

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).

Powers and responsibilities within the Kenyan healthcare system are divided among the national government and the 47 county governments. The national government is responsible for health policy and regulatory functions, technical assistance to counties and management of national referral health facilities. County governments primarily focus on health service delivery to the public and management of county health facilities within the respective counties. Both the national and county governments finance the healthcare economy through a model where the county governments finance healthcare through funds received from the national government and from own source revenue or donations and grants.

Social health insurance (SHI) is mandatory for all Kenyans and non-Kenyans who are ordinarily resident in Kenya for a period exceeding 12 months (ordinary residents). Kenyans and ordinary residents were required to register as members of the Social Health Insurance Fund (SHIF) as from 1 October 2024. SHIF replaced the National Health Insurance Fund (NHIF) in a bid to reform the healthcare financing framework to facilitate the implementation of universal health coverage (UHC) and promotion of affordable and comprehensive quality health services.

Private health insurance schemes by insurance firms also provide supplementary, non-mandatory health insurance plans which are for profit but are regulated as a class of insurance business. Community-based health insurance schemes are another form of private insurance where community members contribute small amounts to a common fund which is used to pay for medical bills at a selected health facility.

In addition to the (national and county) government and private insurance, a huge portion of health expenditure is directly out of pocket by patients or financed by donor contributions in budgetary support to the government or in specific vertical programmes.

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

The Social Health Insurance Act, 2023 (SHI Act) together with its subsidiary regulations is the primary legislation for public healthcare financing and reimbursement. It specifies that SHI is mandatory for all Kenyans and ordinary residents. It also establishes three funds: the primary healthcare fund (PCF), the social health insurance fund (SHIF), and the emergency, chronic and critical illness fund (ECCIF). It further defines the conditions for and level for claims settlement (tariffs) as well as the conditions for empanelling and contracting healthcare

providers or health facilities. The Tariff Regulations under the SHI Act specify the benefits package covered under the three funds.

The Health Act, 2017 provides the overarching framework for healthcare financing by requiring the government to:

- develop mechanisms for an integrated health insurance system including provisions for social health protection and health technology assessment;
- develop policies and strategies that ensure realisation of universal health coverage;
- and to collaborate with the department for finance to develop a framework for public healthcare financing including annual allocations towards reimbursing all healthcare providers responding to disasters and emergencies outlined in the Act.

It also requires contributions from the national and county government for vulnerable and indigent persons.

The Primary Healthcare Act, 2023 delineates the role of the national and county governments in primary health care and requires the national government to appropriate and transfer funds to the county revenue fund of respective county governments for the management of primary health care services.

The Facilities Improvement Financing Act, 2023 provides for the retention of own source revenue by public health facilities. It specifies sources of public health facilities improvement financing to include own source revenues, funds from county governments, conditional grants, and donations and gifts. It also specifies the uses of the finances retained by public health facilities.

The Insurance Act and its subsidiary regulations govern the provision of private medical insurance as a class of general insurance. It also regulates the conduct of medical insurance providers. Medical insurance business is defined as ‘the insurance business of paying for medical expenses, including the business of covering disability or long-term nursing or custodial care needs.’

The Medical Practitioners and Dentists Act and its subsidiary regulations specifies the fees to be charged by healthcare practitioners. The Kenya Medical Practitioners and Dentists Council (KMPDC) prescribes the fees to be charged by healthcare providers.

The Cabinet Secretary for Health in consultation with the Social Health Authority (SHA) is responsible for prescribing tariffs applicable to the benefits package under SHIF. Healthcare providers and insurers participate in the process of determining the tariff rates by providing stakeholder comments to the Cabinet Secretary regarding the proposed tariffs.

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

The Ministry of Health, through the Cabinet Secretary for Health, is responsible for the development of the healthcare financing policy and regulations and setting of SHI tariff rates in consultation with the SHA and the respective stakeholders including medical associations. It is also responsible in collaboration with the national treasury for the development of a framework for public healthcare financing including annual allocations towards reimbursing all healthcare providers responding to disasters and emergencies outlined in the Act. Similarly,

county health ministries are responsible for resource allocations, maintenance of county health facilities and provision of county and community health services.

The SHA is the supervisory authority for the mandatory social health insurance. It is responsible for registering beneficiaries, managing the funds established under the Act, receiving all contributions and other payments for the funds, empanelling and contracting healthcare providers and facilities, and making payments out of the funds.

For private health insurance, the Insurance Regulatory Authority (IRA) is responsible for registering medical insurance providers, safeguarding compliance with the requirements of the Insurance Act, and monitoring the solvency of the insurers.

The Competition Authority of Kenya (CAK) is responsible for monitoring and penalising price fixing by undertakings and associations of undertakings, including professional associations.

The court system plays a key role in determining the legality and validity of healthcare financing laws. The courts also examine the legality and validity of the decision-making process by regulators and supervisory bodies in the exercise of their healthcare financing mandate. Courts may also review the legality of reimbursement decisions by health insurers where such decisions are challenged. In all these instances, courts often issue orders and judgments that have an immediate effect.

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

During the pandemic, the now defunct NHIF cover had an enhanced scheme for Covid-19 services applicable only to the formal sector working in government institutions. Patients enrolled in the general NHIF Scheme or those without health insurance were subjected to out-of-pocket payments for Covid-19 services. The health budget allocated for UHC was increased from KES47.8bn in 2019/2020 to KES50.3bn in 2020/21. However, domestic and donor funds were redirected and re-prioritised to support pandemic response leading to a reduction in financial resources for UHC health benefits package due to decreased membership and statutory contributions for NHIF occasioned by job losses. The national government also introduced Covid-19 conditional grants to allocate funds to each county which the counties utilised to purchase supplies and cover pandemic-related expenses. It also subsidised costs for some medical supplies. The IRA, on the other hand, compelled insurers to promptly settle claims related to Covid-19. The significant resource allocation for pandemic response strengthened previously underdeveloped areas and therefore increased access to healthcare services.

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?

Every Kenyan has the right to the highest attainable standard of health which includes promotive, preventive, curative, palliative and rehabilitative services. SHI is mandatory for all Kenyans and ordinary residents, and they are required to register as members of the SHIF as from 1 October 2024. Every beneficiary under SHIF is entitled to an essential healthcare benefits package as prescribed under the regulations to the SHI Act. The SHI Act specifies beneficiaries to include a contributor to SHIF, persons below 21 years who have no income and are living with a contributor, students below 25 years who do not work for gain, persons

with disability who live and fully depend on the contributor, and a spouse of the contributor. The Tariff Regulations to the SHI Act provide for a schedule of healthcare services covered under the three funds. The SHIF purchases healthcare services from healthcare providers empanelled and contracted by the SHA. Emergency treatment under the ECCIF is accessible to all Kenyan residents irrespective of registration or premium payment status. In such case, emergency care will be provided for a maximum of 24 hours after which the SHIF benefits will apply to beneficiaries with active covers.

For supplementary private insurance, members of the public are free to engage any insurer of their choice and to negotiate terms of their contracts under the principle of freedom of contract. The insurer may decline to accept a person as an insured and the insurer may also include terms and conditions in the insurance policy. Private health insurance plans are funded by premiums paid by the insured. These insurance plans often cover services not covered by social health insurance and may offer extensive benefits to the insured relative to the premium costs paid by the insured. The insurance plans also allow for free choice of doctors, dentists, hospitals and clinics typically from a pre-selected network of healthcare providers by the insurer. Insurers often approve coverage of medical services to the insured immediately prior to the services being offered at hospitals or clinics as individual insurance policies are configured to cover specific healthcare services.

Healthcare facilities and practitioners must be licenced by the KMPDC to offer healthcare services upon submission of the requisite documentation and payment of prescribed fees. Additionally, the SHA makes payments out of the SHIF to empanelled and contracted healthcare providers and facilities. The KMPDC submits a list of licensed and certified health facilities and healthcare providers to the SHA for the purpose of empanelment. The SHA can also pay claims to any licensed and certified healthcare provider or facility which provides emergency treatment to a beneficiary even if it is not an empanelled healthcare provider or health facility.

The mandatory SHI also covers certain treatments abroad. A beneficiary may access health services abroad where the treatment is not available in Kenya and is being provided by a healthcare provider or facility that has been contracted by the SHA and is linked to a locally empanelled and contracted health facility that will follow up on the treatment and management of beneficiary upon their return to Kenya. However, the mandatory social health insurance does not provide travel insurance cover for its beneficiaries. Insurers provide international private health insurance and travel insurance covers under individual insurance policies.

Non-residents travelling into Kenya and who remain within the country for a period of less than twelve months are required to have a mandatory travel insurance cover in Kenya to cover treatment during their short stay. The mandatory SHI does not provide travel insurance cover for its beneficiaries.

HEALTH INSURANCE FINANCING AND COVERAGE

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

The primary source of income for SHIF are statutory contributions, funds appropriated by the national assembly for indigent and vulnerable persons, and gifts, grants, innovative financing mechanisms or donations. Contributions include contributions by every Kenyan household, a non-Kenyan resident ordinarily residing in Kenya for a period exceeding 12 months, the national government, county government and any other employer. Contributions are calculated

at 2.75 per cent of the gross salary for salaried employees while for non-salaried households, the contribution rate is 2.75 per cent of the household's income which is determined using a means-testing formula.

For private health insurance plans, the primary source of income of insurers are the advance payment of premiums for insurance policies by the insured. Premiums are determined by insurers based on factors such as a policy holder's past, anticipated loss experience, the level of risk among other factors. Insurers are required to file their premium rates with the IRA. The IRA has power in setting premium prices as part of its mandate, however, in doing so it must justify that the direct regulation of premium prices is a more rational, reasonable and less costly means of regulation. Generally, courts and the IRA do not interfere in the determination of premiums by insurers as premiums are based on market factors in a free-market economy.

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?

Medical services covered by SHI are specified in the benefits package under the Social Health Insurance Regulations (SHI Regulations). The SHA does not pay for any claims in respect of which medical services are not covered in the benefits package, where medical services are from revoked or suspended healthcare providers and facilities, healthcare providers and facilities have not been empanelled or contracted except for the provision of emergency services, there are unauthorised referrals, costs exceed the annual limits of a beneficiary, and for all costs related to interest charged due to delays in reimbursement claims.

For private health insurance, the Insurance Act does not mandate a minimum or essential benefits package. Health providers are paid for health services offered unless they are excluded from an individual insurance policy or unless insurance premiums have not been paid. Insurers typically cover telemedicine services under the outpatient benefits in individual insurance covers. Telemedicine services are offered only by health facilities that have been licensed by KMPDC to offer e-health services.

HOSPITAL SECTOR

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

Under SHIF, the prescribed benefits package provides a distinction between outpatient services (which includes promotive, preventive, curative, rehabilitative, palliative and referrals) and inpatient healthcare services (which includes management of disease/conditions while admitted in a health facility). The Tariff Regulations provide for a flat pricing per treatment model where the tariff rates are per outpatient and inpatient services subject to respective amount limits and access rules for each health service. The criticism of the flat pricing model is that the limits are too low despite varying levels of contribution by beneficiaries therefore subjecting beneficiaries to out-of-pocket expenditure or supplementary private insurance.

In private health insurance plans, services provided are paid for either through a fee-for-service model where the insured pay hospitals upfront on a fee-for-service basis and claim reimbursement from the insurer; or settled through credit facilities where the insured receives benefits-in-kind, and the insurer directly settles the costs with the hospital. Private health

insurance plans are criticised for a lack of uniform treatment plans which may result in cost escalation due to excessive tests and increased claims.

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

Tariff rates for healthcare services covered under SHIF are set by the Cabinet Secretary for health in the Tariff Regulations in consultation with the SHA and the respective stakeholders including medical associations.

In private health insurance plans, prices are subject to the principle of freedom of contract between the insurer and health service providers. Healthcare facilities and providers submit claims to insurers based on the treatment provided. Insurers through their association may review the pricing of medical bills by healthcare facilities and providers to ensure that bills are not inflated.

The fees for healthcare professionals are subject to the KMPDC's Professional Fees Guidelines For Medical And Dental Practitioners, which specifies the minimum and maximum fees for medical and dental practitioners. These guidelines are developed through a consultative approach with stakeholders including insurers and healthcare facilities and the general public.

Save for the regulation of prices discussed above, hospital prices vary and are influenced by the classification level of a hospital, operational costs, location and other market considerations.

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 private practitioners are financed and reimbursed in the same way as for hospitals for both inpatient and outpatient services (see Q8 and Q9).

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

Prices of such services are set, and their economic efficiency are being controlled similar to the case for hospitals for both inpatient and outpatient services (see Q8 and Q9).

PHARMACEUTICALS AND MEDICAL DEVICES

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

County government procurement is the primary source of essential medical supplies for health facilities using funds from either the national government, own source revenue, reimbursements from SHA or donations. Public health facilities make orders for medical supplies based on pre-determined allocations. Donors fund high priority drugs through vertical programs.

Medication is covered by the PCF and SHIF subject to the applicable tariff limits and access rules. Assistive medical devices to support patients with permanent physical and sensory disabilities, and progressive chronic conditions are also covered under the ECCIF. Notably, the assistive devices benefits package will be rolled out subject to budgetary allocation for it.

Pharmaceutical products can only be utilised after having been granted marketing authorisation by the Pharmacy and Poisons Board (PPB).

Under private insurance plans, pharmaceuticals and medical devices are covered in individual insurance policies. The pharmaceuticals and medical devices covered are determined on the basis of factors such as regulatory standards compliance, cost-effectiveness and availability. Individual policies typically prescribe limits on reimbursement claims and quantities of medication. Where limits are exceeded patients are often subjected to out-of-pocket expenditure. Insurers determine whether their policies cover or exclude rare diseases, registered orphan drugs and early access products.

The Kenya Medical Supplies Authority (KEMSA) is the primary supplier of essential medical supplies to public health facilities. National and county health facilities must prioritise procuring medical supplies from KEMSA and may source from other suppliers if KEMSA lacks the required medical supplies. KEMSA is financed by the national government and donations.

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

There is no defined formal price control policy for pharmaceuticals and medical devices. Prices are dictated by market forces in a free-market economy. The pricing (including base unit costs and markups) is heavily influenced by the number of intermediaries in the supply chain and the price consumers are willing to pay. Various stages of the supply chain have multiple layers of markups which include the location and scale of operations of the distributor or supplier (distribution or retail pharmacy), regulatory and trade licences, the therapeutic classification of the product, whether the product is an innovation or generic, product formulation type (liquid or tablet), and whether it is locally manufactured or imported. Manufacturers sell their products to distributors at a fixed price while also supplying certain strategic healthcare providers (hospitals and large institutional clinics) directly to lower cost barriers and minimise substitutability of their products.

The competition law regime regards rebates including confidential rebates in contractual agreements as likely indicate a presence of buyer power and may potentially trigger abuse of buyer power enforcement by the CAK. The Kenya Association of Pharmaceutical Industry (KAPI) Code of Practice for pharmaceutical and medical devices prohibits rebates as an incentive to healthcare providers and government officials.

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.

***Luco Njagi & 21 Others v Ministry of Health & 2 others* [2015] eKLR**

The High Court ruled that there is a need to balance the healthcare needs of petitioners and the public health insurance system that is contribution based. The petitioners sought the court to compel the Ministry of Health and the NHIF to meet the cost of medical dialysis on their behalf at eight private health facilities or to subsidise the cost of medical dialysis. The case brought out the dilemma that courts face when handling cases in which the use of limited

resources has been prioritised by the government. The High Court noted that it would be reluctant to interfere with policy decisions taken in good faith by the government and medical authorities who are vested with the responsibility of healthcare funding.

***Cabinet Secretary, Ministry of Health v Aura & 13 others* Civil Appeal (Application) No. E565 of 2024**

The Court of Appeal granted a stay of execution of the High Court’s judgment that sections of the SHI Act were unconstitutional and therefore halted the government’s implementation of the new healthcare insurance scheme under the SHI Act. The ruling by the Court of Appeal paved the way for the transition from NHIF to SHIF as from 1 October 2024, and Kenyans were required to register as beneficiaries under SHIF and to pay their statutory contributions to the fund. The orders of the Court of Appeal will be in force until the court delivers its final determination on the merits of the appeal.

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 final judgment of the *Court of Appeal in Cabinet Secretary, Ministry of Health v Aura & 13 others* remains to be seen, especially on whether the impugned sections violate the right to not be denied emergency treatment and whether there was insufficient public participation before enactment of the SHI Act. The Court of Appeal however stated in its ruling that since the SHI Act has been operational, reverting to the NHIF framework would put the health sector in a state of constant change and unpredictability.

Additionally, implementation of the new health insurance framework under the SHIF Act has faced teething problems that are yet to be resolved, such as technical failures in the processing of claims and slow registration of beneficiaries. It also remains to be seen when some benefits package that are earmarked to be offered subject to budgetary allocation will be rolled out given the uncertainty over whether the fund has adequate financing.