

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 German healthcare system is characterised by a dual system of health insurance and the principle of self-governance. This means that patients are either covered by statutory health insurance (SHI) or private health insurance (PHI). In Germany, health insurance is compulsory for all citizens who have their place of residence or habitual abode in Germany. Almost 90 per cent of the German population is covered by SHI, while only about ten per cent is privately insured (mainly civil servants and people with higher incomes). Both SHI and private patients generally have a free choice of approved healthcare providers and access to all necessary treatments.

The principle of self-governance means that the German Government or legislator only provides framework legislation. Within this framework, service providers and health insurance funds are allowed to plan and organise medical care themselves, to a certain extent, and have the power to agree on binding guidelines and framework contracts that determine the coverage of healthcare services and the respective reimbursement.

For example, representatives of the SHI funds, SHI doctors' associations and hospital associations decide in the Federal Joint Committee (Gemeinsamer Bundesausschuss or GB-A) whether new treatment methods or new drugs should be covered by the SHI funds.

The federal states have their own legislative powers, and are responsible for hospital planning and financing, implementation of federal laws and supervision of regional health professionals.

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

The financing and reimbursement of the SHI is mainly governed by the Fifth Book of the German Social Code (Sozialgesetzbuch Fünftes Buch or 'SGB V') for outpatient care, whereas the Health Care Financing Act (Krankenhausfinanzierungsgesetz or KHG) and Hospital Remuneration Act (Krankenhausentgeltgesetz or KHEntgG) set out the legal framework for the reimbursement of hospital care.

As part of the joint self-governance of service providers and financing entities, negotiations between healthcare providers and health insurers are essential in this system. They negotiate tariffs within the legal framework, often represented by their respective associations. However, once an agreement is reached, tariffs must be approved by either federal or state

authorities. In certain cases, such as pricing for pharmaceuticals or laboratory services, the federal government determines the reimbursement levels. If an agreement cannot be reached, arbitration mechanisms are available to resolve disputes.

Disputes on admission to the health insurance system and on the coverage of medical services are subject to the jurisdiction of the social courts. Against this background, case law of the Federal Social Court has a decisive influence on the decision-making of the self-governing authorities.

Private health insurance is governed by the Insurance Supervision Act (Versicherungsaufsichtsgesetz or VAG), which ensures transparency and accountability in private insurers' operations. The Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht or BaFin) monitors the adequacy of insurers' financial reserves, and the fairness of their contractual terms and tariffs, ensuring consumer protection and market stability.

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

The G-BA serves as the highest decision-making body within the self-governance of the SHI system. It is a public legal entity under the statutory supervision of the Federal Ministry of Health. Members of the G-BA are the four umbrella organisations of the self-governing health system: the Federal Panel Doctors' Association (Kassenärztliche Bundesvereinigung and KBV), Federal Dentists' Association, German Hospital Association and National Association of Statutory Health Insurance Funds (GKV-Spitzenverband). Patient organisations participate in the G-BA's sessions, but do not have a vote.

The G-BA determines which medical services are covered by the SHI, conducts health technology assessments and sets quality standards for healthcare providers. The G-BA issues legally binding guidelines to ensure adequate, appropriate and economical healthcare for insured individuals, and regulates the capacity of ambulatory care services.

Other self-governing organisations are the regional and national associations of the various service providers, such as the German Hospital Federation and the regional associations of SHI-accredited physicians.

For private health insurance, the BaFin supervises private insurers to ensure their financial stability and compliance with regulations. BaFin monitors the solvency of private health insurers and oversees their contractual terms to protect consumer interests.

At the state level, each of Germany's 16 federal states has its own regulators for local healthcare regulations, including hospital capacity planning and the approval of healthcare providers.

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

The pandemic has not generally changed the German healthcare financing and reimbursement system. However, most measures taken during the pandemic, such as access to vaccines, the operation of vaccination centres, and the provision of intensive care capacity in hospitals, were financed directly by the federal states and federal government. During the pandemic, government transfers and grants almost doubled. In 2022, their share in the

overall healthcare expenditure of €488bn increased to 20.5 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?

All German citizens and persons with a legal residence in Germany have access to the public healthcare system and to healthcare services that are medically required. At the same time, health insurance is compulsory for all citizens who have their place of residence or habitual abode in Germany.

In principle, service providers in Germany are not obliged to treat patients, that is, they can refuse to treat patients because their practice is overloaded, or for professional or personal reasons. However, there is an obligation to treat patients in an emergency and the general prohibition of discrimination, for instance, on grounds of origin, gender, religion or age, also applies to physicians. In the Member States of the European Union, as well as in Iceland, Norway and Switzerland, insured persons are entitled to medically necessary treatment during a temporary stay. In principle, the same conditions apply as for insured persons in the host country. EU citizens who have statutory health insurance in their home country are also entitled to outpatient or inpatient treatment in Germany in the event of a medical emergency.

Medical service providers must generally be admitted to administer treatment to patients with statutory health insurance. Admission is either granted by way of a contract with statutory health insurance funds (eg, for providers of medical aids) or by way of an administrative order issued by the competent regulatory body (eg, for physicians and medical care centres). Admission to provide physician services in the inpatient and outpatient sectors is subject to capacity planning. For outpatient physician services, capacity planning is implemented at the local level, that is, the admission of panel physicians is linked to the location of their practice and depends on the requirements of the respective regional association of SHI physicians.

In order to provide inpatient services, hospitals must be included in the hospital plan of the federal state where the respective hospital is located. Hospital plans fulfil the purpose of demand planning, for example, to ensure an adequate level of emergency care.

Other service providers, such as physiotherapists, are not subject to capacity planning. They only need to meet quality requirements in terms of space, equipment and staff in order to be admitted to the SHI system.

HEALTH INSURANCE FINANCING AND COVERAGE

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

Both statutory health insurance funds and private health insurance companies are largely financed by contributions from their members, but the premiums are calculated on different bases. Designed as a solidarity insurance system, statutory health insurance contributions are dependent on wage and currently set by law at 14.6 per cent of the gross income of the respective patient. Half of the contribution is paid by the employer and half by the employee, plus an additional contribution of 2.5 per cent on average, which varies according to the health insurance fund and is also paid by the insured person. In addition, pension and unemployment schemes pay contributions for pensioners and the unemployed. The contributions to the SHI are collected at the federal level in the healthcare fund (*Gesundheitsfonds*) and assigned back to statutory health insurance carriers, taking into account

the age, gender and health condition of the insured persons insured with the respective SHI carrier.

The premium for private health insurance, on the other hand, is dependent on the risk profile of the insured people, for example, health status or age.

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?

In principle, health insurance coverage differs between statutory and private health insurance. Statutory health insurance is based on the principle of benefits in kind (*Sachleistungsprinzip*), which means that doctors, hospitals, pharmacies and other service providers generally settle their remuneration directly with health insurance funds. Privately insured people, on the other hand, must pay for their own treatment and are then reimbursed by the insurance company.

Coverage of medical services in statutory health insurance is governed by the principle of economic efficiency (*Wirtschaftlichkeitsgebot*, section 12 SGB V). According to this principle, coverage for medical services must be adequate, expedient and economical. The principle of economic efficiency is reflected in the framework legislation. However, no catalogue of reimbursable services exists. Instead, entitlement to medical services is primarily determined in more detail by binding guidelines issued by the G-BA.

In private health insurance, the coverage of services is determined on a contractual basis.

Telemedicine consultations are generally eligible for reimbursement both in the SHI and PHI. However, until recently, panel doctors could only provide up to 30 per cent of all their individual treatment cases by way of a video consultation. This upper limit was generally lifted in 2024 by the Act to Accelerate the Digitalisation of the Healthcare System (the 'Digital Act'). The KBV and National Association of Statutory Health Insurance Funds were entrusted by law to implement regulations that allow video consultations 'to a large extent'.

HOSPITAL SECTOR

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

Inpatient hospital services in Germany are financed through the so-called dual financing system. This means that the investment costs of hospitals are generally borne by the federal states, while operating costs are financed by health insurance funds. Since 2020, operating costs have been financed via a combination of flat rates per case for certain diagnoses and the reimbursement of nursing staff costs (nursing budget). Under current law, hospitals only receive remuneration for the inpatient services actually provided.

However, the economic situation of many hospitals is extremely precarious, as investment costs are not met in full by the federal states and treatment costs do not cover today's cost level. To counteract this and improve the quality of inpatient treatment, a major hospital reform (Hospital Care Improvement Act) was passed in December 2024 and will subsequently be implemented in the federal states. The reform, inter alia, provides for a major shift in the reimbursement of inpatient hospital services. Hospital remuneration will be changed to a combination of diagnoses-related group (DRG) flat rates, individual hospital

remuneration for nursing staff and, as a new element, a provision budget. The aim of this redistribution is to reduce the economic pressure on hospitals to achieve case numbers. To be allocated a provision budget, a hospital must be allocated a service group and must have reached the required minimum number of provisions, or the service group must be considered necessary for the provision of comprehensive care. The reserve budget comprises 60 per cent of the cost weighting of the DRG-remuneration (see the answer to question 9) and is intended for the provision of the necessary case-independent infrastructure, such as personnel, technical equipment and operating facilities.

To the extent that hospitals provide outpatient services, such services are generally financed and reimbursed in the same way as services provided by private practices and other outpatient service providers (see the answers to questions 10 and 11).

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

At present, remuneration for somatic inpatient treatment is essentially based on the DRG flat-rate fee system and is therefore not subject to contractual freedom, except for a few inpatient services. As already outlined in the answer to question 8, the current hospital reform has introduced a system of a provision budget. However, this does not change the way the DRG system generally works. A fixed price, irrespective of the actual treatment costs, is determined for each inpatient service in the DRG system.

The DRG flat-rate case catalogue is agreed at the federal level by the National Association of SHI Funds and the Association of Private Health Insurance Funds together with the German Hospital Federation. The catalogue lists flat rates per case that reflect the treatment process. The amount of the DRG case flat rates is mainly based on the type of illness (diagnosis), operation and severity of the illness. The agreement in the case of flat rates is legally binding for all health insurance funds and hospital operators.

The base price for individual DRG services is determined by so-called state prime rates, which are negotiated annually by the state hospital associations and health insurance funds at the state level. The prime rate agreement is legally binding for all health insurance funds and hospital operators.

Nursing rate agreements are concluded between the individual hospital and health insurance funds on the basis of the DRG case flat-rate catalogue and agreements on the state prime rate. The core of the nursing rate agreement is the agreement of a revenue budget, which determines the expected income of a hospital through nursing rates in a calendar year.

The hospital does not receive the revenue budget in the form of a one-off payment, but must submit an invoice to the cost bearer for each treatment case separately. If the revenue budget is exceeded or falls short, deviations from the budgeted total amount are only compensated on a pro rata basis.

Since 2020, a separate nursing staff cost reimbursement has been agreed on an individual hospital basis for nursing staff costs for direct patient care on wards with beds. The nursing budget is earmarked for a specific purpose. The budget is calculated on the basis of the nursing staff costs for direct patient care on the basis of the previous year.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service

providers financed and reimbursed?

Healthcare services provided by physicians in private practice (ie, individual panel doctors or medical care centres – *Medizinische Versorgungszentren* or MVZ) in the outpatient sector are financed and reimbursed in the same way as outpatient services provided by hospitals. Remuneration of physician services provided to SHI patients in the outpatient sector is neither effected directly between the medical service provider and the patient nor directly between the service provider and statutory health insurance funds. Instead, payment is effected in two major steps. First, the SHI funds make total annual payments to regional panel doctors associations (*Kassenärztliche Vereinigungen* or KV) for remuneration of all panel doctors and MVZ in the district. Second, the KV distribute these payments among their members according to a Uniform Value Scale (*Einheitlicher Bewertungsmaßstab* or EBM) and additional regulations, inter alia, on budgets and fee caps. The EBM lists all outpatient physician services that can be provided within the SHI systems and allocates a certain number of points to each defined service. This figure determines the relative value of the service, but not an absolute price. However, the EBM Evaluation Committee, which is made up of representatives of the National Association of SHI Physicians and National Association of Statutory Health Insurance Physicians, determines a uniform point value at the federal level for orientation. The precise point value and hence the actual reimbursement of services is determined at the regional level. Reimbursement may therefore vary depending on the total payments available in the region and the volume of services provided.

Remuneration for outpatient physician services for private and self-paying patients is based on a medical fee scale (*Gebührenordnung für Ärzte* or GOÄ), a binding tariff for private outpatient medical services. Medical services are invoiced to patients directly, who may be reimbursed by their private health insurance.

In Germany, laboratory services strictly qualify as physician services, and are financed and reimbursed within the system described above.

The reimbursement of non-medical service providers, such as physiotherapists within the SHI system, is determined in framework contracts between the National Association of Statutory Health Insurance Funds and associations of therapists.

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

As outlined above (question 10), remuneration for outpatient services for SHI patients is set by the EBM in the form of a point value. From the different values of individual services, a rating ratio can be derived.

For this purpose, the SHI funds distribute a portion of their members' contributions to the regional associations of SHI physicians for outpatient care, depending on the number of insured persons receiving care and other criteria, such as their age. Panel doctor associations distribute the budget to individual panel doctors. The distribution of the allocated budget is regulated by each regional panel doctor association itself in its so-called fee distribution scale. However, standard service volumes must be set for distribution, within which doctors receive fixed points for their services. If these volumes are exceeded, there may be discounts, that is, a service is billed at a lower price.

Prices for privately insured patients, on the other hand, are calculated according to the medical fee scale. According to this scale, doctors may only charge a certain multiple of the

individual fee item for each service, depending on the scope and difficulty of the service to be provided. This ensures cost-effectiveness, to a certain extent.

PHARMACEUTICALS AND MEDICAL DEVICES

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

As a general rule, only pharmaceuticals that are admitted to the German market for a specific area of application require a prescription by a qualified physician. They are dispensed by licensed pharmacies that are eligible for reimbursement within the SHI outpatient system. No positive list of reimbursable medicinal products exists. Instead, certain medicinal products that are not considered economically effective are exempt from reimbursement either by law (eg, lifestyle products) or on the basis of guidelines determined by the G-BA. In the case of life-threatening diseases, any available treatment that offers a chance for cure, or at least is expected to have a positive effect on the course of the disease, must be provided and reimbursed (also see the answer to question 14).

Non-prescription drugs (over-the-counter or OTC) and lifestyle drugs are usually financed by patients themselves.

In the inpatient sector, pharmaceuticals are generally reimbursed as part of the typical treatment costs within the DRG flat-rate system. Specific pharmaceutical therapies and new, often expensive, treatments may be reimbursed separately upon agreements between the hospital operator and financing entities.

Medical devices that qualify as medical aids (*Hilfsmittel*) are reimbursed by the SHI in the outpatient sector if included in a list of reimbursable medical aids. Medical devices may also be reimbursed in the SHI if the respective device is included in a list of digital health applications (*Digitale Gesundheitsanwendungen* or DiGA).

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

Finished prescription drugs (*Fertigarzneimittel*) dispensed by pharmacies in the outpatient sector are subject to the statutory pricing regime as stipulated in section 78 of the Medicinal Products Act (*Arzneimittelgesetz* or AMG) and the Ordinance on Pricing of medicinal products (*Arzneimittelpreisverordnung* or AMPPreisV). The primary purpose of the AMPPreisV is to ensure a uniform pharmacy sales price for Rx drugs. Rx drugs dispensed by hospital pharmacies in the inpatient sector are exempt from the statutory pricing regime. Where the AMPPreisV applies, pharmaceutical companies are generally free to determine a uniform ex-factory price for each finished pharmaceutical product upon market entry. The manufacturer's ex-factory price (*Herstellerabgabepreis* or HAP) is published in an official price list. The AMPPreisV determines the sales margins that wholesalers and pharmacies may add to the manufacturer's official list price for finished prescription drugs in the outpatient market.

In addition to the general pricing regime of the AMPPreisV various instruments of price regulation apply to finished Rx drugs that are dispensed and reimbursed in the outpatient SHI system including several types of mandatory rebates that manufacturers and wholesalers have to grant to statutory health insurance funds.

By the ruling dated 19 October 2016, the Court of Justice of the European Union (CJEU) held that the German fixed pricing regime for Rx drugs violates EU law with respect to

foreign mail-order pharmacies that dispense Rx drugs to customers in Germany (Case C-148/15). Despite this ruling, in 2020 the German legislator reintroduced a fixed pricing regime for EU mail-order pharmacies to the extent that they dispense Rx drugs to customers insured in SHI (only). Litigation on whether this new Rx pricing regime violates EU law is currently pending with the Federal Civil Court (Bundesgerichtshof or BGH).

Reimbursement prices for new medicinal products and digital health applications are negotiated between manufacturers and statutory health insurance funds on the basis of a cost-benefit assessment by the GB-A and the Federal Institute for Drugs and Medical Devices (Bundesamt für Arzneimittel und Medizinprodukte or BfArM), respectively.

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.

The most significant ruling on healthcare reimbursement is that by the Federal Constitutional Court (BVerfG) dated 5 December 2005 (1 BvR 1665/07). The BVerfG held that the SHI system restricts the individual's fundamental rights by imposing a compulsory insurance system with a statutory liability for contribution. In order to balance this interference with constitutional rights, the German legislator is generally obliged to provide the medical treatment necessary to fulfil its public duty to protect life and physical integrity. As a consequence of this ruling, new treatment methods and the off-label use of drugs, as well as treatment with orphan drugs are eligible for reimbursement within the SHI, and there is ongoing litigation on the application of the ruling in individual cases.

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 regulatory framework for healthcare financing and reimbursement is undergoing significant changes, with several key developments and trends shaping the landscape for the near future.

Federal elections

New elections to the German Bundestag were held on 23 February 2025, following the end of the coalition government. Predicting the new government's priorities is still difficult. In any scenario, the issue of financing the SHI system in Germany will be the subject of the next government's healthcare policy. The strained financial situation of health insurance companies has already been reflected in the fact that health insurance contributions have increased significantly since the beginning of 2025.

Hospital reform

Moreover, the implementation of the hospital reform from December 2024 will lead to significant changes. In addition to the shift to a provision budget and the shift in care planning to service groups, a transformation fund is also planned. The transformation fund, which is expected to amount to €50bn over ten years, will provide financial support to

hospitals in implementing the hospital reform. Half the transformation fund is financed by the SHI funds and the other half by the federal states. Among other things, the fund will be used to close and merge hospitals, improve outpatient care and set up telemedicine services.

Reimbursement changes for drugs

In addition, new legislation will have an impact on the reimbursement of pharmaceutical products. Measures include: (1) a shorter free pricing period for new drugs; (2) an increase of the mandatory discount granted to the SHI by pharmaceutical companies; (3) the enforcement of confidential pricing agreements for drugs; and (4) a lowered orphan drug threshold.

Digitalisation

Several legislative measures have recently been taken to accelerate digitalisation in the healthcare sector, including the mandatory introduction of the electronic prescription in 2024, the provision of an electronic patient file (*elektronische Patientenakte* or ePA) in 2025 and streamlined certification processes for digital health applications.

Outlook

Healthcare providers will have to master several challenges over the next few years, for example, potential hospital closures and care gaps in the transitional period of the hospital reform, striking a balance between cost containment and maintaining innovation in the pharmaceutical sector, as well as the uncertain long-term sustainability of healthcare financing in light of demographic changes.