

## 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 Denmark is universal and publicly funded. Hospitals are operated and funded by the Regional Administrations (the 'Regions'). By contrast, most non-hospital healthcare services are provided by private healthcare providers who are either wholly or partly funded by the Regions, depending on the level of co-payment applicable to the healthcare service in question. Some non-hospital healthcare services are provided by the municipalities.

Financing through direct government funding is more common than reimbursement, except in certain areas, such as pharmaceuticals. The regulatory powers and responsibilities associated with the financing and management of the Danish healthcare system are divided among the state, the five Regions and the municipalities. The state holds the overall regulatory power, and different central agencies exercise supervisory functions in relation to the Regions, public hospitals and private healthcare providers.

Under the Regional Administration Act, the Regions are the primary actor in the Danish healthcare economy, being responsible for financing, organising and providing the majority of citizen-orientated healthcare services, such as hospital treatment and in-patient psychiatric care. Further, in accordance with the Danish Health Act (DHA), the Regions finance private healthcare providers, such as general practitioners, specialists in private practice, physiotherapists, chiropractors, psychologists, dentists and podiatrists operating within their individual geographic area. For their part, the municipalities finance, organise and provide long-term care services, such as elder care, non-hospital-based rehabilitation, substance-abuse treatment and home nursing, as well as dental care for citizens under the age of 22.

The Danish healthcare system is primarily financed through direct funding provided by the Regions to public and private healthcare providers, and, to a smaller extent, through direct municipal funding. The Regions in turn are jointly financed by the state and the municipalities, with the entirety of said financing stemming from state and municipal tax revenue.

Public funding accounted for 83.52 per cent of Danish healthcare costs in 2023, with private health insurance accounting for only 2.52 per cent, whereas non-profit organisations and co-payment accounted for 0.12 per cent and 13.84 per cent of healthcare costs, respectively.

Because of the level of public funding, private health insurance and private hospitals play a minor role in the Danish healthcare system, even though approximately 2.9 million Danish citizens are covered by some form of supplementary private health insurance. In practice,

such private health insurance is typically provided as an employment benefit, although individual voluntary subscriptions to health insurance carriers are also quite common.

Owing to a statutory healthcare guarantee, persons eligible for publicly funded healthcare services (cf the answer to question 5) can undergo diagnostic tests and routine treatments at select private hospitals at the expense of the Regions, if waiting times in public hospitals exceed 30 days. The programme functions as a safety valve to mitigate long waiting lists for routine procedures in public hospitals.

Co-payment is primarily used to cover some of the cost of pharmacy-purchased pharmaceuticals, various forms of mental health therapy, fertility treatment, physiotherapy and other forms of physical therapy, as well as dental care for citizens over the age of 22.

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

Both the financing and reimbursement of healthcare services are regulated by the DHA, which regulates the provision, financing and reimbursement of healthcare services by the Regions and the municipalities, as well as the Danish Medicines Act (DMA), which regulates the reimbursement of pharmaceuticals.

The financing of the Regions is regulated by the Regional Financing Act, and part of the financing of the municipalities is regulated by the Municipal Redistribution Act. By statute, state grants to both the Regions and municipalities are issued on an annual basis by the Finance Minister, subject to the approval of the Parliamentary Finance Committee.

Industry codes and other private norms exercise a significant influence within the legal framework underpinning healthcare financing and reimbursement in Denmark. Collective agreements play a crucial role in the pricing of private healthcare services (cf the answer to question 10). Further, price-cap agreements between industry associations and the Regions are an important part of the pricing of many hospital-only pharmaceuticals (cf the answer to question 13).

The range, quality and pricing of publicly funded healthcare services offered by healthcare providers in private practice are subject to collective bargaining between the Regions' Wage and Tariff Board (Regionernes Lønnings- og Takstsnævn or RLTN) and the trade unions of the different groups of private healthcare providers, such as the Organisation of General Practitioners (Praktiserende Lægers Organisation or PLO).

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

The Ministry of Finance plays a central role in healthcare financing because it directly determines the size of the annual block grants to the Regions. The said block grants account for approximately 80 per cent of the Regions' funding, and therefore greatly impact the level of financing available for the healthcare system. Various types of grants from the municipalities account for the remaining 20 per cent of Regions' funding.

The practical regulation and supervision of healthcare financing and reimbursement in Denmark is devolved and distributed among a number of state and regional authorities, trade unions and specialised advisory bodies.

The Danish Health Data Authority (DKHDA) is responsible for developing the system of

diagnosis-related-group tariffs ('DRG rates'), which is key to the financing of hospital-based healthcare services. The RLTN is tasked with negotiating flat rates according to which private healthcare providers are remunerated by the Regions for the different healthcare services they provide, for example, consultations, tests and medical checkups. The trade unions of the different healthcare professions, for example, physicians, physiotherapists and chiropractors, negotiate with the RLTN on behalf of their respective memberships (cf the answer to question 10).

The Danish Medicines Agency (DKMA) is a key part of the central government's regulation of healthcare financing and reimbursement in relation to pharmaceuticals. It is responsible for determining which prescription-only ('Rx') pharmaceuticals and pharmacy-only over-the-counter (OTC) pharmaceuticals are eligible for reimbursement based on the recommendations of its internal Reimbursement Committee.

The Danish Medicines Council (DMC) is an independent council funded by the Regions, whose function is to make recommendations on which new pharmaceuticals should be used in public hospitals operated by the Regions based on clinical and health economic assessments.

The Danish courts have jurisdiction to decide all cases concerning decisions made by the Danish authorities, including the authorities tasked with supervising healthcare financing and reimbursement. Given Denmark's universal healthcare system, the courts do not exercise a significant role in connection with the financing and reimbursement of healthcare services.

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

No major, general and permanent changes to the Danish system of healthcare financing and reimbursement occurred following the Covid-19 pandemic.

However, certain areas were temporarily affected, resulting in increased spending on healthcare. During the Covid-19 pandemic, the government deviated from the usual system of financing vaccines. Normally, vaccinations administered to adults in Denmark are, by default, subject to co-payment. Only vaccinations administered against certain predetermined, severe and frequently occurring diseases, or to certain groups of citizens, such as children or pregnant women, are fully financed by the state. Covid-19 vaccines were also financed in this manner during the pandemic and administered on a gratuitous and voluntary basis to the entire population. During the pandemic, the total cost of this vaccination programme amounted to DKK 7.1bn. The total health related expenses borne by the state, Regions and municipalities during the pandemic amounted to DKK 33.7bn.

#### **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?**

Danish citizens and persons legally residing in Denmark have full access to the Danish healthcare system, whereas persons present in Denmark without a valid residence permit can receive emergency and continuing hospital treatment. Non-legal residents are charged for said treatment unless the person can document their entitlement to healthcare treatment in the form of public health insurance in another European Union, European Economic Area (EEA) or Nordic country. All persons under the age of 18 are also entitled to healthcare

services in Denmark.

Danish citizens and other persons eligible for healthcare services in Denmark who have paid for *necessary* medical treatment in the public healthcare system of another EU or EEA country can receive reimbursement of the expenses they incurred in connection with the treatment. Under these reimbursement rules, Danish citizens are required to pay the same amount out-of-pocket for their medical treatment as a citizen of the country in which the treatment was provided would have paid.

Danish citizens and legal residents cannot receive reimbursement for medical treatment received in countries outside the EU or EEA. Expenses associated with such treatment are exclusively covered by the individual's private travel and health insurance or out-of-pocket payment.

Danish hospitals, general practitioners and specialists in private practice are fully tax funded. Financing and reimbursement occur directly between the healthcare providers and either the Regions or the municipalities, depending on the type of healthcare service in question.

Private healthcare providers are eligible for reimbursement if they are authorised to practice under the Authorisation Act. The criterion for authorisation is that the individual has obtained a degree within the relevant healthcare profession at a Danish accredited educational institution or a foreign equivalent. Authorised healthcare providers are subject to the supervision of Danish Patient Safety Authority (DKPSA).

Further, individual private healthcare providers, as well as private hospitals, are required to register their practice, including the type of practice, as well as the name, address and healthcare services it provides, among other things, with the DKPSA.

Private hospitals are only eligible to receive patients through reference from the public healthcare system if they have a special agreement with one of the Regions. The agreements ensure that the private hospitals meet all necessary medical and regulatory requirements and sets out the basis for the Region's payment for healthcare services provided by the private hospital, for example, DRG rates. The agreements contain different mechanisms for ensuring compliance with the regulatory requirements of the DKPSA. Private hospitals are obligated to report any event of relevance to the agreement to the Regions, and to document their compliance with the requirements for quality of treatment and patient safety. In addition to these reports, the Regions may, at any time, audit the patient journals of the private hospitals.

## HEALTH INSURANCE FINANCING AND COVERAGE

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

The Danish public health insurance system is financed solely through general taxation. Taxes are collected at the national level. Municipalities have the authority to set their individual income tax and property tax levels, and the municipal taxes are collected by the national tax administration alongside taxes set at the national level, for example, national income tax. Part of the resulting tax revenue is then used by the national government to fund Danish public health insurance through the distribution of an annual block grant among the Regions.

The annual block grant is distributed among the five Regions based on three components: (1) a base amount of €13,500,000; (2) age-related expenditure needs; and (3) socioeconomic expenditure needs. Accordingly, Regions whose populations are older and/or more socioeconomically disadvantaged receive a greater proportion of the block grant in order to

promote equity in healthcare.

Municipalities also receive block grants from the state, part of which they use to pay for public healthcare. Each municipality is required to pay each Region an amount calculated based on the use of the Region's healthcare services by the residents of the municipality.

There is no mandatory *private* health insurance in Denmark. Private health insurance is optional. Private health insurance carriers are financed by the insurance premiums paid by their customers. The level of private health insurance premiums is determined by the health insurance carriers themselves based on actuarial science, with no governmental involvement.

A judicial review of private health insurance *premiums* is exceedingly rare. Health insurance contracts are regulated by the Danish Insurance Contracts Act, which does not regulate the determination of premiums of private health insurance. Therefore, as a main rule, the principle of freedom of contract applies to the determination of premiums by health insurance carriers. In principle, the levels of such premiums are subject to the specific restrictions concerning for example, unreasonable contract terms in Danish contract law. However, judicial review of health insurance premiums is exceedingly rare.

**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?**

The scope of public health insurance coverage is regulated by statute. Under the Health Act, Regions are required to provide gratuitous healthcare treatment to their residents at public hospitals, general practitioners and specialists in private practice within the Region's geographic area. The Health Act defines the concept of 'treatment' broadly as 'examination, diagnosis, disease treatment, obstetric assistance, rehabilitation, care, as well as prevention and health promotion in relation to the individual patient'. Accordingly, in practice the scope of public health insurance coverage is determined by the treatments offered by public hospitals, general practitioners and specialists in private practice, who generally provide the medical services covered by applicable DRG rates.

Further, the Health Act requires the Regions to provide partial reimbursement for their residents' treatment at chiropractors, and, subject to a referral from a general practitioner, the same applies to treatments at physiotherapists, podiatrists and psychologists.

Under the Elder Act, medical and care services for the elderly are provided gratuitously by the municipalities. Under the Social Services Act, care services for people with mental and physical disabilities are also provided gratuitously by the municipalities.

Alternative treatments, such as acupuncture, are not covered by public health insurance at the municipal or regional level.

Private health insurance carriers have wide latitude in defining the extent of insurance coverage, and there is no specific regulation prescribing mandatory insurance coverage for different medical services. Accordingly, the principle of freedom of contract applies to the health insurance carriers' definition of coverage, limited only by the boundaries of mandatory contract law, for example, the voidability of unreasonable contract terms.

The Insurance Agreements Act contains limited specific regulation of health insurance agreements, mandating, among other things, that health insurance coverage be extended to the harmful consequences of a disease, even when the harm in question occurs after the end

of the insurance term, if the disease occurred during the insurance term. The provision, however, is non-mandatory.

Telemedicine appointments are covered by the 2025 collective agreement between the RLTN and PLO (cf the answer to question 10) and there is no difference between the applicable rate for in-person and telemedicine appointments.

## HOSPITAL SECTOR

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

Each of the Regions provide direct funding to finance both stationary and ambulatory healthcare services provided by all public hospitals within its own geographic area.

Until 2019, the Regions relied on tariff-based financing using DRG rates. In the annual public financing agreement between the government and the Regions for 2019, the tariff-based financing model was abandoned in favour of a value-based framework model. Under the current model, the individual Region allocates a fixed grant for the financing of hospital-based healthcare services in its budget, and the Region's public hospitals are obligated to treat all patients who require healthcare services in accordance with the patient rights enforced by the DKPSA within that financial framework.

DRG rates continue to be used by the Ministry of Finance for assessing the level of block-grants and other forms of public financing (cf the answer to question 3), as well as regional planning and resource-allocation. Further, DRG rates are used for interregional settlements, in instances where residents of one region receive healthcare services from public hospitals in another region. Thus, DRG rates are still a central instrument in the financing of healthcare services in Denmark, and they are decisive in ensuring economic efficiency (cf the answer to question 9).

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

The prices of hospital-based healthcare services are determined using DRG rates (cf the answer to question 8). The DKHDA calculates the applicable DRG rates based on the reported hospital-level operating expenses associated with the provision of healthcare services, in combination with the type and number of specific stationary and ambulatory treatments reported to the National Patient Register on an annual basis by each hospital. Using this data, the DKHDA allocates an average national cost for each unit of the different types of stationary and ambulant hospital treatment, and that cost corresponds to the DRG rate for the treatment in question.

Broadly speaking, the DKHDA develops the DRG rates based on three general requirements: First, the grouping of patients must be clinically meaningful; second, the individual groupings must be resource homogenous; and third, the number of groupings must be manageable.

## HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

Private healthcare providers are financed by the Regions based on a list of fixed treatment-based fees for healthcare services that are set out in collective agreements. Each collective agreement is concluded between the RLTN and the individual healthcare professions' trade unions, for example, the PLO.

Healthcare services provided by specialist physicians, therapists and other private healthcare providers are also financed by the Regions according to fixed rates set out in collective agreements. However, this financing only covers treatments of patients who have been referred to the specialist by their general practitioner. Elective specialist treatments provided without prior referral from a general practitioner are either financed by co-payment or private health insurance.

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

The RLTN is charged with ensuring economic efficiency and determining the prices of healthcare services through negotiations and collective agreements with the various trade unions of the different healthcare professions, for example, the PLO.

**PHARMACEUTICALS AND MEDICAL DEVICES**

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

In Denmark, pharmaceuticals are *primarily* government funded, whereas medical devices are almost *exclusively* government funded. All pharmaceuticals and medical devices used in stationary and ambulant hospital treatment are financed entirely by direct grants from the Regions (cf the answer to question 8). Because medical devices are mostly used in hospital treatments, direct and full government funding is more prevalent in the area of medical devices. Some types of medical devices used outside hospitals, such as hearing aids, are fully financed by the Regions.

Pharmaceuticals used in public hospitals are also fully financed by the Regions. The Regions also determine which pharmaceuticals are to be available as standard treatments at public hospitals, based on the recommendations of the DMC. The recommendations of the DMC are non-binding in principle, but, in practice, they exert decisive influence on the Regions' decision to make pharmaceuticals available at public hospitals. Accordingly, because pharmaceuticals provided as part of treatments at public hospitals are fully financed by the Regions, and the DMC's recommendations de facto determine which pharmaceuticals are available at public hospitals, the DMC occupies a key role in the financing of hospital pharmaceuticals.

The reimbursement of pharmacy pharmaceuticals follows a needs-based system, in which both Rx and OTC pharmaceuticals are eligible for reimbursement, subject to a pharmaceutical-specific grant by the DKMA. The conditions for reimbursement vary for Rx and OTC. Reimbursement is granted based on sections 144 and 152 of the DHA following recommendations by the Reimbursement Committee of the DKMA.

For both Rx and OTC pharmaceuticals, reimbursement occurs through settlement between the pharmacy and the Regions, and the reimbursement is thus deducted from the price paid by the patient at the pharmacy. Rx pharmaceuticals can either be covered by general or conditional reimbursement. General reimbursement applies to all persons eligible for public

healthcare services (cf the answer to question 5). Conditional reimbursement can be granted for a certain patient group, the treatment of specific diseases or a combination thereof. OTC can only be covered by conditional reimbursement. Individual conditional reimbursement can also be granted in certain cases to individuals, if applied for by their general practitioner.

For the individual patient, their co-payment for pharmacy purchases of reimbursed Rx and OTC pharmaceuticals varies based on the patient's total annual expenses for reimbursed pharmaceuticals, as well as the age of the patient. Reimbursement is always granted exclusively to the cheapest pharmaceutical within a given therapeutic indication (cf the answer to question 13).

In addition to public reimbursement, many private health insurance carriers also offer additional reimbursement for healthcare expenses, including some pharmaceuticals.

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

By law, both hospital-only pharmaceuticals and the primary healthcare sector are subject to free pricing in Denmark. The prices of Rx and certain pharmacy-only OTC pharmaceuticals are set by the companies that manufacture, import or sell the pharmaceuticals in Denmark. Prices are standardised across all pharmacies in the country, ensuring the same price for the same pharmaceuticals nationwide. The prices are fixed for a period of 14 days at a time. Every 14 days, companies report any changes in the price of their pharmaceuticals to the DKMA through the DKMAnet system, which ensures that companies cannot view each other's future price changes (whereas the current price in each 14-day pricing period, during the pricing period, is transparent). Subsequently, the cheapest pharmaceutical within each indication gains the right to be offered at pharmacies during the upcoming 14-day pricing period.

This system aims to promote competition and keep prices of pharmaceuticals low. The system also renders the use of rebates between pharmaceutical companies and pharmacies unnecessary, and as such, rebates do not influence the pharmacy-sector of the Danish system of pharmaceutical supply and pricing.

The Regions' procurement of hospital-only pharmaceuticals is centralised through public tenders managed by Amgros I/S (Amgros), which is owned by the Regions. Here, confidential discounts offered by the individual market authorisation holder (MAH) play a significant role in the tender process, and price is often the deciding factor in Amgros' tender awards. Amgros contributes to the economic efficiency of pharmaceutical pricing in the hospital-sector.

Although the Danish healthcare system is characterised by free pricing, the prices of many hospital-only pharmaceuticals are heavily influenced by the price-agreement between the Association of the Pharmaceutical Industry in Denmark (Lägemiddelindustriforeningen or LIF), the Ministry of the Interior and Health, and the Regions. The price-agreement sets a price cap on the list price of all hospital-only pharmaceuticals marketed by companies who are members of LIF, whereas the prices of non-members are not affected. The intention of the price-cap system is to align the prices for hospital-only pharmaceuticals in Denmark with those in nine comparable countries, including Sweden, Norway, Finland, Germany, the United Kingdom and the Netherlands. Because the discounts which Amgros obtains through tenders from the individual MAH are based on the list price of the pharmaceutical, the price-

cap agreement greatly impacts the price-levels of hospital-only pharmaceuticals.

Companies sometimes enter into pricing agreements directly with private hospitals concerning new and innovative pharmaceuticals that have not yet been recommended by the DMC and are thus not available at public hospitals.

Medical devices are procured at the local level by the individual Regions or municipalities through public tenders, thus confidential rebates play an important role in the pricing of medical devices. In the area of medical devices, the newly established Danish Healthcare Quality Institute (DHQI) has a similar role to that of the DMC, although the DHQI is not expected to exercise the same gatekeeping function as its pharmaceuticals-focused counterpart in the DMC. The mandate of the DHQI is to assess health technologies, including medical devices, with a view to free up additional resources and labour for the healthcare system.

## **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.**

Public mismanagement of hospital construction projects is a subject of media coverage, with numerous high-profile projects having suffered significant delays and flaws in their execution. Additionally, the dilemma of balancing patient access to innovative and costly medical treatments against the need to curtail the rising costs of Denmark's public healthcare system is also a prominent part of public discourse. Owing to the universal nature of the Danish healthcare system, healthcare financing and reimbursement are not subject to litigation in Denmark. In connection with the trend of medical clinics becoming organised in chains (cf the answer to question 15), there have been scandals involving alleged abuses of the current system by some chains, as well as problematic levels of patient safety. However, these cases have yet to reach the courts.

## **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 current government has proposed a wide-ranging reform of the Danish healthcare system, comprising a reduction in the number of the Regions (from five to four), as well as the introduction of additional healthcare councils intended to bring healthcare services closer to the individual citizen. Further, the reform includes a series of measures aiming to improve the conditions of citizens suffering from chronic diseases.

Another important ongoing development is the increasing trend of private healthcare providers, such as physiotherapists and, more recently, medical clinics, organising themselves in chains as opposed to individual practices. This change marks a departure from the way in which private healthcare providers have traditionally organised their practices in Denmark, as either individual undertakings or smaller clinics.