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).

As provided for in the Constitution of the Portuguese Republic (Article 64), the fundamental right to health materialised through the National Health Service (Serviço Nacional de Saúde – SNS), which was created in 1979. The financing of this service is generally ensured by the allocation of funds from the state budget and is mainly funded through taxation and social security contributions.

The Ministry of Health receives an overall budget for the SNS from the Ministry of Finance, which is subsequently distributed to the various institutions within the SNS. In addition, in accordance with the Statute of the National Health Service (Decree-Law No 52/2022), users who are not beneficiaries of the SNS and other contractually or legally obliged entities are responsible for the costs of the SNS.

The beneficiaries of the SNS have access to healthcare services through the payment of user fees (*taxas moderadoras*, as explained below), which amount to a reduced cost compared to the real cost of the service provided. The SNS offers a wide range of services, from primary care to specialised treatments, ensuring that financial barriers to care are minimised.

Health services are provided through health centres ('*centros de saúde*'), which offer basic and general medical services, preventive care, family planning, and vaccinations. Conversely, hospitals deliver secondary and specialised medical care, including surgical procedures, diagnostic imaging, laboratory services and advanced treatments. Municipalities are responsible for the management, preservation and equipment of primary healthcare units, as well as the management and execution of logistical support services for the primary healthcare units, which are part of the SNS.

The law also contemplates special social health insurance schemes for certain professions (or 'health subsystems'), consisting of public entities, which make a financial contribution to the costs of providing healthcare to their beneficiaries (namely public servants and other categories of professionals such as members of the security forces) and which provide that same care to those same beneficiaries, generally through a network of private healthcare providers with whom they have signed an agreement or convention or through SNS hospitals. The health subsystems are the ADSE (Direção-Geral de Proteção Social aos Trabalhadores em Funções Públicas), ADM (Assistência na Doença aos Militares da Forças Armadas), SAD-PSP (Serviços de Assistência na Doença), and SAD-GNR.

Portugal also has a robust private healthcare services sector, which is supported by private voluntary health insurance and patients. The private sector is crucial because it often fills the gaps left by the SNS and provides services that complement those of the SNS, ensuring faster access to treatment and more personalised care options. Funding for these services is supported by agreements made with the Government, as well as through insurance policies and direct payments from households.

Finally, there is the social sector, consisting mainly of the União das Misericórdias, which provides primary and hospital care, mental health and long-term care. The Portuguese Government has strengthened the institutionalised relationship between the SNS and the União das Misericórdias to increase the human resources and services capacity of the SNS.

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

The Health Basic Law (Law No 95/2019) provides that the financing of the SNS is the responsibility of the state and must be guaranteed through the allocation of resources from the state budget. Notwithstanding, access to certain medical services provided by the SNS, such as hospital emergency services without prior referral or other specific services stipulated by law, may be subject to the payment of fees ('*taxas moderadoras*'), the amount of which are set out in Ordinance No 306-A/2011.

In addition, the Statute of the SNS (Decree-Law No 52/2022) specifies the entities responsible for the financing of the SNS (as specified below).

The central government also has the power to determine the price tables of healthcare services. In particular, Ordinance No 207/2017 specifies the regulations and price tables of the institutions and services integrated into the SNS.

As the public sector cannot ensure all the necessary health services to its beneficiaries, the entities that are part of the SNS may contract services from third parties. This relationship is formalised through the celebration of a convention and must comply with the provisions of Decree-Law No 139/2013.

Furthermore, there are public-private partnerships (PPPs) consisting of contracts between the state and private entities for the provision of healthcare services. Under these contracts, health facilities incorporated in the SNS are managed by private entities.

Meanwhile, private hospitals charge patients a price determined by them in exchange for providing healthcare services. Most patients who are not covered by a special health subsystem and who choose to resort to the private healthcare sector instead of the SNS subscribe to private healthcare insurances.

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

The central government has a prominent role in allocating resources to fund the SNS. In particular, the DGS (Direção Geral da Saúde), in its quality of a central service of the Ministry of Health with administrative autonomy, has the power to develop public health programmes,

improve healthcare provision and continuously improve clinical and organisational quality, coordinating and ensuring epidemiological surveillance at national level and promoting technical studies on healthcare, amongst others.

The Central Administration of the Health System, IP (ACSS, IP) is responsible for ensuring the integrated management of the financial resources of the Ministry of Health and the SNS, in articulation with the Executive Directorate of the National Health Service.

The Health Regulatory Authority (ERS) has the power to supervise the activities of healthcare establishments, including the licensing of establishments and to verify the legality and transparency of economic relations between the various healthcare operators, funding bodies and users.

Infarmed IP (Autoridade Nacional do Medicamento e Produtos de Saúde) is the national authority responsible for establishing the conditions and requirements for granting direct purchasing authorisation for medicinal products for human use to public or private healthcare establishments and services, and non-profit-making charitable organisations.

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

Covid has led to an increase in public funds allocated to the healthcare systems. According to the National Statistics Institute (INE), current public spending on health grew by 13.1 per cent in 2021, due to the Covid-19 pandemic. Additionally, the pandemic also led to a significant increase in household spendings on private hospitals (+27.9 per cent) and private ambulatory care providers (+20.1 per cent).

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?

The fundamental right to health established by the Constitution is accomplished through a national health service that is universal, taking into consideration the economic and social conditions of citizens.

As such, the law specifies that the beneficiaries of the national health service include the Portuguese citizens, citizens with permanent residence or temporary stay or residence in Portugal, who are nationals of Member States of the European Union or equivalent, nationals of third countries or stateless persons, applicants for international protection and migrants with or without their situation legalised, under the terms of the applicable legal regime. The beneficiaries of the SNS must be registered in the National User Registry (RNU).

The access to the national health service by nationals of Member States of the EU and the European Economic Area is regulated by the Directive on the application of patients' rights in cross-border healthcare, and, on the other hand (Directive 2011/24/EU), Regulations (CE) No 883/2004 and No 987/2009, on the coordination of social security systems.

On the other hand, the practice of the medical profession is subject to registration with the Portuguese Medical Association, the requirements for which are laid down in Regulation

1138/2024. Therefore, only professionals with the appropriate qualifications and duly registered with the Portuguese Medical Association (Ordem dos Médicos), the Portuguese Nurses Bar (Ordem dos Enfermeiros), the Portuguese Dentists' Bar (Ordem dos Dentistas) or the Portuguese Pharmacists' Bar (Ordem dos Farmacêuticos) can practice their respective medical activities.

Nevertheless, the statutes of the Portuguese Medical Association provide for a system of freedom to provide services for professionals legally established in another Member State of the EU or EEA who, on a sporadic or occasional basis, carry out activities comparable to the professional activity of a doctor.

Lastly, regarding medical goods suppliers, the installation and operation of establishments dedicated to the manufacturing, distribution and marketing of medicines for human use, medical devices and active substances must be authorised by Infarmed.

HEALTH INSURANCE FINANCING AND COVERAGE

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

Insurance companies are primarily funded through a combination of beneficiary premium payments, government contributions, and external financing sources.

Regarding external financing, insurance and reinsurance companies are required to maintain minimum solvency capital, as mandated by Law No 147/2015. Solvency requirements are supervised by the ASF (Insurance and Pension Funds Supervisory Authority). This Authority has extensive powers, including the authority to increase the solvency capital requirement of an insurance or reinsurance company in cases of extraordinary risk.

Despite the ASF's supervisory duties, insurance and/or reinsurance companies are responsible for conducting a self-assessment of solvency risks.

In relation to the insurance premium, for the purposes of the Decree-Law No 72/2008 ('Insurance Contract Law'), the insurance premium is the compensation for the agreed insurance coverage and includes everything that is contractually owed by the policyholder, namely the costs of covering the risk, the costs of acquisition, management and collection, and the costs related to issuing the policy. In addition to the premium, tax and parafiscal charges must be borne by the policyholder.

According to Article 52 of the Insurance Contract Law, the premium amount, along with the rules for its calculation and determination, is established in the insurance contract under the principle of freedom of contract. In the absence or insufficiency of the determination of the premium by the parties, the premium shall be adequate and proportionate to the risks to be covered by the insurer and calculated in compliance with the principles of insurance technique, without prejudice to any specificities of certain categories of insurance and the specific circumstances of the risks assumed.

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?

As specified in the response above, the insurance sector is regulated by the general legal framework for insurance contracts, the Insurance Contract Law, which dedicates a small section to health insurance contracts.

This is not a mandatory contract and, in accordance with the principle of private autonomy, the health insurance carriers only cover the payment of the agreed instalments or expenses incurred in each year of the contract.

Therefore, the law does not provide specific rules on the coverage of health insurance. As such, there is no legal obligation to differentiate between coverage for in-person medical appointments and telemedicine appointments.

Furthermore, there are no insurance requirements specifically applicable to telemedicine service providers. Nevertheless, nowadays, most of the health insurance contracts available in the Portuguese market cover telemedicine and, in general, they exclude from their coverage any damage caused by delays or difficulties in accessing this service as a result of anomalies in the telecommunications networks and any consequences of delay or negligence attributable to the insured person in seeking medical assistance, as well as the consequences of deficient, incorrect or inaccurate information provided by the insured person.

HOSPITAL SECTOR

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

The financing of hospitals inpatient and outpatient settings follow the guidelines referred to in Q1 for the public sector and Q11 for the private sector.

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

The prices of health services provided by the SNS are set by the central government through an ordinance, and the prices shall consider the real direct and indirect costs and the necessary operating balance. However, the services and bodies that are part of national health services may enter into contracts that set the prices of certain health services, in accordance with the terms set out in an order issued by the Health Ministry of the government.

Therefore, in accordance with Ordinance No 207/2017, of 11 July, which contains the regulations and price tables of the institutions and services integrated into the SNS, the prices for the inpatient stationary services are determined in accordance with the price table for the different Homogeneous Diagnostic Groups (GDH). Only exceptionally the price will be determined according to the daily stay price rate.

Regarding the ambulatory (outpatient) healthcare services, the service provider shall apply the price table for outpatient services when the patient receives healthcare and stays in the hospital for less than 24 hours. In the event the patient is hospitalised, the inpatient prices regime automatically replaces the outpatient regime.

Since 1 June 2022, with the entry into force of Decree-Law No 37/2022, of 27 May, the flat-rate user fee (*taxa moderadora*) in the SNS is only applicable for emergency services, when users

do not have a prior referral from the SNS (via health centres or the SNS24 line) or are not admitted to inpatient care after the emergency. Outpatient medical appointments, exams, and analyses are free of charge in the SNS.

The economic efficiency of health services must balance the proportionality and fairness of the prices charged, with the need to ensure full cost coverage.

The government has created a unit to follow up and monitor the economic and financial performance of the SNS, through Order No 11154/24, of 23 September. The 'unit for monitoring the economic and financial performance of the SNS' (UADEF), as it is called, aims to ensure, in particular, four functions set out in Article 9 of the Statutes of the SNS Executive Directorate:

1. monitor the performance and economic-financial and budgetary efficiency of the SNS institutions, in coherence with the organisational development plans and programme contracts of the health units;
2. identify, design and disseminate good practices to promote efficient economic, financial and budgetary performance;
3. evaluate and analyse risk management indicators in order to ensure efficient monitoring of management policies; and
4. participate, within the scope of its competences, in the preparation of consolidated financial information for the SNS.

This Order has taken effect from 1 September 2024.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

The private providers of such services are mostly financed by consideration payment by the beneficiaries. These companies may also resort to external financing.

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

Prices for private healthcare services should adhere to objective criteria of proportionality, ensuring they are fair and reasonable in relation to the services provided. Accordingly, these prices are established within the framework of contractual freedom, with supply and demand factors playing a key role in their regulation.

The involvement of insurance companies in the market introduces an additional dynamic, as agreements between providers and insurers, especially concerning service reimbursement, can significantly influence pricing structures.

PHARMACEUTICALS AND MEDICAL DEVICES

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

According to the General Regime for State Subsidisation of the Price of Medicines (Decree-Law No 48-A/2010), the state may subsidise the purchase of medicines prescribed to beneficiaries of the SNS and other public health subsystems by means of:

1. a percentage of the PVP (ie, retail price) of the medicine;
2. a system of reference prices;
3. the weighting of factors related to patient characteristics, the prevalence of certain diseases and public health objectives.

The pharmacotherapeutic groups and subgroups of medicines eligible for subsidisation, the subsidisation levels and the weighting factors are determined by Ordinance of the Government member responsible for health (Ordinance No 195-D/2015, of 30 June).

Exceptional subsidisation schemes may be established by Ordinance of the Ministry of Health, namely for certain pathologies or special groups of users; certain therapeutic indications; medicinal products which are qualified as essential for the preservation of life; among other factors.

The law also regulates the exclusion of medicines from subsidisation, which may be based on the lack of proven effectiveness of the medicine; its lower therapeutic value; a price that is 20 per cent higher than that of subsidised non-generic therapeutic alternatives used for the same therapeutic purpose; among other factors.

Lastly, generic medicines have a special regime of state subsidisation, governed mainly by Decree-Law No 97/2015, of 14 January (Establishes the National Health Technology Assessment System). In general terms, its Article 20 provides that the 'economic advantage of each generic medicine for the purposes of subsidisation, from the fifth generic medicine onwards, is realised by setting a maximum PVP that is 5 per cent lower than the maximum PVP of the generic medicine whose valid application for subsidisation immediately precedes it, regardless of the decision'. As such, the formula to calculate the generic medicine PVP differs from the above-mentioned regime for medicines of pharmacotherapeutic groups.

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

The pricing and financing of medicines and medical devices depends on a technical-scientific evaluation of the medicines and an evaluation for financing by health systems by Infarmed IP. The economic evaluation consists in determining the added value of the medicine in terms of its added therapeutic value and its economic advantage. In this way, economic efficiency is achieved by constantly weighing up the economic benefit of the medicine. Infarmed IP can promote the evaluation or re-evaluation of all health technologies on its own initiative.

For the purpose of determining the PVP of medicines to be placed on the national market for the first time, the PVA to be taken into account (ie, price at the production or import stage)

may not exceed the average of the PVA applicable to the same medicine in the reference countries or, if it does not exist in all of them, the average of the PVA applicable in at least two of these countries.

Subsidised medicines are subject to maximum prices. However, rebates are allowed throughout the pharmaceutical supply chain, from the manufacturer to retailer. In particular, discounts granted by pharmacies on the prices of government-subsidised medicines apply only to the non-subsidised part of the price.

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.

In Portugal, healthcare litigation reflects the complexities of its mixed but predominantly Beveridgean healthcare system. Disputes primarily focus on the allocation of financial responsibility for medical expenses, especially between the SNS and private entities, such as insurers. As such, litigation regarding healthcare financing and reimbursement typically revolves around pharmaceutical reimbursement disputes, medical treatment reimbursement disputes, public-private partnership conflicts and cross-border healthcare disputes.

The Portuguese Constitution recognises health as a fundamental right, requiring the state to ensure universal and equitable access to healthcare. This principle has been central in cases challenging funding decisions. The cornerstone of the Portuguese healthcare financing litigation is the Constitutional Court's Decision No 330/89, which addressed the introduction of user fees ('*taxas moderadoras*') within the SNS. The Court ruled that these fees are permissible as long as they do not undermine the minimum content of gratuitousness, nor violate the principles of universality and generality. This decision demonstrated the delicate balance between ensuring financial sustainability and maintaining equitable access to healthcare.

Disputes over reimbursement of pharmaceuticals are often related to the possibility of the Portuguese Government reimbursing purchasers of prescription medicines in relation to pharmaceutical reimbursement disputes. Additional benefits are given to certain categories of patients, notably pensioners who do not meet certain income thresholds and patients who suffer from certain types of illnesses. Therefore, pharmaceutical pricing and reimbursement disputes are another frequent source of litigation. Additionally, Infarmed IP oversees the inclusion of medications in the SNS reimbursement system and sets drug prices, and often pharmaceutical companies contest decisions to exclude high-cost or innovative drugs from reimbursement.

Finally, with regard to the financing and reimbursement of healthcare by insurers, which is one of the main topics of litigation in Portugal in this sector, we consider it appropriate to highlight that the Lisbon Court of Appeals ruled on 11/05/2019, Case No 11619/18.3T8LSB.L1-7, that: when the insurance policy provides for the reimbursement of health expenses incurred by the insured, provided that they are justified in accordance with good medical practice and within the quantitative limits established in the policy, the insurer cannot refuse to reimburse the health expenses on the grounds that these expenses relate to clinical acts that are not included in its tables.

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 SNS is currently undergoing an organisational and functional restructuring at both the public administration level and health service provider level. At the end of 2024, the Regional Health Administrations IP (ARS, IP) were merged, leading to expected changes in the organisation of the General Directorate of Health and other institutions in 2025.

From an organisational perspective, integrating existing health centre groupings (ACES), hospitals, and hospital centres into the local health unit (ULS) model aims to enhance the SNS's responsiveness. This integration seeks to simplify processes, improve coordination among health professionals, increase management autonomy, and enhance the participation of citizens, communities, professionals and local authorities in defining, monitoring and evaluating health policies.

Additionally, the legislator believes that integrating these entities into the ULS will likely lead to greater efficiency in managing public resources while ensuring and respecting the crucial role of municipal participation in planning, organising and managing the health response for a given geographical area. It is expected that other public business entities providing healthcare services will be restructured into ULS in the upcoming years.

Lastly, the ASF believes the growing socioeconomic importance of health insurance should be matched by an increased ability for policyholders to make informed choices. This can be facilitated by making it easier to compare the various products available on the market. To this end, the ASF proposed a Circular in 2024 containing standard health insurance conditions. Providing a health insurance option that meets a set of comparable conditions – such as the scope of risks covered, insured capital, pre-existing conditions, and exclusions – will allow for more informed choices, improve the suitability of the contractual options chosen by policyholders, and increase market transparency.