medical schools in the Czech Republic must complete a postgraduate training programme in a selected medical specialty if they desire to practise without supervision. The Ministry of Health is responsible for accrediting these programmes, as well as for administering the standardized state licensing exam (státní atestační zkouška), which physicians take at the end of their specialized postgraduate training. A diploma in the respective medical specialty is awarded based both on the results obtained in this exam and the professional qualifications of the applicants. To open a private practice, physicians must also apply for registration with the respective regional authority. For more information on the training and licensing of health professionals, see section 4.2.

The Ministry of Health also accredits similar postgraduate training programmes for dentists, pharmacists, nurses and paramedical personnel. Nurses are granted a permit to work without supervision if they have passed a bachelor-equivalent degree in certain care-oriented fields of study (fully qualified nurses). Otherwise, nurses have to work for three years under supervision to receive this grant. Passing the postgraduate exam, however, is necessary if members of these groups of medical personnel wish to pursue a specialized qualification.

A parallel process involves recognizing the professional qualifications of medical doctors and other health care professionals educated in other EU Member States. This process is in line with Directive 36/2005/EC and is conducted by the Ministry of Health. To obtain the recognition of a foreign qualification the candidate has to go through a two-stage process: 1) the diploma must be recognized by one of the Czech universities as valid and equivalent to a Czech diploma; and 2) the candidate has to pass an exam in
Czech. The exams tend to be very rigorous and demanding, because once they are passed, the applicant is (with some possible additional conditions for certain countries) able to practise in all EU Member States.

The Czech Medical Chamber, the Czech Chamber of Dentists and the Czech Chamber of Pharmacists may determine the conditions under which their members may engage in private practice. They set out the professional requirements for the provision of care and also supervise the content and quality of lifelong education. Within this context, the Czech Medical Chamber grants licences to its members based on their medical specialties. Although the requirements for obtaining these licences generally go beyond those specified by law, they do not replace the diploma granted upon passing the state licensing exam. The Chambers are non-profit-making organizations and their expenses are covered exclusively by membership fees, donations and proceeds from any penalties against members (for example, for violating a Chamber’s ethical code). Membership of a Chamber is compulsory for all practising physicians, dentists and pharmacists. The number of private practices is in principle restricted not by the respective Chambers but rather by the limited number of contracts the health insurance funds are willing to conclude in a given area.

2.8.4 Regulation and governance of pharmaceuticals

Regulation of pharmaceutical products

The Ministry of Health, the SÚKL, the Ministry of the Environment, and the State Office for Nuclear Safety are responsible for the regulation and governance of pharmaceuticals.

The Ministry of Health approves and controls specific treatment programmes; regulates the use of non-registered pharmaceuticals (for example, within specific treatment programmes or in case of a threat to public health (Law no. 378/2007 Coll.)); takes part in the preparation of the European pharmacopoeia; defines the Czech pharmacopoeia that describes the parameters of pharmaceuticals production and manipulation; and controls and makes publicly available lists of individuals authorized to dispose of non-used or expired pharmaceuticals.

The Ministry of the Environment assesses pharmaceuticals containing genetically modified organisms and assesses impacts of pharmaceuticals on the environment. In the case of radiopharmaceuticals, the State Office for Nuclear Safety also takes part in the registration and clinical assessment.

The SÚKL is the main regulatory body for pharmaceuticals. It is a national administrative authority directly reporting to the Ministry of Health. The Institute is responsible for the supervision of properties of medicinal products for humans. All the activities of the Institute relate to monitoring the quality, safety and efficacy of pharmaceuticals in all stages of development, sale and use. For this purpose the Institute uses a system of preliminary reporting, licensing/authorization and registration procedures, inspections, laboratory controls and monitoring of practical use of medicines. The SÚKL classifies the pharmaceuticals in the registration process into one of four categories: only on prescription; only on prescription with restriction (for example, Subutex, cannabis for therapeutic purposes, “abortion pill”); without prescription; and without prescription with restriction (for example, pseudoephedrine – restriction on quantity).

The SÚKL identifies and sanctions illegal conduct. Activities requiring effective authorization and supervision by the SÚKL include manufacturing; import; distribution; supply or sale; preparation and parallel import; performing clinical trials and reference laboratory activities. In order to enforce sanctions the Institute cooperates closely with other institutions in the Czech Republic and abroad (in particular with the Czech Police, the Customs Administration, the Czech Agriculture and Food Inspection Authority (CAFIA), and other control authorities of the EU Member States).

The SÚKL authorizes any proprietary pharmaceutical prior to its placement on the market in the Czech Republic. The marketing authorization procedure includes an assessment of a dossier, in which the future marketing authorization holder (MAH) evidences the safety, efficacy and quality of the product. Furthermore, the indications, contra indications, dosage of the product, and general classification for supply, as well as the package leaflet for the patient and proposed texts on the labelling of the medicinal products, are assessed. The Summary of Product Characteristics (SPC) forms part of the marketing authorization. It serves as the key source of information about the medicinal product for doctors and health care professionals.

In 2013 the surveillance activities of the SÚKL were extended to narcotic and psychotropuc substances.
The SÚKL is also charged with the surveillance of quality and safety of human tissues and cells intended for use in humans.

The Institute is entitled to take action where a risk to public health arises, to impose penalties, and to request necessary documentation. In the area of medical devices the Institute ensures control of health care providers, investigation of adverse incidents and control of clinical trials. Generic substitution has been allowed in pharmacies since 2008. Electronic prescription has been possible since 2009, but it is not used very frequently at the time of writing.

**Regulation of wholesalers and pharmacies**

Wholesalers need permission from the SÚKL to distribute pharmaceuticals. The SÚKL controls wholesalers and may fine them or suspend or cancel the permission to distribute pharmaceuticals. All pharmacies have to be registered by the SÚKL and meet certain requirements on staff education and training. Mail order or Internet pharmacies have to be listed by the SÚKL. They may only sell pharmaceuticals in the category "without prescription and without restriction". Internet pharmacies have to publish all necessary information about sold pharmaceuticals and they have to ensure safe delivery. Ordered pharmaceuticals have to be sent within 48 hours. During office hours pharmacists or pharmacist assistants have to be accessible for consultation.

**System for pricing prescription pharmaceuticals**

Since 2008 the SÚKL has been responsible for determining the maximum prices of medicinal products and for determining the level and conditions of reimbursement of medicinal products. Before 2008 the Ministry of Finance set pharmaceutical prices and the Ministry of Health determined reimbursement conditions.

Only the prices of pharmaceuticals covered by the SHI are regulated. The price regulation is based on a combination of two mechanisms: 1) the maximum end-customer price – this is the average of the three lowest prices in the EU, and 2) a maximum trade margin determined by the so-called Price Decree by the Ministry of Health (usually a certain proportion of the ex-factory price). The conditions of reimbursement from the health insurance system are also regulated (prices usually consist of SHI reimbursement and co-payments from the patients). There is a system of reference groups, each consisting of drugs with similar effects and safety levels (the pharmaceuticals within a group might be substituted at the beginning of treatment). According to the law there should be at least one fully reimbursed pharmaceutical in each of the 195 existing groups. In reality, there are approximately 1500 fully reimbursed pharmaceuticals.

The SÚKL attempts timely re-evaluation of price regulations for pharmaceuticals in order to reduce the cost for pharmaceuticals, but its capacity is limited. Pharmaceutical costs rose until 2009 but have more or less stagnated since then (see section 3.1). In order to reduce pharmaceutical costs, some insurance funds (for example, the VZP) publish “positive lists” of pharmaceuticals. The respective insurance funds list pharmaceuticals with the best price for the fund and encourage physicians financially to prescribe pharmaceuticals from these lists. In theory, insurance funds may negotiate pharmaceutical prices individually with companies.

**2.8.5 Regulation of medical devices and aids**

In aspects of patient safety the key organizations are the Ministry of Health and the SÚKL. The SÚKL controls how providers use medical devices, examines adverse effects and oversees clinical trials. The Ministry of Health controls the SÚKL, re-examines the administrative decisions made by the SÚKL, sets up methodological guidelines for the SÚKL, and maintains international relations and cooperations with regulatory bodies of other EU countries.

Reimbursement rates for medical devices are regulated directly by the health insurance funds. There is currently a ministerial reform proposal aimed at moving this responsibility to the SÚKL. The proposed law also includes the establishment of a registry, as well as a new classification of medical devices and aids. The registry should contain all necessary information about all devices on the market and the new classification is aimed at more clarity and comparability in procurement of these devices.

**2.8.6 Regulation of capital investment**
Generally the responsibility for capital investments lies with the providers. There is no coordinated central oversight of capital investments and providers are more or less free to dispose of financial means obtained through reimbursement by insurance funds (whether to use them for investments, salary increases or current expenditure). However, every provider owned by a public entity (state, regional government or municipality) must adhere to general rules on public procurement procedures. In practice, most significant capital investments are consulted with and approved by the public owner. This is due to both financial and managerial reasons. Some investments are supported directly by the owner and if, for instance, a regional government owns more than one hospital in the region, it may want to regulate capital investments to prevent duplication of purchases of costly devices.