

## HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

### Authors:

Camilla Appelgren, Emmie Montgomery and Michaela Fischerström, Mannheimer Swartling  
[camilla.appelgren@msa.se](mailto:camilla.appelgren@msa.se), [emmie.montgomery@msa.se](mailto:emmie.montgomery@msa.se) and  
[michaela.fischerstrom@msa.se](mailto:michaela.fischerstrom@msa.se)

## 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).

Healthcare is part of the social security system in Sweden and thus mainly organised, structured and provided in the public domain. At a national level, the Ministry of Health and Social Affairs (Socialdepartementet), supported by national agencies, oversees healthcare policy and high-level management and sets budget for governmental grants to the healthcare sector, while the financing, organising and offering of healthcare is delegated on a regional and local level to the regional authorities (ie, the regions (*regioner*) and the municipalities (*kommuner*), the latter regarding healthcare in ordinary and special housing for elderly people, people with functional impairments, and in schools).

Healthcare in Sweden is divided into publicly and privately funded sectors. Public healthcare is mainly funded by local income taxes, supplemented by subsidies and national government grants (which are financed by national income taxes and indirect taxes) and patient fees (which cover only a small part of the cost for a healthcare visit). Publicly funded healthcare can be provided by both public or private actors under contract with the relevant regional authority (see Q5), where the financing/cost for the healthcare should be the same regardless of a public or private healthcare provider.

As to privately funded healthcare, the costs are mainly covered by the patients themselves. Private health insurance coverage represents only a minor part and is usually offered through employers.

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

The Swedish Health and Medical Services Act (*Hälso-och sjukvårdslagen* – the 'Healthcare Act') sets the overall framework for all healthcare in Sweden. The Healthcare Act *inter alia* stipulates that the publicly funded healthcare system must cover all individuals residing (registered) in Sweden. The Healthcare Act also provides the three basic principles that shall apply to all healthcare in Sweden: that healthcare shall be provided with respect for all humans as being of equal value, that those in greatest need take precedence in receiving treatment, and that healthcare shall be organised in such way as to promote cost-effectiveness.

As provided by the Healthcare Act, it is up to the regional authority to set the level of patient fees for healthcare within its geographical area, although they are usually quite similar. The Healthcare Act also provides that annual caps apply on the fees a patient may pay for publicly funded healthcare (high-cost protection scheme), which means that a patient must only pay for healthcare up to a certain amount (per year). Certain healthcare services, such as cervical screening and mammography, are completely free of charge.

With regard to the organising and financing of healthcare providers, the regional authorities may apply different legal frameworks depending on the type of medical services and operations. As further provided under Q5, these legal frameworks include the Swedish Freedom of Choice Act (*Lag om valfrihetsystem* – LOV) and the Swedish Public Procurement Act (*Lag om offentlig upphandling* – LOU), wherein the regional authorities decide the reimbursement levels and which services are to be covered by the healthcare providers operating within their geographical area (this may vary significantly between different areas of operation and regions).

Privately funded healthcare providers are free to organise and determine the costs and prices for their operations (adhering to the general legal requirements and responsibilities of healthcare providers operating in Sweden, eg, regarding quality and safety). In case both private and publicly funded healthcare services are provided by a healthcare operator, only the portion of the operations that is publicly funded must follow the regional authorities' terms and conditions.

For further information regarding the legal framework for financing and reimbursement of medicinal products and medical devices used within the Swedish healthcare system, see Q12.

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

The Swedish Parliament (*riksdagen*) is the highest legislative body in Sweden, enacting all national laws, including those regulating healthcare (such as the Healthcare Act), and is thus responsible for the framework regarding how healthcare is to be financed and organised in Sweden. It also decides on the budget for state-funded healthcare.

The Swedish Government (*regeringen*) is responsible for implementing the laws passed by the Parliament and formulating national strategies for healthcare. The government also allocates the governmental grants to regions and municipalities to support equal care across the country and to finance special initiatives, for example, in digitalisation or primary care development.

The National Board of Health and Welfare (Socialstyrelsen) is a central supervisory authority that issues regulations and general advice for healthcare that supplements legislation in Sweden. The National Board of Health and Welfare is also responsible for monitoring the development and quality of healthcare, including collecting and disseminating statistics and guidelines for the financing and organisation of healthcare.

The regional authorities are responsible for financing and allocating resources and organising healthcare within their geographical area, including to determine local reimbursement models for healthcare providers.

The Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Regioner – SKR) also has a role in, for example, coordinating work between the regions, with

regard to key regulators and supervisory bodies for financing and reimbursement of medicinal products and medical devices used within the Swedish healthcare system (see Q12).

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

The pandemic has not changed the fundamental funding system for healthcare in Sweden. However, there was an impact on which areas of healthcare were focused on and prioritised, and thus where resources were allocated during this period (and where the effects can still be seen today, eg, in that telemedicine is more common and that certain therapeutic fields which were given lower priority during this period still suffer from long queues). Also, national government funding increased during the pandemic.

**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?**

On a patient level, publicly funded healthcare is available to all Swedish (registered) residents, regardless of age, nationality or place of residence in the country. As provided above, patients pay only a small fee for healthcare visits and the annual cost is capped through the high-cost protection scheme, which (together with reimbursed medicinal products and medical devices, see Q12) limits the patient's costs and aims to make care more affordable for everyone.

It should be noted that there are special provisions in Swedish legislation and international regulations regarding healthcare coverage for non-Swedish residents, asylum seekers, foreigners staying in Sweden without the necessary permits and when a person or its family member is in a cross-border situation (for example when a person seeks care in Sweden but cannot be registered here).

With regard to healthcare providers under the publicly funded healthcare system, Sweden operates under a freedom of choice system: the patient has the right to choose its healthcare provider which has been approved and contracted by the regional authorities. The regional authorities control the establishment of publicly funded healthcare providers within their geographical area by contractually regulating eg, requirements for the clinic's opening hours, the scope of services/therapeutic areas that shall be covered, personnel competence and other organisational aspects, and the financial conditions for the provision of such healthcare (including reimbursement models and patient fees).

Since 2010, the freedom of choice system under LOV is mandatory with regard to primary care (outpatient care that does not require special medical or technical resources or other specific competence). For other types of healthcare (such as specialised care) the system is voluntary. Under the freedom of choice system under LOV, the right to establish a practice and be publicly reimbursed applies to all public and private healthcare providers that fulfil the regional authority's conditions for accreditation.

Healthcare areas and providers not covered by LOV are often procured by the regional authorities through public procurement under LOU. This may, eg, be the case for hospital operators. Under such a framework, the operator that best fulfils the regional authorities' requirements may establish the practice and be publicly reimbursed (regarding reimbursement models for hospitals, see Q9 below).

In order for suppliers of medicinal products and medical devices to provide their products within the publicly funded reimbursement scheme, the products must be authorised by the authorities, such as the Swedish Medical Products Agency (the MPA) and the Dental and Pharmaceutical Benefits Agency (TLV) – see Q12.

## HEALTH INSURANCE FINANCING AND COVERAGE

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

As provided above, the Swedish healthcare system is a mandatory, publicly funded part of the social security system rather than a system based on private health insurance companies with individual premiums.

With regard to healthcare providers authorised to operate and financed by the regional authorities, reimbursed levels are determined according to the region's specific rules. With regard to healthcare providers operating under LOV, a region's reimbursement levels can be based on a combination of different payment models such as:

- fixed capitation for individuals registered ('listed') with the healthcare provider as its primary place of contact/primary care centre (usually the main part of payment);
- variable fee-for-service remuneration linked to performed visits or actions, and
- special reimbursements (such as goal-oriented bonuses or add-ons for geographic location etc).

Private health insurance coverage plays a minor role in Sweden and is mainly designed to provide faster or more specialised care, usually to employees through employers. For private health insurance, premiums are set by the insurance companies. They are usually calculated based on risk assessments of the individual's health status, age, and sometimes work-related factors. In principle, the state has no direct involvement in how these premiums are set, and the legal framework follows general rules for insurance companies and consumer protection.

### 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?

Publicly funded healthcare shall be organised and planned so that residents have access to necessary and medically justified healthcare. There is no defined benefit package and as the responsibility for organising and financing healthcare rests with regional authorities, services may vary to some extent throughout the country. Broadly, however, the publicly financed healthcare system covers public health and preventive services, primary care, in- and outpatient specialised care, emergency care, rehabilitation services, disability support services, patient transport support services, homecare and long-term care, dental care and optometry for children and young people, and adult dental care (the latter with limited subsidies).

Publicly funded healthcare generally covers both physical and telemedicine visits and treatments, as long as the healthcare provider's agreement with the relevant regional authority covers such services and the authority's requirements and guidelines are followed. The regional authorities may have imposed conditions under which telemedicine visits will be reimbursed, eg, that it must qualify as healthcare in accordance with the National Board of Health and Welfare's definition, that the visit is preceded by a sorting in order to exclude

symptoms or diagnoses that should be managed otherwise (eg, through physical examination), and that the requirements for medical record keeping and reporting are met.

## HOSPITAL SECTOR

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

Hospital care in Sweden (both inpatient and outpatient specialised, advanced and emergency healthcare services) is mainly provided through and covered by the publicly funded healthcare system, ie, mainly financed by taxes and supplemented by patient fees. With regard to hospitals, the Swedish regions are grouped into six healthcare regional areas to facilitate cooperation among healthcare providers and to maintain a high level of advanced medical care. Publicly funded hospitals are either state-owned university or regional hospitals (main part), or private actors contracting with regional authorities. Reimbursement to hospital healthcare service providers is determined on a regional level (including in agreement between all involved regional authorities where applicable), see further below.

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

Prices and reimbursement models for publicly funded healthcare in hospital settings are mainly decided by the regional authorities. The healthcare providers are mainly reimbursed through a combination of fixed global budgets/grants, variable fees-per-service payments, or per-case payments based on diagnosis-related groups (DRGs) determined in agreement between the involved regional authorities. The DRG model means that hospitals receive a fixed reimbursement based on diagnosis or treatment category, rather than for each individual healthcare service. Price or volume ceilings and quality-related bonuses may also apply.

For inpatient care, the DRG model is often used, where prices are set per treatment category or diagnosis. The regional authorities define which treatments are included in the DRG system and set the standard tariffs for such services. These tariffs are sometimes adjusted to take into account local cost levels or specific types of care.

In outpatient care, pricing may be a more specific fee-per-service model, often with predetermined fees per consultation or treatment set by the regional authorities.

As provided in Q3, bodies and organisations on both the national and regional levels are involved in the financing, allocation of resources and control of economic efficiency in the healthcare sector. The state (Parliament, government and other national agencies) has a role in guiding the overall principles and standards for financing and reimbursement, and the National Board of Health and Welfare monitors the development and quality of healthcare, including collecting and disseminating statistics and guidelines for financing. The details of pricing and control of economic efficiency are however delegated to the regional authorities and, as provided above, SKR also has a role in coordinating work between the regions.

## HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

In accordance with the above, privately funded healthcare operators are financed through patients' out-of-pocket payments or through private health insurance coverage. Such healthcare providers have more freedom to set their own prices, leading to individualised pricing based on, for example, market conditions, the reputation of the provider, and the complexity of the specific service. Private insurance can cover all or part of the cost of private care. Insurance companies often negotiate specific prices with healthcare providers and may offer package deals.

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

Privately funded healthcare providers are free to set their own prices, with respect to competition rules and other mandatory general laws.

**PHARMACEUTICALS AND MEDICAL DEVICES**

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

Most prescription medicinal products are covered by the Swedish pharmaceutical benefits scheme (the so-called high-cost threshold). The high-cost threshold limits how much patients pay for their reimbursed medicinal products each year. TLV decides which medicinal products are to be covered by the scheme, ie, reimbursed. For a medicinal product to be reimbursed, the pharmaceutical company must submit an application to TLV. A medicinal product that is covered by the pharmaceutical benefits scheme may be substituted for another substitutable product that is also covered by the scheme. TLV designates the product that will constitute a generic substitute in pharmacies for a particular period of time (the so-called 'product of the month').

TLV is also responsible for determining whether a medical device shall be reimbursed by the state, and the pricing and reimbursement of such products. However, the Swedish reimbursement scheme of medical devices is limited to certain medical device consumables (administration of pharmaceuticals, self-monitoring of pharmaceutical levels, and stoma products to patients). For medical devices that are not covered by the Swedish reimbursement scheme but are procured by the Swedish regions, TLV performs health economic assessments to provide the regions with the best possible basis for their decisions.

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

TLV decides on pricing and reimbursement for medicinal products included in the pharmaceutical benefits scheme. The decision is based on clinical evidence and health economic documentation provided by the pharmaceutical companies. Decisions on pricing and reimbursement of pharmaceuticals need to be in-line with the ethical platform, ie, the following three principles: the human value principle; the need and solidarity principle; and the cost-effectiveness principle.

In Sweden, so-called three-party negotiations between the pharmaceutical company, the Swedish regions and TLV often play an important role in pricing. Such negotiations may result in a side agreement, including a confidential rebate, between the pharmaceutical company and the Swedish regions.

For medical devices, freedom of pricing applies. The main rule is that each Swedish healthcare provider decides what medical devices are to be purchased and used within their operations. However, medical devices that are to be used in healthcare shall, as a main rule, be purchased through public tender.

## 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.

One landmark case is the so-called *Cimzia* case. The question in the case was whether TLV could prohibit Region Skåne from entering into a price agreement with a pharmaceutical company regarding refunds on the sale of a medicinal product included in the pharmaceutical benefits scheme. The Supreme Administrative Court held that TLV could not prohibit such price agreements, however the court did not examine whether the actual price agreement was compliant with the Transparency Directive. The judgement was therefore criticised, and the industry expressed a need for clarification.

## 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.

One specific topic currently being discussed is how to improve patient access to medicinal products for rare diseases. TLV was appointed by the Swedish government to investigate this matter; the authority recently published a report and proposed new methods and working procedures in order to strengthen patient access.