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 eyes view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

The UK healthcare economy consists of taxpayer-funded public healthcare provided by the National Health Service (NHS), and private healthcare that patients can choose to fund themselves.

The NHS is structured differently in each country in the UK (England, Wales, Scotland and Northern Ireland), and responsibility for financing healthcare is devolved to each country's government.

These answers focus on healthcare financing in England, which comprises over 80 per cent of the UK's population, although other parts of the UK use broadly similar systems. Additionally, while these responses focus on the main areas of activity, rules differ for certain specific healthcare services such as dentistry and these are not specifically covered.

Funding for healthcare is decided in the government's annual budget. The Department of Health and Social Care (DHSC) implements policies and distributes the healthcare budget to NHS England, which allocates this proportionately to each geographical region. Healthcare commissioners in each region procure and enter contracts with local service providers using allocated funds. Local service providers are usually local NHS trusts, such as ambulance trusts or acute trusts (which manage hospitals).

There is a growing market for private healthcare, which patients can opt to use instead of or alongside public services. Patients do this by either paying for a private service or goods or financing these through optional and voluntary insurance plans.

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

The Health and Care Act 2022 (the 2022 Act) provides much of the legal framework for the publicly-funded delivery of primary and secondary care. The 2022 Act formally established Integrated Care Systems (ICSs), which determine how healthcare is financed in each ICS's respective region and the process for entering into contracts with local providers.

Whilst most public bodies use competitive tendering to grant public contracts under the procurement regime, healthcare services are instead governed by the Provider Selection

Regime established by the 2022 Act. This allows healthcare commissioners to use a new process to assess and identify the most suitable provider for a given contract, without having to undergo the usual competitive tendering procedure.

Pharmacies seek reimbursement from the NHS under the terms set by the Community Pharmacy Contractual Framework (CPCF). The reimbursement amount for each medicine is dictated by the Drug Tariff, updated monthly. The Human Medicines Regulations 2012 categorise the different types of medicine that can be provided and reimbursed, such as prescription-only or general sale medicines.

The sale of medical products to the NHS is regulated by the National Health Service Act 2006, which facilitates the creation of a 'statutory pricing scheme' to set rules limiting the prices of various branded medicines and require suppliers to pay rebates to the NHS after they have sold a particular volume of their product. A statutory scheme currently operates under the rules set out in the Branded Health Service Medicines (Costs) Regulations 2018, although a voluntary scheme also runs in parallel with different rules that suppliers can opt to join as an alternative.

Which products the NHS purchases is primarily determined by recommendations given by the National Institute for Health and Care Excellence (NICE), whose powers derive from the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

Private healthcare providers are also regulated. The Health and Social Care Act 2008 established the Care Quality Commission (CQC), which regulates public and private healthcare providers. The Competition Act 1998 prohibits anti-competitive practices which harm patients (such as fixing prices), and providers of health insurance will be subject to insurance law, including the Financial Services and Markets Act 2000.

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

The DHSC is responsible for healthcare policy and allocates funds from the annual healthcare budget to NHS England. This is then distributed across England to 42 different ICSs, one for each region.

ICSs partner with local organisations to finance and deliver services in an agreed way, using funds provided by NHS England. Each ICS contains an Integrated Care Board (ICB) to commission services from local primary and secondary healthcare providers.

Both public and private healthcare providers need to register with the CQC, which regulates health and social care providers in England.

The Competition and Markets Authority (CMA) regulates competition and consumer law and carries out market investigations and studies and issues regular guidance to assist businesses with compliance.

Suppliers of branded medicines to the NHS must adhere to specified price limits and pay rebates to the NHS under a statutory scheme, unless they join a voluntary scheme with alternative rules, negotiated by the Association of the British Pharmaceutical Industry (ABPI) with the DHSC and NHS England.

Suppliers must obtain authorisation to sell their medicines to the NHS from the Medicines and Healthcare products Regulatory Agency (MHRA), which ensures the safety of medical products. The NHS will generally only purchase medicines that have been recommended by NICE.

Providers of health insurance are regulated by both the Financial Conduct Authority (FCA) and the Prudential Regulatory Authority (PRA), subjecting them to various conduct requirements to protect policy holders.

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

Covid-19 required the government to make significant changes to its operations to combat the virus, and there have been changes to the system of financing and reimbursement since the pandemic started. It is probably inaccurate to say that significant changes have been directly caused by the pandemic.

The pandemic necessitated a spike in healthcare spending to respond to the increased demand on public services, although since 2022 spending gradually reduced.

NHS organisations were granted emergency powers to respond to the pandemic, and more contracts were awarded to suppliers directly to meet increased demands, without using the tendering process normally required by procurement law. Additional funding during the pandemic was directed at various measures, such as the 'Coronavirus emergency response fund' to help finance public services. However, these measures were temporary and have not remained as permanent changes to healthcare financing and reimbursement.

Although England was already moving towards financing healthcare through ICSs before the pandemic, it is arguable that the pandemic expedited their formal introduction with the 2022 Act, as NHS England has remarked that different healthcare organisations had to collaborate further to respond to the emergency.

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?

NHS treatment is generally free for any patient who is 'ordinarily resident' in the UK, which includes individuals who live in the UK on a lawful and properly settled basis for the time being or have been given immigration status with indefinite leave to remain. Overseas visitors may have to pay for NHS services, subject to limited exceptions. Most ordinary residents will still need to contribute to the cost of specified NHS services, including prescriptions, dental and eye care. Alternatively, individuals may opt to pay for private care.

In relation to the supply side, medical service providers (both within and outside the NHS) must register with the CQC, which includes any entity, partnership, or organisation that provides a regulated activity in England. Registered providers also need an NHS provider licence to provide services through the NHS if their turnover is reasonably expected to be at least £10m in the next 12 months. A licence will also be required if the provider's services have been requested by a commissioner, or NHS England identifies them as a hard to replace service provider.

Individual practitioners may also be subject to professional registration requirements depending on their role; for example, doctors must register with the General Medical Council (GMC).

Medical goods suppliers must obtain authorisation to market and sell the product from the MHRA and comply with product safety legislation before they can market and sell their products.

HEALTH INSURANCE FINANCING AND COVERAGE

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

Health insurance in the UK is optional, offered by private providers and not financed by the government. As such, insurance providers are financed just like any other private business, and income from customers is earned through insurance premiums. Premiums are generally determined by market forces and/or by regulation, as set out below.

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?

Health insurance in the UK is optional and is regulated by both the FCA and the PRA. The PRA ensures that insurance providers have the financial resources to pay out claims when required. Insurers must submit regular returns to the PRA to prove that they remain financially buoyant so that policyholders are protected.

The FCA regulates conduct, and imposes a general obligation to act honestly, fairly and professionally in accordance with the customer's best interests. Insurance providers are also required to communicate financial promotions in a clear, fair and nom-misleading manner. Additionally, the FCA's rules for firms carrying out e-commerce activities require prices to be clear and unambiguous.

Policy holders can complain to the Financial Ombudsman Service about a variety of issues, such as their insurer not contributing enough towards a treatment or taking too long to pay for a claim.

A patient's entitlement to any treatment, whether in person or through telemedicine, will depend on the terms of their insurance plan. Telemedicine is increasingly used, particularly for initial triage and referrals to specialists, and will often be covered by insurers in same way as in-person appointments.

HOSPITAL SECTOR

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

Most of the NHS's stationary and ambulatory services are free at the point of use for anyone who is ordinarily resident in the UK. Services are financed through contracts between local providers (such as hospitals and ambulance trusts) and ICBs in each region's ICS.

Providers and ICBs collaborate to deliver services efficiently, and ICSs have relative freedom to finance healthcare in their region to best meet local requirements, subject to guidance given by NHS England.

Whilst primary care providers are reimbursed in accordance with specific rules, reimbursement for medicines and services in secondary care is generally determined by the policies adopted by the relevant ICS. However, guidance provided by NICE is likely to influence what services an ICS will reimburse.

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

As hospital services are commissioned and funded within each ICS, prices are determined by the terms agreed between the hospital and ICB. ICBs normally use a standard contract provided by the NHS, using various payment mechanisms following the rules of the NHS Payment Scheme. This establishes how much is payable for NHS secondary healthcare, although the mechanism used will depend on the nature of the service.

At the start of every financial year, the ICB and hospital will agree the expected value of their contract, depending on the level of services provided. In most cases, the payment will consist of a 'fixed' and 'variable' element. ICBs will agree a fixed sum to pay for the hospital's non-elective (emergency) care services, based on its expected level of activity for that year. This will vary for each hospital, and the NHS publishes guide prices which can be used to help calculate the appropriate amount.

Hospitals also receive a variable payment to cover the elective care provided during the contract. This means that the price of the hospital's services partially depends on its activity levels, including the number of patients treated. The sums payable for the variable element are based on mandatory national unit prices that are published centrally by the NHS, rather than decided locally.

This enables the NHS to control economic efficiency by limiting how much hospitals will be paid for their services, encouraging hospitals to reduce costs and deliver services more effectively. The NHS calculates unit prices with reference to the price that was payable in previous years, and then adjusts upwards for inflation. However, at the same time the NHS adjusts prices downwards to account for the increases in efficiency that it expects from hospitals.

Hospitals therefore need regularly to improve their efficiency to ensure that their costs do not exceed the prices they can charge to commissioners. The NHS also provides an online data-driven improvement tool enabling hospitals to compare their performance to other NHS trusts and identify how to improve productivity and efficiency.

Although most hospitals will be paid a combination of fixed and variable prices, contracts for less than £0.5m can be paid for using only fixed payments, even if some services would otherwise come under the variable element. This reduces administrative burden for smaller-scale contracts, although ambulance trust contracts are never financed using this mechanism (regardless of their value).

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

Patients who seek treatment privately will usually pay their chosen provider on a per treatment or per service basis. Patients can pay the provider directly, or if they have taken out an insurance plan, then the insurer will pay for part or the whole treatment, depending on the cost and what the plan covers.

Generally, practitioners will charge for an initial consultation, after which the patient may pay a 'packaged' price covering the entire treatment or make separate payments at each stage. Private practitioners are generally free to choose how they charge for their services but must provide pricing information to help patients make informed decisions before agreeing to a treatment.

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

There are no specific legal restrictions to determine private providers' prices, and economic efficiency is generally ensured through market forces. However, generally applicable laws in relation to pricing will apply, such as competition and consumer law. Professional obligations may also be relevant.

Consumer and competition laws might intervene if there are anti-competitive price fixing arrangements or other unlawful practices or perceived market failures. For example, following an investigation into the provision of information to patients in private healthcare, the CMA issued the Private Healthcare Market Investigation Order 2014 and established the Private Healthcare Information Network (PHIN).

The 2014 Order requires private practitioners to provide pricing information to improve transparency and restricts the use of certain incentive schemes, which could influence who practitioners refer their patients to. PHIN provides guidance on how private service providers can charge for services and requires private consultants to provide pricing information to prospective patients on an online system.

These pricing and transparency controls are intended to ensure market efficiency by preventing anti-competitive conduct and enabling patients to make informed decisions about their purchase of private healthcare services.

PHARMACEUTICALS AND MEDICAL DEVICES

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

Suppliers can sell pharmaceuticals to the NHS through the Medicines Procurement and Supply Chain (MPSC), a centralised process for suppliers to sell to multiple NHS organisations. The NHS can purchase medical devices in various ways, such as through framework agreements with select suppliers, or a Medical Technology Innovation Dynamic Purchasing System (DPS), which new suppliers can join after it is set up (unlike conventional frameworks).

The NHS will reimburse organisations which purchase medicines, although its approach differs between primary and secondary care. Secondary care providers, such as hospitals, are reimbursed for their costs in general, rather than the cost of individual medicines (see above), so this section focuses on reimbursement in primary care.

The NHS reimburses independent pharmacies which supply medicines and medical devices prescribed to patients, to pay for the cost of the product and any services provided (eg, a fee for dispensing the medicine to the patient). The reimbursement mechanism derives from the CPCF, and the reimbursement amount for each product is set out in the NHS Drug Tariff, updated monthly.

Patients with rare conditions may require specialised treatments that are not commonly developed or prescribed. Such treatments (including so-called 'orphan drugs') might not be routinely offered by the NHS, although they may still be reimbursed if a health professional makes an 'individual funding request', explaining why the treatment is the best option to address their patient's exceptional circumstances.

The NHS uses various other mechanisms to finance specialist treatments. For example, the Early Access to Medicines Scheme helps people with life threatening or seriously debilitating conditions access necessary treatments that are not yet authorised. Additionally, as orphan drugs are often expensive to develop, they can be given special 'orphan status' to incentivise their production. This grants a manufacturer up to ten years of market exclusivity where similar drugs cannot be marketed by competitors.

In private practice, products are typically financed through agreed sales contracts (as with other goods).

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

As unbranded generic pharmaceuticals are usually offered by many different suppliers, competition and market forces typically reduce prices and ensure economic efficiency.

As branded medicines (including branded generics) are not as likely to be constrained by competition, their price is restricted to seek to ensure efficiency. Suppliers must sell these to the NHS within specified price limits and pay rebates to the NHS based on how much they sell. The rebates payable for branded medicines are either decided by statute or by the voluntary scheme, if the supplier is a member. Voluntary schemes last for a fixed number of years and are re-negotiated once they end. The rules for the statutory scheme can be changed with relatively short notice.

The current Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) will last for five years from the beginning of 2024. Unlike the statutory scheme and previous voluntary schemes, the VPAG introduces a new approach to rebates, with different rules for 'newer' and 'older' medicines. Whilst newer medicines (those within the first 12 years of receiving initial marketing authorisation) are subject to dynamic rebate rates that can change during the scheme, older medicines are subject to a flat rebate rate of ten per cent which can be added to, based on how much or little the price of the medicine has eroded.

The NHS generally only purchases medicines that have been recommended by NICE, which promotes economic efficiency by assessing whether new medicines will be cost-effective. This is determined by measuring the additional 'quality-adjusted life years' (QALYs) that a drug will add to a patient's life. The QALYs measurement estimates both the number of additional years that a patient can live thanks to a drug, and the quality of life that will be experienced for those years. If the cost per QALY for a new drug sits within NICE's cost-effectiveness threshold, then it will be recommended to the NHS.

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.

Perhaps unsurprisingly there are disputes and litigation across the financing and reimbursement topics mentioned above. Some non-exhaustive examples follow.

Although NHS trusts have seen action taken against them by patients, suppliers and other parties, many NHS disputes are now handled using NHS Resolution, which handles claims against the NHS without going to court.

This includes handling disputes in primary care contracts, such as those with pharmacies who administer prescriptions and claim reimbursements. For example, NHS Resolution has heard appeals from pharmacies challenging allegations from the NHS that they claimed overpayments for drug reimbursement during the pandemic. NHS Resolution rejected appeals where the pharmacy could not provide sufficient evidence that its services met the criteria for reimbursement.

Numerous procurement decisions by NHS trusts are challenged. For example, in 2024 healthcare supplier Wincanton Ltd challenged the NHS's decision to exclude it from the process for awarding a £4.4bn contract. When the NHS offered to re-admit it to the process,

Wincanton decided instead to proceed with litigation, arguing that it would have reached the final stage if the procurement process had been conducted lawfully.

In 2023 the British Medical Association (BMA) commenced a strike calling for a pay increase for doctors, arguing that real wages had fallen due to the effects of inflation. The strike ended in September 2024 when the BMA voted to accept an offer that would increase doctor salaries by 22.3 per cent on average, although the BMA has commented that further pay increases will be required in future.

In *NHS Darlington* [2020] EWCA Civ 449 the court considered whether commissioners can finance a drug even when the supplier had not received authorisation to sell it for a specific purpose. A Clinical Commissioning Group (CCG, the precursor to ICSs) administered the drug Avastin to treat a particular eye disease and purchased this from a supplier who was authorised to sell this drug but not for ophthalmic use. The appellants, who supplied alternatives, unsuccessfully challenged the CCG, and the court decided that the NHS should be able to purchase Avastin to treat this condition. Avastin was cheaper, safe to use, and the CCG's policies allowed it to take cost considerations into account when choosing what to prescribe.

Competition investigation and litigation in relation to healthcare pricing is common. For example, in 2020 the CMA fined a private healthcare group £1.2m for facilitating an agreement with ophthalmologists to fix the price of consultations. The UK has also seen various competition decisions and appeals in relation to excessive pricing of pharmaceuticals. Most recently in *Phenytoin* ([2024] CAT 65), Pfizer and Flynn Pharma challenged the CMA's decision that they had set excessive prices for phenytoin capsules. The CAT set aside the CMA's infringement decision, but on its own analysis still decided that the prices were excessive and unfair, as there was no real justification for why they were so high.

The new VPAG makes significant changes to how suppliers sell pharmaceuticals to the NHS, although the entities involved in negotiating it became a subject of litigation. The British Generic Manufacturers Association (BGMA) was given 'formal observer status' without being involved in negotiations, and attempted to challenge this through judicial review, arguing that manufacturers of branded generics will be unfairly disadvantaged because they cannot be fully represented by the ABPI.

The judgment denied that BGMA had a right to participate on various grounds, although it is worth noting that the VPAG introduced separate, less stringent rules for branded generics to reflect the cost savings that they provide.

Litigation has also clarified when the NHS is obliged to fund certain care. For example, in *R. v North and East Devon HA Ex p. Coughlan* [2001] QB 213 a patient successfully challenged a decision to transfer responsibility for her care from the NHS to a local authority. The patient, who had significant care requirements, had been promised a home for life at a purpose-built NHS facility, although when this closed she was required to pay her local authority to receive treatment. The court agreed that the patient had a legitimate expectation that she would receive free NHS care for life.

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 UK's exit from the EU has led to some legislative divergence affecting the healthcare sector. For example, the procurement of products by NHS organisations will be regulated by the new public contracts regime with notable differences from the EU regime. The Procurement Act 2023, in force from 24 February 2025, introduces new options for structuring competitive tender processes and a wider scope of duties placed on public bodies.

The Health and Care Act 2022 made significant changes to how the NHS operates, as part of a general move to reform the healthcare sector by reducing administrative burden and further integrating different services.

The VPAG also affected how medicines are sold to the NHS. The previous voluntary scheme was criticised for imposing increasingly high rebate rates on suppliers, with pharmaceutical companies leaving in protest on the basis that the rebates demanded were making the effective price of medicines too low for suppliers. Although the scheme is still relatively new, a report from the ABPI notes that the rules for older medicines may stop some companies supplying their older products, as the new higher rates might prevent further sales to the NHS from remaining financially viable.

However, the report also examines the VPAG's positive effect on investment into new medicines. For example, the report suggested that the scheme enables NHS England to introduce special innovative payment models to help facilitate access to certain advanced therapies, and has already agreed such a payment model for a new gene therapy for adults suffering from haemophilia B.

Given the recent change in government in the UK from the Conservatives to the Labour Party, and Labour's pledge to provide more money for the public healthcare system, we would expect significant further changes to the financing and reimbursement of healthcare over at least the next four years.