

HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

Authors:

David Geral, Julie Oppenheim, Robyn Culverwell, Mangi Malada and Sarah Longdon, Bowmans

julie.oppenheim@bowmanslaw.com, david.geral@bowmanslaw.com and robyn.culverwell@bowmanslaw.com

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 Constitution of the Republic of South Africa, 1996 (Constitution), places a positive obligation on the State to respect, protect, promote, and fulfil the rights enshrined in the Bill of Rights, including the right to access healthcare services, including reproductive healthcare. Everyone, therefore, has the right to equal access to quality and affordable healthcare. The Constitution further requires the State to take reasonable measures, within its available resources, progressively to realise this right. The National Department of Health (NDOH) is the department responsible for providing healthcare services in South Africa.

The healthcare system in South Africa is a two-tier system/sector, with both a public and private health component. Each component provides healthcare facilities, healthcare products (including drugs, devices and equipment), and healthcare professionals.

The public healthcare system is overseen and managed by the NDOH, headed by the Minister of Health (MOH), although most public sector health infrastructure is operated by provincial governments. The NDOH also oversees its affiliated regulators, such as the Office of Healthcare Standards Compliance (OHSC), the Health Professions Council (HPC), and the Healthcare Products Regulatory Authority (SAHPRA), and it convenes the National Health Council (NHC) in which the MOH, provincial health heads, and related stakeholders deliberate on national health policy.

The private component is funded by private investors and premiums from members of medical schemes and holders of health insurance policies. The public and private facilities and professionals are subject to the supervision of the same regulators. Medical schemes and insurers are subject to financial sector conduct and prudential regulation by other regulators, discussed below.

The majority of South Africa's population is dependent on the public health system for the realisation of their constitutional right to access quality and affordable healthcare. However, the public healthcare system faces many inefficiencies due to, among other things, inadequate funding. The private healthcare system, which often offers better quality healthcare services than the public healthcare system, therefore becomes an alternative for those who can afford it, often being the middle and upper class of the South African population.

The overall healthcare sector in South Africa is primarily financed from the following sources:

- *Public funding* – from tax revenue, primarily allocated to provinces through their equitable share, as conditional grants, and funding allocations to other spheres of government (national, provincial, and local).
- *Medical scheme contributions and/or insurance premiums* – paid by individuals and/or their employers. Taxpayers who belong to a registered medical scheme can claim a tax credit, reducing the total tax they need to pay to the South African Revenue Service. Medical schemes are not-for-profit entities, and their reserves are private fund assets belonging to the medical scheme members.
- *Out-of-pocket expenditure* – by individuals who purchase healthcare services in the public or private sector not covered by any other form of insurance.

Other less significant contributors include donor funding, statutory insurance entities, such as the Compensation Fund (in respect of workplace injuries and diseases) and Road Accident Fund, and employers.

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

The Constitution

As previously mentioned, the Constitution requires the State to take reasonable measures, within its available resources, progressively to realise the right to healthcare services.

National Health Act 13 of 2013 (NHA)

The NHA, which gives effect and content to the right to access healthcare services as provided for in the Constitution, establishes a national health system that seeks to unite and improve South Africa's health system through cooperative governance, decentralised management, and shared responsibility among all health sectors. It sets norms and standards for health services, including financial management and cost control measures, ensuring that healthcare is made available within the limits of the State's available resources. It further assigns the competencies of the national, provincial, and municipal governments.

The Medical Schemes Act 131 of 1998 (MSA)

The MSA consolidates and outlines the laws and regulations related to registered medical schemes in South Africa. South African medical schemes operate on a basis of pooling funds for healthcare services through cross-subsidies from the healthy to the sick and from high-income earners to low-income earners. The MSA regulates medical scheme benefits offered to members (including prescribed minimum benefits (PMBs), which all medical schemes must offer on all benefit plans) and provides broad regulation of how contributions, co-payments, fees, etc., must be managed in the medical schemes space.

Health Professions Act 56 of 1974 (HPA)

The HPA provides for the control over the education, training, and registration for practising health professions registered under the HPA and matters incidental thereto, including, among others, fees charged by registered healthcare professionals.

National Health Insurance Act 20 of 2023 (NHI Act)

The NHI Act was signed into law in May 2024 but has not yet been declared in force by the President. It was enacted to achieve improved universal health coverage for the South African population, in line with the Constitution. The NHI Act intends to consolidate various sources of healthcare funding within the country into a National Health Insurance Fund (NHI Fund), which will eventually be the sole entity that purchases and pays for healthcare services on behalf of the population, gradually displacing the role of private medical schemes and insurers. This is discussed further in the response to question 15 below.

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

NDOH

The NDOH is the primary department of state responsible for overseeing the health system in South Africa by setting national health policies and regulations, including those related to healthcare financing and reimbursement.

CMS

The CMS is a statutory body established by the MSA to regulate private health financing through medical schemes in South Africa. It oversees all registered medical schemes, ensuring compliance with the MSA, which governs healthcare financing and reimbursement for services offered by these schemes. Additionally, the CMS advises the MOH on regulatory and policy interventions to support national health policy objectives.

The Health Professions Council of South Africa (HPCSA)

The HPCSA is a statutory body established under the HPA. Its mandate is to protect the public and to guide and regulate the health profession. The objects of the HPCSA, as outlined in the HPA, include, among others, determining strategic policy in accordance with national health policy as determined by the MOH, and making decisions regarding the professional boards and the health professions on matters such as finance, education, training, registration, ethics and professional conduct, disciplinary procedures, scope of the professions, inter-professional matters, and maintenance of professional competence.

OHSC

The OHSC is the regulatory body established under the National Health Amendment Act 12 of 2013 for healthcare services. It is mandated to protect and promote the health and safety of service users by enforcing compliance with prescribed norms and standards. The NHI Act

states that healthcare providers or establishments must possess and produce proof of OHSC certification to be accredited by the NHI Fund and benefit financially from the NHI Fund.

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

A notable change in healthcare financing and reimbursement in South Africa due to the Covid-19 pandemic was the increased collaboration between the private and public healthcare sectors. The pandemic, which severely affected the health sector and economy since 2020, including HIV screening and essential maternal and childcare services such as cervical cancer screening and childhood immunisations, required constructive collaboration in the emergency response, procurement, funding, and rollout of the vaccination programme for a rapid and effective response. Examples of this collaboration, which influenced healthcare financing and reimbursement in South Africa, included:

- *The nationwide vaccine programme* – funded by both government and private sector contributions, provided vaccines free at the point of care at accredited facilities, showcasing a successful model of a common benefit package with a clear contracting framework.
- *The Solidarity Fund* – formed by the President in response to the dire impact of Covid-19, united the South African nation by bringing together the government, businesses, and civil society to fight Covid-19. The fund mobilised and coordinated financial and in-kind contributions from South Africans and the international community to address both the health crisis and social consequences of Covid-19.
- *The Public Health Enhancement Fund (PHEF)* – established by the Department of Health and the private sector in 2012, aimed to strengthen and improve public healthcare in South Africa through cross-sector collaboration and pooling of corporate social investment in health. Managed by the private sector, the PHEF focused on expanding health professionals, supporting the training of Masters and PhD students in combating HIV/AIDS and tuberculosis, and the academy for leadership and management in healthcare.

Other notable changes in healthcare financing and reimbursement included the following.

In April 2021, South Africa received a US\$1bn emergency Programme Loan from the New Development Bank to support economic recovery from Covid-19, focusing on creating new employment opportunities. Additionally, the US Government contributed US\$54m to South Africa's Covid-19 response, with USAID providing US\$17.9m for vaccine distribution, field hospitals, and surveillance data.

In August 2024, the President of South Africa signed the Presidential Health Compact (PHC), a presidential initiative with a monitoring and evaluation component assigning roles and responsibilities to a broad range of stakeholders to support health systems strengthening and preparation for the implementation of the NHI Act. The PHC consists of ten pillars: development of human resources, improving access to medicine, vaccines, and health products, upgrading infrastructure, private sector engagement, quality healthcare, public sector financial management improvements, governance and leadership, community engagements, information systems, and pandemic preparedness.

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 Constitution guarantees that everyone in the country, regardless of status or nationality, has the right to access healthcare services and that no one may be refused emergency medical treatment. The NHA mandates that state-run primary healthcare facilities provide free healthcare to all, including migrants and refugees. Pregnant or breastfeeding women and children under six are entitled to free healthcare services, including HIV treatment, at any level. Refugees and asylum seekers have the same right to access healthcare as South African citizens, as outlined in the Constitution and the Refugees Act 130 of 1998.

However, South Africa remains an unequal society where the quality and type of healthcare services people receive are significantly influenced by their socio-economic status and ability to access services. While primary healthcare services are free, higher levels of care are subject to fees, determined by a means test based on patient income. Individuals can also access private healthcare services, funded through medical insurance or out-of-pocket payments. Private facilities typically require proof of medical insurance or upfront payment. Access to private healthcare, like public healthcare, is available to citizens, expatriates, refugees, and asylum seekers.

For context on how the right to healthcare is actually realised in South Africa, according to the 2016 General Household Survey by Statistics South Africa, only 17 per cent of South Africans have medical insurance, leaving approximately 45 million people, or 82 per cent of the population, reliant on public healthcare. The actual number of people depending on the public health system is likely to be higher, as many undocumented individuals also rely on it for healthcare services.

Tertiary healthcare services, which are highly specialised referral services, are provided at central and tertiary hospitals (declared by the MOH). However, these services are not equitably distributed, with only 35 hospitals offering them, mostly in urban areas. Consequently, patients are often referred from one province to another, necessitating strong national coordination and cross-subsidisation through the national tertiary services grant. This grant compensates provinces for providing tertiary services to patients from other regions. The grant allocation for 2024/2025 is ZAR15.3 billion, and ZAR15.9 billion has been earmarked for 2025/2026 (approx. US\$840m and US\$873m, respectively).

The provision of medical services in both the public and private healthcare systems is governed by various laws and regulatory bodies, including the HPA, the MSA, the Medicines and Related Substances Act of 1965 (MRSA), and regulatory authorities such as the HPCSA, the OHSC, and the CMS. Consequently, individuals or entities providing medical services, devices, equipment, consumables, and health infrastructure facilities management must ensure compliance with the relevant laws and regulations.

HEALTH INSURANCE FINANCING AND COVERAGE

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

Medical schemes in South Africa are non-profit organisations governed by boards of trustees elected by the membership of each scheme. There are approximately 70 schemes currently registered with the CMS. Due to their nature, medical schemes in South Africa are financed in the following ways:

- *Member contributions* – are collected as monthly premiums. The contributions are pooled to cover the healthcare expenses of the medical scheme.
- *Employer subsidies* – employers may contribute to the medical scheme in full or in part (often on a scale as an employee benefit) premiums on behalf of their employees.
- *Investment income* – medical schemes invest the funds collected from member contributions in various financial instruments. The income generated helps supplement the funds available for paying out claims and managing the scheme.

Medical schemes in South Africa are regulated by the MSA and the subordinate legislation enacted under the MSA, including circulars, guidelines, and publications of the CMS, which regulate, among other things, the way premiums paid to medical schemes are determined.

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?

The MSA mandates that all medical schemes must provide coverage for PMBs, which include emergency medical conditions, a defined list of diagnoses, and chronic conditions. The CMS oversees the implementation and compliance with these regulations, in addition to publishing circulars or guidelines that further regulate the coverage of medical services by medical schemes.

Specifically, regarding the differences in coverage for in-person medical appointments and telemedicine appointments, the extent of coverage can vary between different medical schemes. Therefore, the terms of coverage for in-person and telemedicine appointments would be detailed in the individual scheme documents, which must, in turn, comply with the MSA and the subordinate legislation enacted thereunder.

HOSPITAL SECTOR

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

Inpatient and outpatient service at public hospitals are primarily government funded. Private hospitals operating within the private sector determine the rates charged for inpatient treatment and ambulatory services by negotiating rates with medical aid schemes.

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

The Uniform Patient Fees Schedule (UPFS) billing system simplifies charges for public hospitals, mortuaries, and ambulance services, ensuring a transparent and consistent fee

structure for both in-patients and out-patients. Fees are categorised based on patient type and medical situation. The revised 2024 fees will apply to all patient categories. Fees are determined using the UPFS as a guide for billing and payments. There are three patient categories under the UPFS:

1. *Full Paying Patients* – treated by private physicians, externally funded, or non-citizens.
2. *Partially Subsidised Patients* – eligible for partial coverage of care costs based on income.
3. *Fully Subsidised Patients* – referred to hospitals by Primary Healthcare Services.

NHI Act

Once the National Health Insurance Act is implemented, it is anticipated that the NHI Fund will become the single purchaser and payer of healthcare services. The Act also creates: a Benefits Advisory Committee (BAC), which will determine what the healthcare service offering will be; a Health Care Benefits Pricing Committee, which will determine what the NHI Fund should pay for and the available services included; a District Health Management Office, which will coordinate the roll-out of primary healthcare (PHC) treatment at district level; a Contracting Unit for Primary Health Care, which will contract with service providers at district level; and, within the NHI Fund, a Health Products Procurement Unit to determine what health products the NHI Fund should procure and to manage supply chain and pricing matters. The HPPU and the BAC must collaborate to determine the national Essential Medicines List, Essential Equipment List and Formulary.

Before the BAC is established, the Minister is required to establish four advisory committees, on Tertiary Health Services, Training and Development, Health Care Benefits, and Health Technology Assessment.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

The National Health Laboratory Service (NHLS), established under the National Health Laboratory Service Act (2000), provides pathology services to the majority of South Africans through its 233 laboratories nationwide. State funding for these services will be provided through the laboratory tests programme, with an allocation of ZAR33.4bn (apprx. US\$1.85bn) over the medium term, representing 76.6 per cent of total expenditure.

The UPFS billing system's revised fees for 2024 will be applicable to all categories of patients, medical schemes, Road Accident Fund, Workman's Compensation, intergovernmental bodies such as the South African Police Service (SAPS), non-subsidised categories of foreign nationals treated at State Health Facilities and differentiated amenities, and all subsidised patients within the following categories except for those categories that are exempted or qualify for free services.

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

Again, a UPFS is published yearly, which accounts for changes in inflation and ensures fair pricing.

Medical schemes and healthcare services providers negotiate tariffs directly usually through the agency (representing the schemes) of registered Medical Scheme Administrators and/or registered Managed Healthcare Organisations, both of which are also regulated by the CMS.

PHARMACEUTICALS AND MEDICAL DEVICES

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

In the public sector, pharmaceuticals and medical devices are financed through the State. The Central Chronic Medicines Dispensing and Distribution (CCMDD) public programme also facilitates access to chronic medication.

In the private sector, pharmaceutical and medical devices are financed through medical aid or paid for by the patients privately, depending on whether the patient has medical aid, and whether the medical aid covers the specific pharmaceutical/medical device.

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

The pricing of pharmaceuticals and medical devices is regulated by the MOH, in consultation with the Minister of Finance and SAHPRA. These regulations, established under the MRSA, outline fees for medicines and medical devices.

The price of medicines is governed by the single exit price or ‘SEP’ regime, which provides that a manufacturer, importer, distributor, or wholesaler may not charge any fee or amount other than the SEP in respect of the sale of a medicine or scheduled substance to a person other than the State. The SEP comprises the following three components:

- the price set by the manufacturer or importer of a medicine or scheduled substance in terms of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, as amended (the so-called ‘manufacturer price’);
- the logistics fee; and
- VAT (value added tax).

The logistics fee, a component of the SEP, is the fee payable by manufacturers and/or importers to distributors and/or wholesalers for certain services, which include, but are not limited to, warehousing, inventory or stock control management, order and batch order processing, delivery batch tracking and tracing, cold chain storage, and distribution of medicines and scheduled substances.

Logistics fees are currently determined by agreement between a logistical services provider and the manufacturer or importer. However, as mentioned above, the Proposed Logistics Regulations seek to impose a statutory maximum.

The price of medical devices is not currently regulated but this may change when medical devices come under registration with the SAHPRA in future.

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.

Covid-19 PCR testing excessive pricing matter

On 8 October 2021, the CMS lodged a complaint with the Commission, alleging that private laboratories were charging between ZAR850-900 for a Covid-19-test. The CMS believes that these prices are exorbitant and unjustifiable in the context of alleged reductions in costs.

The Commission's investigation revealed that prices have decreased across pathology suppliers, that is, suppliers who supply the laboratories have lower prices, thus reducing their costs. A basic average of the costs (ie, not accounting for differences in volume) from individual Covid-19 PCR test kit suppliers, shows that the costs have decreased between March 2020 and September 2021.

The Commission's investigation also revealed that the pathology groups have been earning significant profits since March 2020, especially in the current financial year to date. The significant increases in profitability indicated to the Commission that excessive pricing on Covid-19 PCR tests may be present.

The Commission found that, prima facie, pathology groups including Ampath and Lancet have engaged in conduct amounting to a contravention of section 8(1)(a) of the Act.

Whilst the investigation was under way, and following preliminary discussions with Ampath, Ampath voluntarily reduced its Covid-19 PCR test price to ZAR710 (including VAT) on 29 November 2021. Lancet too, from 2 December 2021, reduced its price to ZAR725 (including VAT). However, an assessment by the Commission concluded that Ampath and Lancet were capable of profitably selling tests at ZAR500 (including VAT).

On 8 December 2021, the Commission sent letters of demand to Ampath and Lancet requiring them to reduce the cost of Covid-19 PCR tests immediately to no more than ZAR500 inclusive of VAT, failing which it would launch an urgent application in the Tribunal for appropriate relief aimed at the reduction of Covid-19 PCR tests to ZAR500 inclusive of VAT.

On 9 December 2021 Ampath responded and on 10 December 2021 Lancet responded to the Commission's request and agreed to reduce the price for Covid-19 PCR tests to no more than ZAR500 inclusive of VAT. Consequently, the Commission and the two laboratories concluded the respective consent agreements.

Discovery Health (Pty) Ltd v Road Accident Fund and Another [2024]

The Gauteng High Court dismissed a case between Discovery Health and the Road Accident Fund (RAF), reaffirming the legal separation between medical aid schemes and the RAF. Discovery Health sought reimbursement from the RAF for medical expenses it had covered for its members injured in road accidents, based on the principle of subrogation. The court ruled that medical aid schemes cannot claim directly from the RAF under subrogation, as this principle does not apply to them. Discovery's argument was found to lack a proper legal basis. The RAF's primary obligation is to accident victims, not to private entities or insurers. Allowing such claims would create inequities in the distribution of public funds.

Vertex Pharmaceuticals – Cystic fibrosis

Cheri Nel (Nel), a Johannesburg-based investment banker, has withdrawn her landmark court case against Vertex Pharmaceuticals. The case sought a compulsory licence to import generic versions of Trikafta, a cystic fibrosis medication, into South Africa. Trikafta's US list price exceeds US\$300,000 (approx. ZAR5.4m) per person per year, while it can be produced for under US\$6,000 (approx. ZAR109,000). Generic Trikafta from Argentina is priced at about US\$60,000 (approx. ZAR1.09m) per person per year.

Nel's case contended that Vertex was abusing its patent rights by not making Trikafta available in South Africa on reasonable terms and by blocking other manufacturers from supplying the medication. The case aimed to facilitate the direct importation of generic Trikafta, thereby eliminating the need for South Africans to travel to Argentina to obtain the medicine. This travel requirement posed significant logistical and financial challenges for patients, who had to rely on an informal network or Buyers' Club to access the Argentinian product.

In response to the mounting pressure from the case, Vertex eventually permitted the importation of Trikafta into South Africa through Equity Pharmaceuticals, utilising Section 21 authorisations granted by the South African Health Products Regulatory Authority (SAHPRA).

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 NHI Act is a significant legislative development in the South African health system. Signed into law on 15 May 2024, its effective date has not yet been proclaimed. The NHI Act aims to achieve universal health coverage by consolidating various sources of healthcare funding into an NHI Fund, which will be the sole purchaser and payer of healthcare services.

Key impacts of the NHI Act on the health system in South Africa include:

- *Committees and units* – The Act establishes several committees and units, such as the Benefits Advisory Committee, Health Care Benefits Pricing Committee, District Health Management Office, Contracting Unit for Primary Health Care, and Health

Products Procurement Unit. These bodies will determine healthcare service offerings, pricing, and procurement.

- *Funding* – The NHI Fund will be financed through new taxes, including a surcharge on personal income tax and an employer and employee payroll tax. The individual medical schemes tax credit will be removed, and almost the entire provincial health budget reallocated to the NHI Fund.
- *Amendment of other Acts* – The NHI Act amends, among other acts, the MRSA and the MSA.
- *Transition period* – current healthcare structures, including medical schemes, will continue to operate until the NHI Act is fully implemented. Once in force, private medical schemes will only offer complementary cover for services not reimbursed by the NHI Fund.

There are currently four court cases instituted in the South African High Court challenging the signing of the NHI Act into law. These cases are still at the pleading stage and have not yet been decided. However, the ultimate relief sought by the applicants is for the High Court to set aside the NHI Act.