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>Swedish and English</th>
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<tr>
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<td><a href="http://www.lagrummet.se">www.lagrummet.se</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>
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**Legal UHC start date**

1955

**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)
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Regulation

Sweden
HIT: 2012 - Anell A, Glenngård AH, Merkur S
HSPM Members: Vårdanalys, The Swedish Agency for Health and Care Services Analysis - Lund University School of Economics and Management
HSPM Contributors: Anell A, Glenngård AH, Östh T, Lennartsson F, Merkur S
Sweden: Regulation

2.8 Regulation

The Ministry of Health and Social Affairs is responsible for developments in areas such as health care, public health, social insurance and social issues. The Ministry draws up terms of reference for government commissions and draft proposals for parliament on new legislation, and prepares other government regulations. The most important law regulating the provision of health care is the Health and Medical Services Act of 1982. The Act requires the county councils to promote the health of their residents and to ensure equal access to health care. Care for older and disabled people by municipalities is regulated by the Social Services Act of 1980, which states that older people have the right to receive public services and help at all stages of life. People with disabilities are entitled to support also under the Act Concerning Support and Service for People with Certain Functional Impairments (1993). The most important law regarding dental care is the Dental Care Act of 1985 (1985), which states that the county councils are responsible for providing high-quality dental care for all their citizens. Other laws regulate the responsibility and obligations of personnel, confidentiality, the qualifications needed to be able to practise medicine and rules on how to handle patients’ records.

2.8.1 Regulation and governance of third-party payers

The market for VHI is still small in comparison with other European countries but it is growing. An important reason for having individual private insurance is to be able to get quicker access to a specialist in ambulatory care and to avoid waiting lists for elective treatment. In 2000, about 103 000 people had private health insurance compared to 382 000 people in 2010. More than 80% of all private health insurance was, however, paid for by employers in 2010 and only 6% was paid for directly by individuals (Swedish Insurance Federation, 2011). Private health insurance is thus to a large extent linked to occupational health care services.

2.8.2 Regulation and governance of providers

The National Board of Health and Welfare is the government’s central advisory and supervisory agency in the field of health services, health protection and social services. The agency must follow up on and evaluate the services provided to determine whether they correspond to the goals laid down by the central government. Regulations produced by the National Board of Health and Welfare state that regular, systematic and documented work should be conducted to ensure the quality of care. Furthermore, all members of staff are formally obliged to participate in quality assurance programmes.

In 2011 a new Patient Safety Act (2010) came into force. According to the Act, health care workers are personally responsible for their own actions. The Act states that responsibilities of health care providers include: the implementation of systematic patient safety work and preventive work; an obligation to analyse adverse events; a requirement to inform patients and relatives as soon as possible when harm occurs; and that patients and relatives should be a part of the patient safety work. If a patient suffers an injury or disease in connection with his/her medical treatment, or is exposed to risk because of his/her treatment, the provider is obliged to report the incident to the National Board of Health and Welfare. Also patients and relatives can make referrals to the National Board of Health and Welfare. The Board can then issue a critique of the provider and may send a report to the HSAN with a request regarding disciplinary measures.

All public procurement of goods and services over a certain threshold value (€125 000 for central government and €193 000 for other contracting authorities, including municipalities and county councils in 2010) is governed by the Swedish Public Procurement Act (2007). The Act is largely based on the EU Directive 2004/18/EC concerning public procurement. The aim of the procurement rules is to ensure that contracting authorities, such as central government authorities and county councils, use public funds to finance public purchases in the best possible way by taking advantage of competition in the relevant market. At the same time, the rules and regulations aim to afford suppliers the opportunity to compete on equal terms for each public procurement.
Five principles apply to all public procurement according to the Act. The “principle of non-discrimination” means that it is prohibited to discriminate against suppliers, directly or indirectly, on the grounds of nationality. The “principle of equal treatment” means that all suppliers should be treated equally, for example, have access to the same information. The “principle of transparency” means an obligation for the contracting authority to create transparency by providing information about the procurement procedure and how it will be conducted. The “principle of proportionality” means that requirements for the supplier and requirements in the specification must have an obvious link with and be proportionate in relation to the subject matter of the contract. The “principle of mutual recognition” means that diplomas and certificates issued by authorities authorized by a Member State will also apply in other EU/European Economic Area countries.

A county council cannot prevent a practitioner from establishing a private practice; the regulatory power is restricted to controlling the public financing of private practitioners. County councils regulate the establishment of new private primary care practices that are eligible for public funding through conditions for accreditation. A private health care provider must have an agreement with the county council in order to be publicly reimbursed. If the private provider does not have an agreement, the provider is not reimbursed and the patient will have to pay the full charge to the provider. However, there are private providers (physicians and physiotherapists) who are reimbursed by the county councils but based on earlier state regulation (nationella taxan). This old principle for reimbursement of providers operates in parallel, and sometimes in conflict, with more recently adopted principles of payment to private providers.

In 2009, in connection with the choice reform in primary care (see section 2.9.2 Patient choice) a law giving private and public providers equal conditions for establishment was adopted (Act on System of Choice in the Public Sector, 2008). According to the law, payment of providers should follow the patients’ choice of provider.

Since the responsibility for provision of care is decentralized to the 21 county councils and regions the conditions for accreditation vary throughout the country. Regarding the recently implemented primary health care reform, it is regulated by law (Act on Freedom of Choice in the Public Sector) that freedom of establishment applies to all (public and private) health care providers that fulfil the requirements decided by the local county council. The requirements primarily focus on the minimum level of clinical competences represented in the primary care unit. The same requirements apply to both private and public providers.

2.8.3 Registration and planning of human resources

All health care personnel come under the supervision of the National Board of Health and Welfare. The Board is also the licensing authority for physicians, dentists and other health service staff (see section 4.2.3 Training of health workers). In addition, the Board is the designated authority under European Community Directives for the mutual recognition of diplomas and certificates relating to the health professions. The licences are not given for a specific period of time, that is, health care personnel do not have to re-apply in order to keep their licence. However, in cases of malpractice the National Board of Health and Welfare can withdraw a licence after a decision by the HSAN (see section 2.9.4 Complaints procedures).

2.8.4 Regulation and governance of pharmaceuticals

The MPA is the government agency charged with approving new pharmaceutical products and granting permission for drug production. Its activities are regulated by a law governing medical products, which has been adapted to fit EU regulations. The MPA is also responsible for providing information about medicines, giving permission to carry out clinical trials, approving licences and controlling natural remedies and other medicine-related products.

The Medical Products Act of 1992 constitutes the basis for all activities connected with pharmaceuticals and drug distribution in Sweden. The fundamental requirements for medicinal products stated in the Medical Products Act (1992) also apply to natural remedies. A new natural medicine should only be sold when the MPA has granted marketing authorization. The authorization is valid for five years and can then be renewed for each subsequent five-year period.

The list of drugs included in the National Drug Benefit Scheme has been established by the TLV since 2002. Moreover, in 2010 the mandate of the TLV was augmented to also include assessment of hospital
The Swedish government has set a time limit of 120 days for decisions on reimbursement and pricing in Sweden. Value-based pricing is practised for prescription drugs, which means that the price of a drug should reflect its value to society rather than the marginal cost of production or prices in other countries. A societal perspective is used when the TLV assesses the cost–effectiveness of a pharmaceutical and makes decisions regarding reimbursement. All costs and benefits related to treatment should be taken into account, irrespective of where in society they occur. Preferably the cost–effectiveness should be expressed as costs per quality-adjusted life-years when companies apply for reimbursement. The Swedish reimbursement system is mainly product oriented. This means that medicines are either granted or denied reimbursement status for the whole of its approved area (by the MPA). The TLV may, however, restrict the reimbursement of a pharmaceutical to a narrower patient group than it is approved for by the MPA.

With regard to new products, the TLV makes decisions on applications from companies that want their medicines to be eligible for reimbursement. In 2010, the TLV handled 100 applications regarding new products – 54 regarding pharmaceuticals and 46 regarding medicinal products. Of the applications for pharmaceuticals, 44 decisions regarding new original preparations were made. Of those, 2 applications were denied reimbursement and 28 were approved with restrictions, for example regarding a narrower patient population than had been applied for (TLV, 2011). Another task for the TLV is to assess the medicines included in the benefit scheme before 2002. This exercise started at the end of 2003 and is ongoing. The medicines are reviewed according to therapeutic groups.

The Swedish pharmacy monopoly was deregulated in 2009, allowing new owners and chains to operate pharmacies in Sweden. In 2011 there were 13 pharmacy operators in Sweden, compared to the previous monopoly situation with one state-owned pharmacy. There are about 1200 pharmacies throughout the country. Pharmacies are obliged to provide all prescribed drugs within a time limit of 24 hours. The sale of selected OTC drugs, such as nasal sprays and painkillers, in licensed facilities outside pharmacies was also allowed from 2009.

Since 2002, generic substitution has been mandatory between medically equivalent drugs. The pharmacy dispenses the least expensive generic drug or parallel-imported drug available, regardless of what brand name the prescribing physician has written on the prescription. Physicians may oppose substitution for medical reasons, but this rarely happens. If a patient refuses a generic product, they have to pay the difference between the generic product and the more expensive branded pharmaceutical out of pocket.

At the local level, county councils have formulary committees (läkemedelskommitét) whose responsibility is to make recommendations concerning the use of pharmaceuticals. By law every county council should have at least one formulary committee (Medical Products Committees Act 1996).

The regulation of medicinal products is similar to that of pharmaceuticals. The MPA works to ensure that medicinal products are safe, effective and of good quality and the TLV decides which medicinal products are to be included in the subsidies system (see section 2.8.4 Regulation and governance of pharmaceuticals).

### 2.8.5 Regulation of medical devices and aids

According to the Swedish Medical Devices Act (1993) and the Medical Devices Ordinance (1993) a medical device must achieve its intended purpose as designated by the manufacturer and involve no unacceptable risk to patients, staff or third parties. The medical devices legislation is supervised by the MPA. Each medical device placed on the market must comply with the requirements in the Medical Devices Act, irrespective of how the device is to be used and risks associated with its use. A device is considered suitable if, when used as intended, it achieves the performance intended by the manufacturer and meets high standards for the protection of life, personal safety and health of patients and others.

### 2.8.6 Regulation of capital investment

There are recurrent and capital budgets for health care at different organizational levels, that is, county council, district and clinic levels. Decisions about capital investments can take place at any of these levels, depending on the size of the investment. For smaller investments, the decision can be made at clinic level, while larger investments require a decision at a higher level. Thus, the clinic requests funding from the
district board, which in turn may request funding from the county council. All public procurement over a certain value is subject to the Public Procurement Act (section 2.8.2 Regulation and governance of providers).