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).

In 1983, Law 1397/1983 established the Greek National Healthcare System (ESY), whereby the provision of basic healthcare became an exclusive responsibility of the Greek state. Health services including emergency care (EKAV), primary care in public hospitals, specialised medical centres and regional health centres are provided both by ESY and insurance funds. Although Law 1397/1983 banned the establishment and expansion of private healthcare, structural problems within ESY allowed for the former to flourish and be continuously subject to legal reforms. Indicatively, according to the recently enacted Law 5102/2024 providing measures to strengthen the public health sector, ESY physicians are now allowed to maintain a private practice or provide their services to any type of private company – as long as they have the necessary licensing – in parallel with their work in public healthcare.

ESY is financed through both public and private sources. Public sources include Social Security Funds (public insurance) and the country's state budget. Insurance is mandatory and depends on the insured's profession. The revenue of Social Security Funds comes from the income of the insured (employees, employers, self-employed, farmers and the retired), as well as government subsidies. The state budget comes from general taxation.

There are insurance funds, however, that have their own healthcare structures where specialised doctors offer preventive, diagnostic and other services, free of additional charges. Some of these funds include IKA (for salaried employees), OGA (for farmers) and OPAD (for public servants), accounting for 95 per cent of the country's population, which were later merged to form the National Organization for the Provision of Health Services (EOPYY). The private sector, on the other hand, receives its funding from private payments of households, private insurance and informal, untaxed payments to doctors.

In terms of other providers/payors, some municipalities have developed local healthcare units, premised on voluntary work. Equipment and doctors are paid for by municipal businesses, and such units offer preventative and prescription services, for free, to local residents, with a focus on the poor, immigrants, the uninsured and other marginalised groups.

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

The legal framework for healthcare financing and reimbursement in Greece is characterised by a multi-level structure that includes fundamental legislation, regulatory acts and specialised provisions. In 2011, Law 3918/2011 established EOPYY to regulate and manage a single unified health insurance fund and act as the sole purchaser of all publicly funded health services. This law was a landmark reform that consolidated various insurance funds under a unified administrative structure (Law 3918/2011, Official Government Gazette 31/A/2011). Law 4052/2012 further regulated primary healthcare services, while Law 4931/2022 sets out the framework for the reimbursement of specific categories of pharmaceuticals, such as early-access drugs or off-label medications. Additionally, Law 5102/2024 introduces measures to strengthen the public healthcare system and EOPYY regulations include cost-containment mechanisms, such as clawback and rebate mechanisms.

Private codes of conduct and market standards also play a significant role. The Code of Ethics of the Hellenic Association of Pharmaceutical Companies (SFEE) governs relationships between pharmaceutical companies, healthcare professionals and patients. Additionally, EOPYY has adopted private-sector practices, such as pay-for-performance agreements, which link reimbursement to the effectiveness of pharmaceuticals and services.

Negotiations are central to determining prices and reimbursement terms. EOPYY negotiates with public hospitals, private providers and pharmaceutical companies. Pricing for public hospitals is often based on diagnostic-related groups (DRGs), while private providers collaborate through collective agreements. For pharmaceuticals, the Pricing Negotiation Committee considers cost-effectiveness and real-world evidence. Furthermore, clawback and rebate mechanisms are essential tools for managing cost overruns, but remain a contentious point in negotiations.

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

The dominant agency that regulates both ESY and the private healthcare sector is the Ministry of Health, under whose jurisdiction is EOPYY, which functions as the sole purchaser of all health services. EOPYY manages both publicly and privately contracted healthcare costs for over 95 per cent of the country's population. EOPYY also has a role within the European Union's healthcare framework; among others, acting as the Greek liaison body for the reimbursement of sickness benefits under Regulation (EC) 883/2004.

The Ministry of Labor and Social Affairs also plays an important role, collecting social insurance contributions through a single fund, Unified Social Security Fund (EFKA), and then transferring the portion corresponding to health to EOPYY. In addition, the Ministry of Finance regulates the national budget and the amount of funds to be allocated to healthcare. Professional associations in the industry are also very influential. The Association of Hospital Doctors of Athens and Piraeus, among others, is quite large and exercises considerable influence on various healthcare-related matters, including financing, while the Pan-Hellenic Medical Association even has an official advisory role to the Ministry of Health.

Finally, the Hellenic Competition Commission, an administratively and financially independent authority, overlooks and promotes competition in all markets, including healthcare. It is Greece's primary competition body, responsible for the implementation of

Law 3959/2011 and EU competition rules (Articles 101 and 102 of the Treaty on the Functioning of the EU). In terms of healthcare, the Hellenic Competition Commission evaluates the quality and pricing of healthcare services, insurance premiums and the scope of insurance coverage, as well as the bargaining power between insurance providers and healthcare providers.

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

Covid-19 in Greece exacerbated already existing health inequalities between those who can afford private healthcare and those who face barriers (refugees, immigrants and people from a low socio-economic background), especially given the strain put on the public sector.

To address those inequalities, the Greek Government exercised considerable intervention in public healthcare financing. In the second half of 2020, financing reached €786m, of which €200m was used for the wages of newly hired medical staff, €293m was allocated to EOPYY, and €293m was used for medical equipment and supplies. In 2021, the government reserved an additional €3bn budget. However, such expansionary fiscal policies did not produce sustainable and structural changes in the healthcare financing system. According to the Greek Statistical Authority, in 2021, while 30 per cent of the total health expenditure came from the general government and 32 per cent from mandatory health insurance schemes, a striking 33 per cent came from out-of-pocket payments. The share of out-of-pocket payments was considerably high given the persistently low public coverage for pharmaceuticals, and disruptions in the provision of routine and other basic healthcare services. As a result, patients were forced to seek alternative routes, which led to overall decreased household incomes and further undermined the system of financial medical protection.

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?

In principle, all Greek citizens, regardless of residence, age and so on, can access free healthcare through ESY. National health insurance is mandatory and anyone who applies is given a social security number, known as AMKA. To access medicine, one must have AMKA and an electronic prescription. The medicine can then be procured in most pharmacies, sometimes requiring a 25 per cent copayment.

Legal residents can also access free medical care, including expats and EU citizens. EU citizens who don't possess AMKA can alternatively show their European Health Insurance Card (EHIC) and an identification document to both benefit from health services and access medicine. EU citizens can also be treated in hospitals: for free at an ESY hospital or an EOPYY-contracted private clinic for up to 30 per cent of the cost. However, if the EHIC card is not accepted and the costs are fully covered by the patient, it is possible to apply for reimbursement later.

In terms of special cases, such as the treatment of non-residents in Greece, there are also provisions. Law 4368/2016 established the right to free healthcare for migrants and asylum seekers. Asylum seekers are specifically issued with a temporary insurance and healthcare

number, which grants them access to free primary and secondary care, as well as emergency care within the public healthcare system.

In terms of medical service providers and suppliers of medical goods, admission into the healthcare system is regulated by strict licensing and accreditation requirements. Physicians and healthcare professionals must be registered with the competent medical association and hold a valid license to practice. Similarly, hospitals, clinics and laboratories must meet the operational standards set by the Ministry of Health and be contracted with EOPYY to provide reimbursable services under the public healthcare system. Suppliers of medical goods, such as pharmacies and medical equipment vendors, must also comply with the applicable regulatory framework, including adherence to pricing and distribution policies determined by the state.

HEALTH INSURANCE FINANCING AND COVERAGE

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

The healthcare insurance system in Greece operates on the basis of mandatory insurance, financed through contributions from employees and employers, as well as state subsidies. The EFKA manages these contributions and transfers healthcare funds to EOPYY (Law 4387/2016). Premiums are determined based on the income of the insured and are calculated as a percentage of salaries or self-employment income. The state budget plays a significant role in supplementing resources, especially for vulnerable groups (Law 3918/2011).

The government is actively involved in determining premiums and regulating the system. The Ministry of Labor and Social Affairs collaborates with EOPYY to monitor financial flows and ensure the sustainability of the system. In cases of disputes or challenges regarding premiums, administrative courts have jurisdiction to review such matters, particularly concerning premium increases or transparency in resource management (Law 2690/1999).

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 coverage of medical services by health insurance carriers in Greece is primarily regulated by EOPYY, which defines the scope and terms of coverage. According to the Health Benefits Regulation (HBR) issued by EOPYY, insured individuals are entitled to coverage for in-person appointments to contracted doctors, diagnostic tests, pharmaceuticals and other medical services. In-person medical appointments with public healthcare providers are generally covered under the Greek national health system, while in-person appointments with private practitioners may require copayments or full payment thereof, unless such a practitioner is contracted with EOPYY.

Private insurance carriers have greater flexibility in defining the extent of coverage they provide, including terms for specialised medical centres or high-cost diagnostic tests.

However, these terms must align with the law and the guidelines set by EOPYY. The government actively participates in defining coverage through EOPYY. The HBR is regularly updated to include new services or medications based on population needs and technological advancements. Indicatively, Law 4931/2022 expanded coverage for certain high-cost medicines and early-access products.

Regarding telemedicine, during the Covid-19 pandemic, provisions were introduced to reimburse telemedicine services (Law 4683/2020). While telemedicine offers increased accessibility to medical consultations, telemedicine implementation in Greece remains limited due to insufficient infrastructure and low adoption rates among providers, according to the World Health Organization (WHO). Currently, telemedicine consultations may not always be reimbursed at the same rate as in-person medical appointments; their coverage depends on specific agreements between providers and insurers.

Equally significant are the procedures concerning the provision of medicines for rare diseases, where EOPYY applies expedited approval mechanisms in accordance with the SFEE. Additionally, applications for the reimbursement of off-label drugs are reviewed by specialised committees to ensure appropriateness and cost-effectiveness.

HOSPITAL SECTOR

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

The financing and reimbursement of hospital services in Greece rely on a mixed system combining public funding, fixed pricing per treatment category and fee-for-service models. Public hospitals are primarily funded through the state budget and social security contributions managed by EOPYY, as established by Law 3918/2011, which unified insurance funds under a central administration.

For reimbursement, the DRG system was introduced through Law 4472/2017, setting fixed prices for specific treatment categories and hospitalisations to ensure transparency and cost control. Although DRGs were designed as an effective management mechanism, their full implementation remains limited due to gaps in digital infrastructure and hospital organisational capacity. Conversely, the fee-for-service model, where reimbursement is based on individual medical acts, dominates in outpatient settings and specialised services, particularly in private hospitals contracted with EOPYY.

The fee-for-service model has been criticised for promoting the overutilisation of services, which increases costs and reduces efficiency. As an alternative, pay-for-performance models, linking reimbursement to the quality and outcomes of services, have been proposed. However, these models are mostly in pilot phases and have not been systematically implemented in Greece.

Overall, public funding remains the backbone of hospital operations, while the application of modern reimbursement methods, such as DRGs and pay-for-performance, remains

limited, highlighting the need for organisational and technological improvements.

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

The pricing of healthcare services in Greece is primarily regulated by the government through EOPYY, which acts as the central purchaser of healthcare services. The system combines fixed tariffs set by the government, negotiations with private providers and expenditure control mechanisms to ensure economic sustainability.

Prices in public facilities are set by the state, with the DRG system introduced under Law 4472/2017. DRGs provide standardised tariffs for each treatment or hospitalisation category, based on cost studies. However, the implementation of DRGs remains limited due to technological and data management limitations. In the private sector, prices are negotiated between EOPYY and providers, following collective agreements that align with state budget constraints.

Professional associations, such as the Hellenic Association of Private Clinics, participate in negotiations to define tariffs, representing private providers. These associations play a key role in ensuring sustainable financial terms for services provided by the private sector. Tariffs are defined based on economic analyses that account for providers' operational costs and population needs. To address overspending, mechanisms such as clawback and rebate are implemented, requiring providers to return funds to EOPYY when predefined expenditure limits are exceeded. Additionally, pay-for-performance models have been proposed to link reimbursement to the quality and efficiency of services. Although still in a pilot phase in Greece, those models are seen as a potential solution for improving economic efficiency.

In practice, pricing in Greece remains heavily reliant on government regulations and control mechanisms, while innovative approaches such as pay-for-performance have yet to be systematically implemented.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

The financing and reimbursement of services provided by physicians, therapists, laboratories and other healthcare providers in Greece are based on a mixed system that includes fixed tariffs, individualised pricing and public funding. For most basic healthcare services, fixed tariffs set by EOPYY apply, as outlined in the HBR. Fees for doctor visits, laboratory tests and physiotherapy sessions are predetermined, providing a uniform basis for reimbursement for all providers.

In certain cases, particularly for specialised services or new treatments, individualised

pricing is used. Providers negotiate their fees directly with EOPYY or with patients. Individualised pricing is mainly utilised in the private sector, where fees are adjusted based on market demand and the complexity of services.

The state plays a central role in financing healthcare services. Through EOPYY, funded by social security contributions and state subsidies, a significant portion of the costs for services provided by physicians, laboratories and therapists is covered. Additionally, cost control mechanisms like clawback and rebate are implemented, requiring providers to return funds when expenditure exceeds set limits.

Overall, the financing of healthcare services heavily depends on government regulations, while individualised pricing in the private sector and cost control mechanisms remain essential tools for resource management within the healthcare system.

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

The prices of services provided by physicians, therapists, laboratories and other healthcare providers in Greece are primarily determined by the government through EOPYY, while in some cases, they result from negotiations or individualised pricing. For most basic services, prices are set by fixed tariffs outlined in EOPYY's HBR, which governs reimbursements for visits, tests and other medical acts. These prices are based on cost studies and are periodically revised to reflect economic and technological developments.

For specialised or new services, prices are often negotiated between EOPYY and providers. Individualised pricing is also common in the private sector, where providers adjust their fees based on service complexity and market demand.

Professional associations, such as the Hellenic Association of Private Clinics, play an active role in negotiations for price-setting, representing the providers' interests. These associations also contribute to the formulation of tariffs that align with market needs while ensuring compliance with state policies.

Economic efficiency is controlled through mechanisms like clawback and rebate, which cap spending by requiring providers to return funds to EOPYY when expenditure exceeds predetermined limits. While pay-for-performance models, linking reimbursement to service quality and effectiveness, have been proposed, their implementation in Greece remains limited.

PHARMACEUTICALS AND MEDICAL DEVICES

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

As mentioned above, both medicines and health services are financed by a mix of compulsory social insurance, state subsidies and voluntary private health insurance, with over 95 per cent of the insured population covered by EOPYY. Greece has also implemented a clawback system for pharmaceutical products to control public spending,

requiring pharmaceutical companies to return a portion of their revenue to the state when spending exceeds budgeted amounts. In terms of medical devices, EOPYY maintains a medical devices approval register, and the National Centralized Health Procurement Authority (EPY) is responsible for the centralised purchasing of medicines and medical devices for the Ministry of Health.

In terms of reimbursement, Law 4931/2022 provides for the procedure of submitting and managing applications for the reimbursement of: (1) foreign medicines; (2) medicines administered outside approved indications; and (3) early-access medicines. According to the law, applications regarding reimbursement for foreign medicines should be submitted to the Electronic Pre-Authorization (EPS) system of EOPYY. Relevant information regarding the marketing authorisation of the medicine, its prescription within or outside approved indications and the potential existence of free-of-charge programmes for said medicine, is then shared with the person submitting the application, within five days, along with the decision of whether the application is accepted or rejected. Similar processes are applicable to the other two categories, under points (2) and (3) above.

In February 2024, the Ministry of Health also adopted Decision D3(a) 6295/09.02.2024 on medicine pricing, which specifically addressed which medicines are classified as reimbursable or non-reimbursable (in greater detail below), whereby some medicines can be transferred from a reimbursable list to a non-reimbursable list. However, medicines related to life-threatening diseases, including oncological and neurological cases, as well as orphan drugs, cannot become non-reimbursable.

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

According to the Ministry of Health's Decision D3(a) 6295/09.02.2024 on medicine pricing, the prices of all medicines should be reviewed once per year. To determine the price of medicines, the Pricing Department of the National Organization for Medicines (EOF) should survey the prices of other eurozone Member States.

Marketing authorisation holders (MAHs) have the power to decide whether to classify medicines in a reimbursable or a non-reimbursable list. If the estimated retail price of a given medicine is less than or equal to €10 and the MAH wishes to change the category of this medicine from reimbursable to non-reimbursable, it can submit their request to the Committee for the Evaluation and Reimbursement of Medicines for Human Use, which is an advisory body to the Ministry of Health. Classifying a medicine under the non-reimbursable list is followed by a price increase of 15 per cent, as long as it does not exceed the average price of the two lowest eurozone prices and the retail price of €10. In cases where the current retail price of a product is higher than €10, MAH can still submit a request to the Committee for the Evaluation and Reimbursement of Medicines for Human Use, however, with no possibility of a price increase.

In any case, EOF can submit proposals with the purpose of applying specific criteria for the pricing and repricing of different medicines, considering their market share, the adequacy of similar products in the market and the burden of a price increase, among others.

Finally, as per Law 4931/2022, MAHs or pharmaceutical companies may apply to the Pharmaceutical Price Negotiation Committee to reduce the price of a medicine so that the

Daily Treatment Cost resulting from its use is no more than €0.2. An additional rebate of up to three per cent may be applied to medicines classified under the therapeutic category of the WHO Anatomical Therapeutic Chemical Classification 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.

Greek case law regarding healthcare financing and reimbursement has focused on three main areas: the constitutionality of limits on public funding; emergency financing for hospitals; and access to orphan drugs and early access products.

Decisions by the Council of State (CoS) serve as the cornerstone of legal interpretation in this field. CoS Decision No 1128/2020 ruled that public funding limits must be assessed in light of the constitutional protection of the right to health (Article 21, section3 of the Greek Constitution). While the court acknowledged the necessity for the financial sustainability of EOPYY, it emphasised that such limits should not exclude patients from life-saving treatments.

In cases of emergency financing, particularly during the Covid-19 pandemic, court rulings highlighted the 'state's obligation to ensure adequate resources for hospital operations. The Greek courts underlined that crisis conditions cannot justify prolonged delays in providing financial support to healthcare institutions.

Regarding access to orphan drugs, CoS Decision No 2274/2021 held that reimbursement for off-label medicines or treatments not listed in EOPYY's approved catalogue may constitute a constitutional obligation when addressing severe diseases with no alternative therapies. The court drew on studies underscoring the critical role of early access to innovative treatments.

The operation of clawback and rebate mechanisms, which are used to control healthcare spending, has also been under significant legal scrutiny. Council of State Decision No 612/2022 referred the constitutionality of the clawback mechanism to the Plenary of the Council of State, recognising the critical impact of this issue on healthcare providers. The anticipated decision is expected to clarify the legality and future application of the clawback system, which remains a pivotal tool for expenditure control, despite widespread criticism.

Greek case law in the healthcare sector reflects a continuous effort to balance the sustainability of the healthcare system with the fundamental rights of patients, particularly in complex and high-stakes scenarios, such as rare diseases and public health emergencies.

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.

Recent legislative and financial developments in Greece reflect ongoing efforts to modernise the healthcare system. Law 4931/2022 introduced improvements in funding for orphan drugs and early-access products, while the pilot implementation of the DRG system is ongoing. The DRG system aims to improve transparency and reduce resource wastage, although the full implementation thereof has been delayed due to organisational and technological challenges.

The operation of clawback and rebate mechanisms, used to control healthcare spending, has sparked significant reactions from healthcare providers. Court rulings, such as Council of State Decision No 2274/2021, have addressed issues of constitutionality surrounding these mechanisms, while discussions on their reform are ongoing.

On the financing side, healthcare expenditure increased by five per cent in 2023, with the share of private payors (out-of-pocket payments and private insurance) exceeding 35 per cent of total funding. This shift raises concerns about equitable access to healthcare services, particularly for vulnerable parts of the population.

At the same time, proposals for pay-for-performance models, linking reimbursement to the quality of services provided, remain at pilot stages. While these approaches have the potential to enhance efficiency, their broader implementation requires extensive planning and adoption.

Overall, legislative and financial developments in the healthcare sector are shaping a dynamic environment that is expected to bring significant changes to the operation and funding of the medical field.