Ministry of Health

Regulatory Impact Statement for The Social Health Insurance (General) Regulations, 2024

This Regulatory Impact Assessment (RIA) has been prepared by the Ministry of Health in consultation with the Social Health Authority for the proposed Social Health Insurance (General) Regulations, 2024 pursuant to Section 6 and 7 of the Statutory Instruments Act (No. 23 of 2013)

JANUARY, 2024

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DEFINITION OF TERMS

I**njuries** means result from road traffic crashes, falls, drowning, burns, poisoning and acts of **violence** against oneself or others, among other causes.

"regulation-making authority" means any authority authorized by an Act of Parliament to make statutory instruments;

Purchasing - This is the process by which pooled contributions are used to pay providers to deliver a set of health interventions.

"statutory instrument" means any rule, order, regulation, direction, form, tariff of costs or fees, letters patent, commission, warrant, proclamation, by-law, resolution, guideline or other statutory instrument issued, made or established in the execution of a power conferred by or under an Act of Parliament under which that statutory instrument or subsidiary legislation is expressly authorized to be issued.

Violence means the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment, or deprivation."

CHAPTER 1

INTRODUCTION AND BACKGROUND

1.1 PURPOSE OF THE REGULATORY IMPACT STATEMENT

The *Statutory Instruments Act, 2013* under sections 6 and 7(1) and (2) requires a Regulatory Impact Statement to be prepared by the regulation making authority for any proposed statutory Instrument that is likely to impose significant costs on the community or a part of the community. It also requires that that there is a process of public consultation in developing the proposed regulatory measures. The Regulation-making Authority for this Regulations is the Cabinet Secretary for Health and the Board of the Social Health Authority.

Under the *Statutory Instruments Act, 2013*, a regulatory impact statement shall contain;

a) a statement of the objectives of the proposed legislation and the reasons for them;

b) a statement explaining the effect of the proposed legislation, including in the case of a proposed legislation which is to amend an existing statutory instrument the effect on the operation of the existing statutory instrument;

c) a statement of other practicable ,means of achieving those objectives, including other regulatory as well as non-regulatory options;

d) an assessment of the costs and benefits of the proposed statutory rule and of any other practicable means of achieving the same objectives;

e) the reasons why the other means are not appropriate;

f) any other matters specified by the guidelines;

g) a draft copy of the proposed statutory rule

The Regulatory Impact Statement process is intended to ensure that regulations are only implemented when there is a justified need and that only the most efficient forms of regulations are adopted. The regulatory impact statement (RIS) process involves an assessment of regulatory proposals and allows members of the community to comment on proposed regulations before they are finalized. Such public input provides valuable information and perspectives, and improves the overall quality of regulations.

Section 5 of the *Statutory Instruments Act 2013* requires that a regulation-making authority conducts public consultations drawing on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument and ensuring that persons likely to be affected by the proposed statutory instrument are given an adequate opportunity to comment on its proposed content.

1.2 Scope of the Regulatory Framework

The proposed Social Health Insurance (General) Regulations, 2023 (Proposed Regulations) are made pursuant to Section 24,30,46(2),47(5) and 50(1) of the Social Health Insurance Act (Act). The proposed regulations seek to provide for the management of the 3 Funds, payment of claims to healthcare providers and healthcare facilities and ensure equitable access to essential healthcare for all Kenyans.

The scope of the proposed Regulations is to:

a) set out the procedure for registration of members, change of particulars of beneficiary details and deregistration of a member;

b) set out the manner of contributions;

c) set out the criteria and procedure for empanelment and contracting of healthcare providers and health facilities;

d) provide for the measures that the Funds shall take to enhance access to safe and quality services offered by healthcare providers and to ensure that the public can access healthcare services from qualified and licensed healthcare providers;

e) implement a system for pooling of resources and risks based on the principles of solidarity, equity and efficiency so as to guarantee access to health care services for all;

f) define the benefit package;

g) outline the benefits payable and how the payment of claims will be processed; and

h) establish a Centralised Digital Platform for purposes of claims administration, recording beneficiaries' data, inputting health care service delivery data, and maintaining healthcare providers data.

1.3 Objectives of the Regulations

The objective of the Proposed Regulations is to give full effect to the Act. In particular, these regulations have given a focus on key areas under the Act that must be operationalized as a matter of priority to facilitate the attainment of Universal Health Coverage (UHC).

1.3.1 THE OVERALL OBJECTIVE

The overall objective and reasons for these Regulations is to provide for the implementation of the Primary Healthcare Fund, the Social Health Insurance Fund and the Emergency, Chronic and Critical Illness Fund under the Social Health Insurance Act.

1.3.2 SPECIFIC OBJECTIVES

Specifically, these Regulations provide for-

(a) how health facilities will be empanelled and contracted for the provision of quality health care services which are based on the tariffs prescribed pursuant to section 32 (2) of the Act;

(b) the registration of beneficiaries and mode of identification under the Social Health Insurance Fund;

(c) the benefit package under the Primary Healthcare Fund, the Social Health Insurance Fund and the Emergency, Chronic and Critical Illness Fund under the Social Health Insurance Act;

(d) establish a pool for receipt and payment of funds in the country;

(e) establishment of the emergency medical care code for purposes of handling medical emergency;

(f) stakeholder engagement through the convening of fora through meetings, colloquiums, webinars, workshops or such other consultative platforms for purposes of facilitating consultations, co-ordination and collaboration in the implementation of the Act and these Regulations; and

(g) the means testing instrument in the manner provided in regulation 21 to identify the indigent households that require financial assistance and for whom the National Government or the County Government is liable to pay their contributions pursuant to section 27 of the Act.

1.4 JUSTIFICATION FOR THE PROPOSED REGULATIONS

The Proposed Regulations will-

I. Provide a framework on health financing to ensure equitable access and improved health outcomes for all Kenyans without exposing them to financial hardship;

II. Provide a framework on how emergency health services will be financed through a non-contributory mechanism to safeguard the population from catastrophic health expenditure;

III. Provide a framework for purchasing healthcare to ensure value for money;

IV. address the high burden of communicable, non-communicable conditions, violence and injuries on households and the health system; and

V. cushion the health system from emerging and re-emerging disease outbreaks and changing demographic patterns.

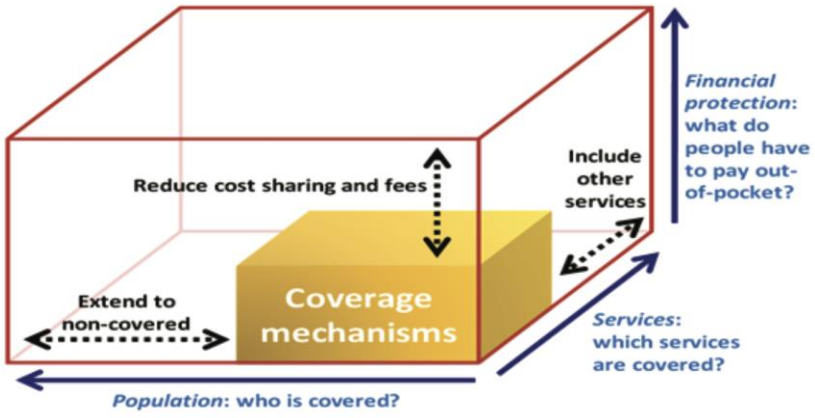
CHAPTER 2

CONTEXT FOR THE PROPOSED REGULATIONS

2.1 UNIVERSAL HEALTH COVERAGE (UHC)

Universal health coverage (UHC) is the access to safe, effective, quality essential health care services, including affordable essential medicines and vaccines for all without suffering financial hardship.

The UHC aims to expand access to healthcare services to all including the indigents and vulnerable population while progressively increasing the healthcare services provided and aiming to minimise out of pocket spending on healthcare.



Source: *World Health Organization 2010*

Universal Health Coverage (UHC) is firmly based on the World Health Organisation (WHO) constitution of 1948 declaring health a fundamental human right, and on the Health for All agenda set by the Alma-Ata of 1978. The goal of attaining UHC was also established by global nations as part of the 2015 Sustainable Development Goals (SDGs). This commitment was reiterated by countries during the United Nations General Assembly High Level Meeting on UHC in 2019. The incorporation of UHC within the SDGs offers a chance to advance a holistic strategy for healthcare, centred around bolstering health systems. Nations moving towards UHC will concurrently advance other health-related objectives as well as broader goals. Consequently, achieving universal health coverage has emerged as a key aspiration for healthcare improvement across various countries including Kenya. It reaffirms the country's commitment to the African Union Agenda and commitment to the Astana declaration on Primary Health Care (PHC) 2018 – galvanizing commitment and action on PHC for the 21st century and stimulating global investment in PHC.

2.2 Universal health coverage in Kenya

The Constitution of Kenya, under the Bill of Rights, Article 43 provides for socio-economic rights which under Article 43(1) (a) gives citizens the right to the highest attainable standards of healthcare.

Currently, limited progress has been made in attaining this goal. According to the Tracking Universal Health Coverage 2023,Global monitoring report in 2015, Kenya's Universal health coverage (UHC) service coverage index (SCI) was 53 as compared to the global average index of 65 (the 2030 target is 100). The same year, 5.2% of the Kenya population incurred catastrophic health expenditure (at 10% of household total consumption or income) leading to 1.3% of the population pushed into poverty by OOP health spending (at the 2017 PPP US$ 2.15 a day poverty line) and 14.7% further pushed into poverty.

UHC is expected to enhance socio-economic development, and contribute to poverty reduction as well as build solidarity and trust. To accelerate progress towards UHC in the past, Kenya has implemented several key reforms with varied degrees of success. While these reforms have facilitated progress towards UHC, health insurance coverage remains low at 25% and lowest among the low-income group at less than 5%. The out-of-pocket payment by households for health stands at Kshs. 150 Billion shillings annually, this expenditure is catastrophic to households and is responsible for pushing 5% of households into poverty every year as households sell their wealth to cater for health bills, many more do not seek care when they fall ill due to affordability barriers.

The Social Health Insurance Act 2023 establishes the Primary Healthcare Fund, the Social Health Insurance Fund and the Emergency, Chronic and Critical Illness Fund. These three (3) funds demonstrate concrete steps taken by the government to ensure UHC for all Kenyan. These interventions include:

(a) a fully publicly financed primary healthcare comprising of preventive, promotive, curative, palliative and rehabilitative services;

(b) integrating Information Communication and Technology systems to enhance telemedicine and health management information systems to improve efficiency, address fraud and enable patient data portability;

(c) ring-fencing funds for healthcare at the facility level to enable availability of funds at the public facility for improvement of health services in collaboration with County Governments;

(d) setting up an emergency medical treatment fund to cater for emergencies, cancer treatment and referrals; and

(e) providing a National Health Insurance Fund coverage for all Kenyans without exclusion in the policy of “Leaving No One Behind”.

2.3 The Concept of Social Health Insurance

Social health insurance is a system where a group of people collectively pool resources and funds to provide health coverage and services to its members. It involves the mandatory or voluntary participation of individuals, usually through contributions or premiums, to finance the cost of healthcare. The pooled funds are then used to cover medical expenses, ensuring that individuals have access to essential healthcare services without facing financial hardship. This model is often managed or regulated by the government or other governing bodies to ensure equitable access to healthcare for the population.

It is important to note that there is no Free Healthcare (FHC) in anywhere. If one accesses health services for free, someone else somewhere is paying for it, or must pay for it in the future. The government has been subsidizing and providing funding for the provision of free services or supplemented through conditional grants, user fee foregone, output based financing as well as providing in-kind support through supplies of medicines, vaccines and medical equipment.

The Government has often provided policy direction that eliminated user fees at the point of service for level 2 and 3 health facilities and for selected population groups usually characterised by medical or economic vulnerability.

The Global Burden of Disease ranks Kenya at an approximate UHC index of 55 percent and predicts that by 2030, the UHC index will be at 60 percent. The Social Health Insurance Act is a strategic initiative to progressively enable everyone to access the services that address the most important causes of disease and death, and ensure that the quality of these services is good enough to improve the health of Kenyans for the country to achieve close to 100 percent UHC.

The proposed Social Health Insurance (General) Regulations will accelerate the realisation of Universal Health Coverage in Kenya by making the Social Health Authority a strategic purchaser of health services with a sustainable revenue base.

CHAPTER 3

PROBLEM DEFINITION

3.1 INTRODUCTION

The health sector in Kenya is governed at two levels: national and county. The national level has overall stewardship; policy formulation, standards and regulations, capacity building and national referral facilities, while the counties are responsible for policy implementation and service delivery. The levels conduct their activities based on mutual consultation, collaboration, and cooperation. Kenya has a mix of public (41%), private (49 %), faith based and NGOs (10 %) health service providers (KMHFL, 2023).

The country has made massive investments in health infrastructure, which has improved access to and coverage of health services in the country, albeit with substantial variation across counties. The number of government health facilities increased by 33.6 percent from 4,456 to 5,953 nationally from 2013 to 2018. As the number of health facilities increased, access to health services also improved, especially in previously neglected and remote areas. Today, more than 90 percent of Kenyans live within five kilometres or one-hour travel time to a health facility.

Most public health facilities are managed by county governments. All healthcare providers are organised in levels or tiers of health service provision ranging from community health services (Level 1), dispensaries and health centres (Level 2 and 3), primary referral hospitals (Level 4), secondary referral hospitals (Level 5) and tertiary referral hospitals (Level 6). Each of these levels is expected to provide the Kenya Essential Package for Health (KEPH): a

life-cycle oriented package of preventive, promotive, curative, and rehabilitative health services.

The health workforce comprises a variety of cadres developed through both private and public training institutions. The workforce is likewise engaged in both public and private sectors. Also, the country has made progress in filling the gap in skilled human resources for health (HRH), yet availability remains a major bottleneck to improving quality of care. Since FY 2014/15, Kenya has increased the total number of health staff (national and county levels) by 68 percent, reaching 17,000 staff in total in the health sector, with most of the increases occurring at the county level following devolution. However, counties report that they continue to be constrained by health worker shortages When compared to the Kenya normative requirements for HRH, in 2016 Kenya had an average gap of 281 percent. This was reduced to 152 percent by FY 2019/20, following recruitment in light of the UHC agenda suggesting that in a large number of some counties, even a double in the current number of technical staff would not be enough to meet the normative requirement.

Access to health products and technologies is through three main channels: public by the Kenya Medical Supplies Authority (KEMSA), private not-for-profit (PNFP) by the Mission for Essential Drugs and Supplies (MEDS) and private for profit (PFP) suppliers. However, Insufficient funds result in delays in payment to suppliers, which creates a lack of trust between the suppliers and purchaser. Poor quantification and delays in procurement have also been big challenges in the country. This poor coordination has led to an overestimation and underestimation of drugs, which created large stock-outs and inefficiencies in the procurement process. The devolved government system has significantly increased county-level decision-space in deciding and purchasing their own drugs. Although some counties experienced improvements with health products and

technologies procurement, many counties also experienced shortages, wastages, and stock-outs.

The Kenya Health Information System (KHIS) provides the overall framework for health information management in Kenya. Over the last two decades, Kenya has increased investments towards strengthening Health Information systems. To accomplish the vision for the health sector, "to provide equitable and affordable quality health services to all Kenyans", the first Medium Term Plan 2008- 2012 of the Vision 2030 identified the need to strengthen the national health information systems with timely and understandable information on health. Furthermore, health information was identified as a key investment area in the Kenya Health Policy 2014-2030 to ensure generation, and management of information to guide evidence-based decision making in the provision of health and related services at the national and county levels. However, Inadequate Government financial allocation to health information monitoring and evaluation activities leads to over-reliance on donor support at both the national and county levels, under-prioritisation of HIS activities at both the national and county levels, irregular data review meetings due to inadequate funding and Inadequate data-collection and reporting tools at the service delivery points.

Kenya is facing a changing health financing landscape with the government taking an increasing role, while contributions from donors and corporations are shrinking**.** Over the past 20 years, total health expenditures have increased continuously, with varying contributions by each source. The government's contribution in financing health care increased from 27 percent of total health expenditure in 2009/10 to about 52 percent in 2018/19. During the same period, the role of households declined from 30 percent of total health expenditures in 2009/10 to 24 percent in 2018/19, showing the impact of reforms to increase financial protection of the poor and of households in the informal sector. According to the Kenya National Health Accounts 2018/2019, the Total Health

Expenditure (THE), in Kenya in FY 2018/19 was KSh 497.7 billion (USD 4,920 million), a 13 percent increase from KSh 442 billion (USD 4,315 million) in FY 2016/17. Total health expenditures in FY 2018/19 were 5.6% of GDP, a slight increase from 5.5% in FY 2016/17. The government expenditure on health as a percent of total government expenditure increased from 10.8 % in FY2016/17 to 11.7 % in FY 2018/19. The per capita spending on health also increased by 9 percent from USD97.4 in FY 2016/17 to USD 105.8 in FY 2018/19.

3.2 FINANCIAL BARRIERS AS THE BIGGEST OBSTACLES TO ACCESS AND QUALITY HEALTHCARE.

Impoverishing health spending continue to be a problem globally [1] . In 2017, approximately half a billion people were pushed or further pushed into extreme poverty, and 2.2 times as many went further into relative poverty. Across all country income groups, the poor spending any amount of Out of Pocket (OOP) on health represented between 83% and 89% of the people incurring impoverishing health spending.

According to the Kenya Household Health Expenditure and Utilization Survey (KHHEUS) 2018, out of pocket expenditure was at 32% and the incidence of catastrophic health expenditure was estimated to be 4.9%, an improvement from 6% recorded in 2013. As mentioned in Section 2.2 above, in 2015, 1.3% of the Kenya population were pushed into poverty due to OOP health spending (at the 2017 PPP US$ 2.15 a day poverty line) and 14.7% were further pushed into poverty.

Further, approximately 28% of Kenyans do not seek healthcare shows the dire need to pay attention to ensuring coverage policies aim to reduce financial hardship among the poor, even in relatively well-resourced health systems.

[1] Global monitoring report on financial protection in health 2021 (WB and WHO)

Although out-of-pocket expenditure has gradually reduced over the years, Kenyans are still at risk of being exposed to catastrophic health expenditures.[2] When out-of-pocket payments are required, households with elderly, persons with disability, or chronically ill members are generally more likely to be confronted with catastrophic health spending than others. This is both because they usually have a greater need for health services and because they lack financial resources.[3] The proposed regulations will cushion the members from out-of-pocket payments by ensuring enrolment to the social health insurance for all and highlighting the benefits payable to healthcare providers.

The regulations have designed a benefit package which covers emergency, chronic and critical illnesses that are often associated with catastrophic health expenditures.

Moreover, the Primary Health Care(PHC) fund promotes increased investment in the provision of primary health care services and strengthens PHC systems. The strengthening of PHC systems is the most cost effective pathway towards the attainment of UHC. A very robust and well-resourced PHC system is able to meet more that 80% of the population essential health needs.

3.3 FRAGMENTED POOLING OF FUNDS

Pooling is the accumulation and management of prepaid financial resources on behalf of some or all of the population. Pooling is an enabling function, creating opportunities for efficient redistribution of resources to support equitable access to needed services, with financial protection from any given level of prepaid funding.

[2] World Health Organization Global Health Expenditure database (apps.who.int/nha/database)

[3] World Health Organization. (2005). Designing health financing systems to reduce catastrophic health expenditure. World Health Organization. https://apps.who.int/iris/handle/10665/70005

The pooling arrangements in Kenya's public health financing system are fragmented due to the many schemes with different entitlements and associated high cost of administration. Evidence has shown that the pooling function of a health financing system works better and optimally if there is more consolidation than fragmentation. Fragmented pools do not achieve a high level of redistributive effect through cross-subsidization and consequently offer low levels of financial risk protection. Given this, it is essential that funds are pooled in a way that enables their redistribution towards people with the greatest health needs, to ensure that they can access the services they need, without financial hardship. This is fundamental to the goals and objectives of universal health coverage.

These proposed regulations aim at progressive financing such that payments for health care rise as a proportion of an individual's income as it rises. Fragmented and overlapping schemes within the current NHIF (Linda Mama, indigents, civil servants' scheme, secondary school children and elderly support) and the various disease-based donor-driven financing schemes, undermine the principle and benefits of the widest possible risk pooling that a social health insurance scheme is supposed to provide. This financing system has significant poverty/equity implications given that households directly bear most health-care costs.

These Regulations seek to enhance the capacity of Social Health Authority to effectively deliver UHC in the following ways:

1. Revision of the contribution rates to be a percentage rate of gross income for employed households shall pay a monthly statutory deduction contribution to the Social Health Insurance Fund at a rate of 2.75% of the gross salary
2. Revision of the contribution rates for non-salaried households an annual contribution to the Social Health Insurance Fund at a rate of 2.75% of the proportion of household income as determined by the means testing instrument

3. Provision for government contributions for the indigent and vulnerable in society at a base premium rate calculated using statistical data and actuarial models and guided by the essential healthcare benefits
4. The provision of benefit package that offers inpatient care, outpatient care, emergency care and several specialised services,
5. The Digitalization of several core functions including claims management, member registration, and premium contributions, and
6. Streamlining the empanelling and contracting process for healthcare providers to ensure that beneficiaries have access to affordable and quality healthcare services.

3.4 LOW INSURANCE COVERAGE

Prepayment mechanisms have been shown to be more equitable than payment at the point of seeking care. Over reliance on out-of-pocket payments means that access to health is based on ability to pay rather than on need for services. This puts the lower socio-economic groups at a disadvantage. The uptake of health insurance coverage is still relatively low in Kenya at approximately 26%. Many Kenyans do not access health services due to cost factors and when they do, access is limited by socio-economic and geographical barriers. Health insurance coverage is inequitably distributed across socio-economic status and geographically (rural vs urban). Health insurance coverage is higher among the rich than among the poor and also higher in urban areas than in rural areas. The 2022 KDHS report shows that in the poorest quantile, insurance coverage is 5% among both men and women but 56% and 60% among women and men respectively in the richest quintile of the population. Similarly, insurance coverage is higher in urban areas ((39% among women and 41% among men) as compared to rural areas (20% among women and 19% among men (KDHS 2022).

The goal of UHC under the Bottom Up Economic Transformation Agenda 2022-2027 has been to eliminate the social and economic challenges that Kenyans face due to the cost of healthcare by purposefully restructuring the health financing landscape. Prepayment for health services through insurance has been shown to cushion households from impoverishment in the event of illness. Additionally, the community health insurance schemes and private health insurance schemes pools operate independently and are not linked to other insurance pools which undermines the principle of social insurance. To accelerate the achievement of UHC through health insurance, the proposed regulations will implement mandatory health insurance for all Kenyans to bring coverage to 100%. This will see sufficient resources raised for health, making health care services affordable and equitably accessible to all Kenyans irrespective of their ability to pay or where they happen to live.

3.5 LIMITED ACCESS TO EMERGENCY SERVICES

Emergency medical care is the necessary immediate health care that must be administered to prevent death or worsening of a medical situation. Emergency services are life-defining and protect life. Nevertheless, emergencies occur daily in Kenya contributing to increased morbidity and mortality. Emergencies are presenting to emergency departments across the country occasioned by an increase in the incidence of NCDs (such as cancer, diabetes, and hypertension), trauma mostly due to road traffic crashes (RTC), and communicable diseases. The leading causes of injuries in Kenya are assault (42%), road traffic crashes (28%), (occasioned by I the increase in the number of motorcycles), unspecified soft tissue injuries (11%), cut-wounds, dog bites, falls, burns and poisonings each (< 10%). Globally, Up to 54% of deaths are due to a lack of optimal emergency care, yet this is their constitutional right. This is attributed to lack of access to the needed emergency health services due to weak financial protection. The proposed regulations cover Kenyans' access to life-saving emergency health services across the

health service providers, a move that will lead to reduced incidents of premature mortality among Kenyans and significant improvement in quality-adjusted life years (QALY) for Kenyans faced with life-threatening health emergencies.

3.6 FINANCIAL SUSTAINABILITY

Ensuring health insurance coverage for all allows for better risk pooling by allowing the higher costs of the less healthy to be offset by the relatively lower costs of the healthy, either in a plan overall or within a premium rating category.

The multiple sources of the revenues to the SHI and strategic purchasing guarantees the scheme's financial viability. The financial sustainability of the SHI depends on how the scheme ensures both technical and allocative efficiencies, identify the new sources of financing, and supports country governments to make tough choices based on evidence.

The renewed focus on and investment in Primary health care implies that up to 90% of people's health needs could be addressed at lower levels and controlling escalating expensive specialised curative services at higher levels.

3.7 THE URGENCY TO IMPLEMENT RECOMMENDATIONS FROM THE HEFREP REPORT

The Health Financing Reforms Experts Panel (HEFREP) that was appointed by the Cabinet Secretary for health in 2018 was tasked to spearhead reforms towards the transformation and repositioning of NHIF as Strategic Purchaser of Healthcare services towards attainment of UHC. The panel in their report discussed recommendations on-

a) Healthcare Purchasing

b) Business Process Re-engineering

c) Strengthening the Financial Sustainability of NHIF

d) Governance, Legal And Regulatory Reforms

Since independence, the core of the former NHIF had been the insurance of the payroll people, who were only 20% of the Kenyan population. While the economic structure of the Kenyan economy changed way long after independence, the need to ensure the majority of the Kenyan population who are non-payroll (80% of the Kenyan population) has never been the key point of address by the former NHIF. NHIF relied heavily on only 20% of payroll Kenyans to finance health care for the whole country is setting the country for failure and leaves the poor and the vulnerable households to the mercies of gods.

The financing mechanism of NHIF was unsustainable, since it is impossible for the employed (payroll) persons to contribute enough to cater even for the health needs of the 80% non-payroll Kenyans, such a system promoted inequality and disadvantages for majority of Kenyan households.

Moreover, the lack of a robust end to end digital system for NHIF constrained unique identification of patients causing the insurer the loss of Billions of shillings through fraud and poor management of claims.

The former NHIF contribution structure was regressive and punished households for being poor. The manner in which the determination of contributions was done was not based on the principle of social insurance where there is more risk pooling in relation to the risk of incurring medical expenses. This is the same case for the employed and the non-employed. The less income a household has the more they are charged for NHIF. This is unfair treatment of the less advantaged in the society and is completely against the principle of natural justice.

Table 1: *Former NHIF Formal Contribution Structure.*

Gross Income	Monthly Premiums	%_Premium/Earn	Number of Principal members	% Change in premium	Total contributors
0-5,999	150	5.00%	45,320	-2.25%	**1,653,052 (54%)**
6000-7,999	300	4.29%	76,689	-1.54%	
8,000-11,999	400	4.00%	209,585	-1.25%	
12,000-14,999	500	3.85%	386,039	-1.10%	
15,000-19,999	600	3.43%	343,995	-0.68%	
20,000-24,999	750	3.33%	247,457	-0.58%	
25,000-29,999	850	3.09%	195,224	-0.34%	
30,000-34,999	900	2.77%	148,743	-0.02%	
35,000-39,999	950	2.53%	136,317	0.22%	**1,389,985 (46%)**
40,000-44,999	1000	2.35%	150,055	0.40%	
45,000-49,999	1,100	2.32%	126,892	0.43%	
50,000-59,999	1,200	2.18%	181,566	0.57%	
60,000-69,999	1,300	2.00%	124,641	0.75%	
70,000-79,999	1,400	1.87%	124,470	0.88%	
80,000-89,999	1,500	1.76%	88,965	0.99%	
90,000-99,999	1,600	1.68%	72,126	1.07%	

100,000 and above	1,700	1.12%	384,953	1.63%	

The former NHIF operated as a passive rather than a strategic purchaser. NHIF's sole focus was primary and secondary curative care, with limited scope of primary health care, health promotion and preventive health services. This is the firefighting principle, where one waits for a disease to happen then invests in treatment of the disease, instead of preventing the occurrence of that disease.

The "legacy NHIF" performed the function of revenue collection, decided the benefit package, choose providers, did claim verification, paid the providers, and resolves disputes. With this arrangement as an entity, it was bedevilled with structural inefficiencies and fraud. The best practice globally recommends the separation of functions so as to leave the social insurer as a strategic purchaser of health services while other functions are handled separately. The Social Health Insurance Act aligns to global best practice.

The NHIF was plagued by inefficiency and governance challenges. It was against the backdrop above that the Ministry of Health proposed a paradigm shift in the provision of Social Health Insurance through the Social Health Insurance Act, 2023 that repealed the National Health Insurance Fund Act, No. 9 of 1998.

The repealing of the National Health Insurance Fund Act, No. 9 of 1998 was necessary and the Social Health Insurance Act essentially separates the functions of registration, claims management, empanelment and dispute resolution that were hitherto being performed by one entity(former NHIF) .This separation will enhance efficiency through reduction of administrative costs. The monies saved from this reduction can then be expended for the payment of a comprehensive and optimal health cover for Kenyans

CHAPTER 4

POLICY, LEGAL AND INSTITUTIONAL FRAMEWORK

4.1 INTRODUCTION

An evaluation of the legal and policy frameworks related to the Social Health Insurance Fund is intended to bring out the context and legal environment within which the proposed Regulations, 2024 are being developed. Regulatory processes should be structured so that all regulatory decisions rigorously respect the principles of 'rule of law'. This means that there should be explicit responsibility for ensuring that all regulations are authorised by higher-level regulations and are consistent with the supreme law and treaty obligations. In addition, they should complement other legal requirements and ensure statutory harmony of the entire statute book.

4.2 The Constitution of Kenya 2010

The Constitution of Kenya 2010 provides the overarching legal framework to ensure a comprehensive rights-based approach to health services delivery. It sets out the general

rights and duties that a public body is expected to adhere to and the values of equity, social justice, equality, inclusiveness, and public participation[4].

More specific rights and duties are enshrined in the Bill of Rights under Chapter Four of the Constitution. Article 43(1)(a) provides that every person has a right to the highest attainable standard of health, which includes reproductive health rights. It further states that a person shall not be denied emergency medical treatment[5] and that the State shall provide appropriate social security to persons who are unable to support themselves and their dependents.

The Constitution requires the State and every State organ to observe, respect, protect, promote, and fulfil the rights in the Constitution and to take "legislative, policy and other measures, including setting of standards to achieve the progressive realisation of the rights guaranteed in Article 43. These measures include addressing the needs of vulnerable groups within society and the international obligations regarding those rights[6]. Article 20 (5) (b) requires that in allocating resources, the State will give priority to ensuring widest possible enjoyment of the right or fundamental freedom having regard to prevailing circumstance, including the vulnerability of groups or individuals amongst other rights. These vulnerabilities are addressed in the Constitution which pays special attention to the health of children[7], minorities and marginalised groups[8] and the elderly[9]. As such, barriers to health care services of whatever kind should not hinder access and the government is duty bound to remove such barriers so that health rights are genuinely

[4] Article 10(2)(b)

[5] Article 43(2)

[6] Article 22

[7] Article 53(1)(c)

[8] Article 56(e)

[9] Article 57(d)

met. It is to fulfil these constitutional obligations that the Cabinet Secretary for Health in consultation with Social Health Authority Board the has drafted these regulations.

4.3 The Social Health Insurance Act

The principal statute that governs Social Health Insurance Fund is the Social Health Insurance Act. The Act establishes the Social Health Authority.[10]

One of the objectives of the Act is to provide a framework for improved outcome and financial protection in line with the right to health and universal health coverage. The Board intends to facilitate the registration of members, identification of beneficiaries, contributions to the Fund, claims and benefits and empanelment and contracting of Healthcare Providers.

The Social Health Insurance Act, 2023, establishes three funds: Primary Healthcare Fund established under Section 20, the Social Health Insurance Fund established under Section 25 and the Emergency, Chronic and Critical Illness Fund under Section 25.

The draft regulations will provide for the payment of claims (including those for emergency treatment), the functions and access to the centralised digital platform as well as the benefit package.

The Act further provides for contributions to the Fund.[11]This Act requires contributions by the national government on behalf of the indigent and vulnerable. The proposed Regulations will implement the rates of contribution for each category of contributor.

[10] Section 4,Social Health Insurance Act.
[11] Section 27,Social Health Insurance Act.

The empanelment and contracting of Healthcare Providers will be done in consultation with the body responsible for accreditation for quality of care.[12] It also sets out how the Authority will negotiate and enter into contracts with healthcare service providers.

The principal object of the Social Health Insurance Act, 2023 is to establish a legislative framework to regulate the provision of social health insurance, promote the implementation of Universal Health Coverage and to ensure that all Kenyans have access to affordable and comprehensive quality health services. The Act establishes the Social Health Authority that is mandated to manage three public Funds established under the Act, namely the Primary Healthcare Fund, the Social Health Insurance Fund, and the Emergency, Chronic, and Critical Illness Fund.

The Primary Healthcare Fund is intended to purchase primary health care services from health facilities in level 2 and 3. Kenyans need not pay any contribution to this Fund as the Fund will be financed by the exchequer through monies appropriated by the National Assembly. This Fund is a major shift from the current NHIF as the latter currently does not pay for healthcare services provided at the primary health care level. The Fund will therefore take services to the people and make them available closer to the people. The Fund also anchors the country's healthcare system on a prevention pathway. The Fund is therefore a game changer as prevention of disease is the only known sustainable health care financing model.

The Social Health Insurance Fund is intended to pay for healthcare services provided in the contracted level 4, 5 and 6 health facilities. Kenyans will contribute 2.75% of their income to the Social Health Insurance Fund only. This is the first time that the social health scheme in Kenya will not punish the poor for being poor, as it abandons the regressing system and moves towards proportional contribution where one contributes based on

[12] Section 23(2),Social Health Insurance Act.

the ability to pay. The 2.75% will be an equalizer, regardless of a person's income and employment status. In addition, it is actuarially fair premium based on the country's epidemiology and cost of health care. Actuarially fair premium sets the insurance premium to be paid that is equal to the insurer's expected pay out making the insurance payment stable and realisable in the event disease occurs.

The Emergency, Chronic and Critical Illness Fund is intended to cover the costs of emergency treatment (including 24 hrs stabilisation) and to defray the costs of management of chronic illnesses after the depletion of the social health insurance cover. The Fund is financed by the exchequer through monies appropriated by the National Assembly. In the past, due to the lack of a pool where health facilities could claim payment for responding to emergencies, hospitals have been unable to take care of Kenyans at their hour of need as the bills incurred would become a bad debt to a hospital constraining the hospital's existence.

Previously, the focus of health insurance coverage in the country has also only been on emergency evacuation, majorly ambulances, which has seen some health facilities refuse to take in patients as no one would pay for the cost incurred by the health facility in the provision of emergency hospital care. Through the Act, this will change as the government will provide two-pronged emergency medical treatment by paying healthcare providers for both the provision of emergency hospital care and ambulance services through the Fund. This depicts that the law is aligned to Article 43(2) of the Constitution which provides that no Kenyan should be denied emergency medical treatment.

The Emergency, Chronic and Critical Illness Fund will also pay for the treatment of chronic illnesses such as cancer which has impoverished numerous Kenyan families even after they have sought financial assistance through *harambees.* The Fund will therefore come in where a person has depleted their benefits under the Social Health Insurance Fund and still requires treatment for their chronic or critical illness.

The Social Health Authority is mandated to register beneficiaries and to receive all contributions from beneficiaries, to contract healthcare providers and health facilities upon successful certification by the relevant body responsible for quality of care in the country, to make payments to the contracted health care providers and health facilities, to advise the Cabinet Secretary on matters of social health insurance including the formulation of policies and to implement all government policies on social health insurance among others.

The Act also establishes a Claims Management Office within the Social Health Authority to review and process claims made by health care providers and health facilities. The Act further establishes a Dispute Resolution Tribunal to hear and determine complaints, disputes and appeals arising from decisions made on matters pertaining to social health insurance.

The Social Health Authority plays a key role in supporting the delivery of the aspirations of Kenya Vision 2030, under the social pillar, and the Bottom-up Economic Transformation Agenda (BETA) plan under the Big Four agenda, which envisions a nation that is healthy and prosperous as earlier mentioned. The Social Health Authority is intended to respond to the health needs of Kenyans as contemplated in the Kenya Universal Health Coverage Policy, 2020-2030. The Social Health Authority will further provide a healthcare package that is aligned to the Kenya Health Financing Strategy, 2020-2030 as there will be fairness in the financing of health services in a manner that guarantees that all Kenyans have access to essential high quality healthcare services based on their ability to pay.

The Act promotes the attainment of Universal Health Coverage in the country as it seeks to ensure that all Kenyans have access to affordable and comprehensive quality health services. This is through the provision of a health cover for older persons, indigents and other vulnerable persons in society including persons in lawful custody who have for a long time been forgotten. In this way, the Act is therefore aligned to the policy of "Leaving

No One Behind" and the Constitution of Kenya, 2010 which requires the government provide appropriate social security to persons who are unable to support themselves and their dependants.

The Act also provided for mandatory registration of members. The draft regulations on registration of members set out the details of how contributors to the Fund and their Beneficiaries will be registered. The draft regulations on identification of beneficiaries further provide for how those registered will be identified at the point of registration.

In addition to these provisions, the Act provides for-

(a) Providing for emergency treatment;

(b) Providing for the use of a digitalized system to process claims and services;[13]

4.4 The Health Act of 2017

The Health Act also mandates that every person has a right to emergency medical care[14] which includes pre-hospital care, stabilisation and arranging for referral of the patient. This impacts the benefits payable by the Social Health Authority and will be relevant in the proposed regulations which acknowledge that the Fund will cater for certain types of emergency care.

With respect to health insurance, Section 86 of the Health Act requires the government to:

(a) develop mechanisms for an integrated national health insurance system including making provisions for social health protection and health technology assessment

(b) develop policies and strategies that ensure realisation of universal health coverage

[13] Section 47 ,Social Health Insurance Act.
[14] Health Act, Section 7

(c) define in collaboration with the department responsible for finance, public financing of healthcare framework, including annual allocations towards reimbursing all health care providers responding to disasters and emergencies as contemplated under this Act.

The SHI Act and the proposed regulations are geared towards facilitating this financial access through UHC. The regulations set out the rates for contributors to pay (the main source of revenue for social health insurance) and how the Social Health Authority will reimburse the medical benefits its members and their beneficiaries receive from healthcare providers and healthcare facilities.

The Health Ministry is also required under Section 86 to provide for vulnerable groups and indigents as well as provide a framework for examining means of optimising usage of private health services. The Ministry has done this through various instruments including the Universal Health Coverage Policy 2020-2030 which provides, amongst other matters, coverage for indigent Kenyans. This obligation requires contributions from the National and County government for vulnerable and indigent persons. The draft regulations would implement this aspect of the Health Act as they provide for the rate of contribution that the Government will pay for indigent and vulnerable persons.

Section 86 of the Health Act, 2017 also affects the empanelment, contracting and payment of benefits to private healthcare providers. The Proposed Regulations provide how healthcare providers and healthcare facilities will be empanelled and contracted including onboarding into the centralised digital platform.

Primary healthcare providers are also critical in the provision of primary health care and the Health Act sets out the division of duties between national government and county governments with respect to public health facilities. PHC is through formation of primary care networks. In the PCN model, the Community Health Units (level 1) are linked to the level 2(dispensary) and 3(Heath centre) facilities (spokes) which serve with both preventive

and curative health services. The level 2 and 3 facilities are spokes that are then linked to a primary-level hospital (level 4) as the hub which provides support and coordination and acts as the first point of referral. The PCN is managed by a multidisciplinary team that coordinates primary health care services for the catchment population at the primary health facilities and the community level.

4.5 The Insurance Act (Cap 487)

The Insurance Act provides for, among other things, the regulation of the business of insurance in Kenya. The Social Insurance Act under Section 52 shall apply to the Authority only in respect to the administration of claims.

4.6 The Children Act of 2022 No.29 of 2022

The Children Act makes provision for parental responsibility, fostering, adoption, custody, maintenance, guardianship, care, and protection of children. It makes both the parents of a child and the Government responsible for the health and medical care of children.[15]

The Act is important to SHI not only because it is the specific legislation that deals with the welfare of children (including their mental and physical health), but because it is also the principal statute that domesticates Kenya's obligations under the Convention on the Rights of the Child.

The most relevant parts of the Children's Act with respect to the draft regulations are those with respect to protection for children in need of care and protection who are particularly vulnerable. These include the following:

[15] Children Act, Section 9

(a) orphan children;

(b) adopted children;

(c) children living with mental or physical disability; and

(d) children in conflict with the law.

The Act provides for the appointment of guardians for children through testamentary documents, by deed or by a court of law.[16] The Act also provides for the responsibility of guardians including for medical treatment of these children.[17] This is important because the SHI Act only recognizes that persons over the age of 18 will register as members and this may lock out orphaned children from access to affordable medical treatment unless a guardian can register them under his/her household. This is addressed by the draft regulations on registration of members which will provide for guardians registering the relevant child upon proof of guardianship.

The same issue arises with respect to adopted children. The Children Act provides for eligibility to adopt a child and the adoption process. Such children can only benefit from Social Health Insurance if there is proof of adoption and the adopting parent registers them as his/her household. The draft regulations provide for adopted children in line with the Children Act: they can be registered for Social Health Insurance upon proof that they have formally completed the process of adoption.

4.7 The Digital Health Act

The Act provides a framework for the provision of digital health services and establishes a comprehensive integrated digital health information, communication and technology system. This system will provide for data governance and protection of personal health

[16] Children Act, Section 102

[17] Children Act, Section 24 read with Section 27

information and service delivery through digital health interventions such as telemedicine, e-waste disposal and health tourism.

The Act establishes the Digital Health Agency which is mandated to regulate the provision of digital health services in Kenya.

The Agency is required to develop, operationalize, and maintain a Comprehensive Integrated Health Information System. To this end, the Agency is required to establish registries to create a single source of truth; to facilitate collection and analysis of data to inform policy and research in the health sector; to strengthen existing health information systems; to certify digital health solutions based on best practices and standards, and to advise the Cabinet Secretary on matters related to digital health.

The Comprehensive Integrated Health Information System established under the Act is intended to generally manage the core digital systems and the infrastructure required for seamless health information exchange. Having an integrated system addresses the challenges posed by fragmented and siloed health data systems. Further, by centralizing health information in a secure and standardized manner, healthcare providers can access comprehensive patient data leading to more informed diagnoses and treatment decisions.

The system is, in particular, intended to facilitate a people-centered quality health service delivery, to facilitate data collection and reporting at all levels of health care provision, to enable secure health data sharing for timely and informed inter-facility health service delivery, to facilitate data processing and use for informed decision-making at all levels, to safeguard the privacy, confidentiality, and security of health data for information sharing and use, and to facilitate the tracking and tracing of health products and technologies in the country, among others.

Several other statutes affect the operating context of Social Health Insurance, however because they have an indirect legislative impact on Social Health Insurance's functions and role, they are simply listed below:

(a) State Corporations Act

(b) Public Finance Management Act

(c) Public Audit Act

(d) Data Protection Act

(e) Primary HealthCare Act

(f) Consumer Protection Act

(g) Criminal Procedure Code

(h) Public Procurement and Assets Disposals Act

(i) Work Injuries Benefits Act

4.8 Policy Framework

The following key policies guide the development of these regulations. These include the following:

(a) Vision 2030 ;

(b) The Kenya Health Policy 2014 – 2030;

(c) The Universal Health Policy 2020-2030; and

(d) The Bottom Up Economic Transformation Agenda (BeTA) 2022-2027;

4.8.1 VISION 2030

Vision 2030 is an overarching national development policy that was unveiled in 2007 and has been implemented in rolling out 5-year plans. It is anchored on three pillars: economic, social, and political. It is under the social pillar that health-related goals are found. The aim is to improve the overall livelihood of Kenyans: with respect to health, the country aims at an equitable and affordable healthcare system of the highest possible quality.

The strategy advanced by Vision 2030 includes:

(a) Enhancing the regulatory regime

(b) Increasing finances available to the health sector and ensuring that they are utilised more efficiently.

(c) Develop a social health insurance scheme.

The SHI Act and the draft regulations advance these strategies by providing for increased financing for the health sector through national government contributions for the indigent and vulnerable.

4.8.2 KENYA HEALTH POLICY

The Kenya Health Policy 2014-2030 gives directions to the relevant implementation stakeholders to ensure significant improvement in overall status of health in Kenya in line with the Constitution of Kenya 2010, the country's long-term development agenda, Vision 2030, and Kenya's global commitments.

The goal of the Policy is to attain the highest possible standard of health in a responsive manner. This goal will be achieved by supporting equitable, affordable, and high-quality health and related services at the highest attainable standards for all Kenyans. Achievement of this goal involves Social Health Authority because the policy orientation, among other things, targets investment targeted towards health financing to improve

access to, quality of, and demand for services. The policy commitment anchoring this is that financial barriers hindering access to services will be minimised or removed for all persons requiring health and related services; guided by the concepts of Universal Health Coverage and Social Health Protection.

In particular, the policy's commitment is to progressively facilitate access to services by all by ensuring social and financial risk protection through adequate mobilisation, allocation, and efficient utilisation of financial resources for health service delivery. The primary responsibility under this policy of providing the financing required to meet the right to health lies with the national and county governments.

These regulations will help ensure that indigent and vulnerable persons have adequate financial risk protection and lower their financial barriers to accessing health care by implementing national government contributions for these groups.

4.8.3 KENYA UHC POLICY 2020-2030

The Universal Health Coverage Policy 2020-2030 provides a framework to ensure that all Kenyans have access to essential quality health services without suffering financial hardship. The Policy's objectives are to:

(a) Strengthen coverage and access to health services;

(b) Ensure quality of health services;

(c) Protect Kenyans from the financial risks of ill-health,and

(d) Strengthen the responsiveness of the health system in Kenya.

The policy embraces the principles of equity, people centredness, efficiency, social solidarity and a multi-sectoral approach. It focuses on four objectives and their related strategies to support attainment of the Government's goal in health. It is cognizant of the functional responsibilities between the National and County levels of Government

with their respective accountability mechanisms and frameworks. It aims to ensure adequacy, efficiency and fairness in financing of health services in a manner that guarantees all Kenyans access to the essential health services that they need, an all-inclusive well-designed financing model through the health financing strategy. Primary health care shall be the vehicle for the delivery of Universal Health Care in Kenya and shall be repositioned as the foundational service delivery platform for the Kenyan health system. PHC seeks to improve access, availability, safety, efficiency, and equitable health service delivery. PHC will lead to the refinement of existing service delivery arrangements by establishment of PCNs that will result in a network of public and private facilities offering responsive, accessible, coordinated, comprehensive and continuous health services, while addressing the determinants of health to individuals, families and communities. The goal of adopting a PCN service delivery model is to ensure efficiency and continuity of care for clients. Good linkages and referrals within and outside the PCN will thus be required. The PCNs led by the Family Medicine Professionals and consisting of the MDTs will ensure availability of comprehensive UHC-EHBP services by facilitating seamless movement and referral services for needy patients and clients within the network. The private facilities shall be contracted to deliver services within the network to meet the needs of the community.

CHAPTER 5

PUBLIC PARTICIPATION AND CONSULTATION

5.1 LEGAL REQUIREMENTS RELATING TO PUBLIC PARTICIPATION AND CONSULTATION

It is a constitutional requirement to carry out public participation whenever a state or public officer enacts any law or makes or implements a public policy. This requirement is based on Article 1 of the Constitution on the sovereignty principle which vests all sovereign power to the people of Kenya. This power entitles the people access to the process of making public decisions through their involvement. Public participation ought to be inclusive, transparent and accountable.

Article 174 gives powers of self-governance to the people and enhance their participation in the exercise of the powers of the State and in making decisions affecting them and recognize the rights of communities to manage their own affairs and to further their development.

The values and principles of public service require the involvement of the people in the process of policy making through provision of timely and accurate information to the public.

The Statutory Instruments Act obligates a regulation making authority to carry out appropriate consultations before making statutory instruments (Regulations) where the proposed regulations are likely to have a direct, or a substantial indirect effect on business or restrict competition. It further provides that in determining whether any consultation that was undertaken is appropriate, the regulation making authority shall have regard to all relevant matters, including the extent to which the consultation:

(a) drew on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument; and

(b) ensured that persons likely to be affected by the proposed statutory instrument had an adequate opportunity to comment on its proposed content.

The Statutory Instruments Act also states that the persons to be consulted should be notified either directly or by advertisement through representative organizations. They shall also be invited to make submissions by a specified date, which should not be less than 14 days or be invited to participate in public hearings concerning the proposed instrument.

5.2 INITIAL PARTICIPATION OF THE STAKEHOLDERS

To ensure nationwide public participation, the Institute carried out consultations and stakeholder engagement forums.

5.3 APPROACH AND METHODOLOGIES

The stakeholders were invited to submit comments on the zero draft regulations within a specified time through letters and emails. The stakeholder consultations were intended to be undertaken during the months of January and February 2024.

CHAPTER 6

OVERVIEW OF THE PROPOSED SOCIAL HEALTH INSURANCE (GENERAL)REGULATIONS

6.1 PROPOSED REGULATIONS

The proposed regulations will bring to effect to Section 24,30,46(2),47(5) and 50(1) of the Social Health Insurance Act, 2023.The proposed regulations provide for the following salient features:-

6.2. CLAIMS AND BENEFITS

The proposed regulations for the establishment of Centralised Digital Platform that is accessible to the empanelled and contracted health care providers for purposes of claims administration, recording beneficiary data, inputting health care service delivery data, and maintaining health care providers data. The system will permit user rights to authorised persons and apply to the board for rights and access to the system in line with data protection Act 2019 and the Digital Health Act,2023. There is provision for the system to maintain an audit trail of all processes and have the capability of data retrieval.

Moreover, beneficiaries undergoing treatment for a chronic illness shall access service s which shall be payable under the Emergency, Chronic and Critical Illness fund established under Section 28 of the Social Health Insurance Act. The funds for critical illness shall be limited to benefits that have been specified by the Fund. The Fund shall provide the benefits provided in the schedule.

These regulations have provided for the provision of emergency treatment without discrimination as well as provision of overseas treatment upon satisfaction of the requirements on overseas treatment as well as the relevant authorization.

6.3 REGISTRATION OF MEMBERS

The Social Health Insurance Fund regulations provide that the following persons who has attained the age of 18 years and is a resident of Kenya shall register as a member and make contributions to the Fund. The provisions of these regulations require each member to provide their biometric details at the point of registration.

To enhance registration for the accelerated achievement of UHC the regulation has provided for the fund to utilise existing National Population Databases to enable actualization of mandatory registration.

6.4 MEANS TESTING

These regulations provide for the use of a means testing instrument to identify the indigent households that require financial assistance and for whom the National Government or the County Government is liable to pay their contributions.

6.5 FEES AND ADMINISTRATIVE COSTS

The Authority particularly intends to collect the monies in order to minimize administration costs. Such costs include service, notices and information to be served to beneficiaries ,healthcare providers or healthcare facilities centres through registered post, hand delivery, or email as deemed convenient.

The Authority proposes to charge contributions as prescribed in the regulations.

6.6 ADMINISTRATIVE MEASURES

The Authority particularly intends to collect the monies in order to minimize administration costs.

CHAPTER 7

THE COST-BENEFIT ANALYSIS FOR THE PROPOSED SOCIAL HEALTH INSURANCE (GENERAL)REGULATIONS

7.1 INTRODUCTION

This section seeks to assess the changes proposed by the regulations in terms of their costs and benefits to justify the proposals pursuant to Section 7(d) of the Statutory Instruments Act.

7.2 BENEFITS AND COSTS ON THE PROPOSED SOCIAL HEALTH INSURANCE (GENERAL)ACT.

The analysis of the expected costs and benefits of the proposed regulations contained in this part seeks to answer the question of whether the benefits justify the costs. This would

enable the Regulator to estimate the total expected cost and benefit of every aspect of the Regulations. The objective of the proposed Regulations is to provide a framework for improved outcome and financial protection in line with the right to health and universal health coverage.

In considering the benefits for the proposed Regulations the key questions to be answered include:-

1) *What is the nature and extent of constraints faced by the Kenyan citizens in the access to quality essential healthcare services and financial protection to all people;*
2) *To what extent is it the role of the government to cushion the health system from emerging and re-emerging disease outbreaks and changing demographic patterns?*
3) *To what extent do Regulations contribute to address the high burden of communicable conditions and non-communicable conditions?*

Kenyans will benefit greatly from the Proposed Regulations. The proposed Regulations will-

(a) provide access to quality essential healthcare services and financial protection to all people;

(b) provide access to quality essential healthcare services and financial protection to all people in Kenya

(c) address the high burden of communicable conditions and non-communicable conditions; and

(d) cushion the health system from emerging and re-emerging disease outbreaks and changing demographic patterns.

Annexure 2 provides a detailed analysis on the costs and benefits of the three options available in responding to the challenges in ensuring the implementation of these regulations.

CHAPTER 8

SOCIAL ECONOMIC IMPACTS

8.1 INTRODUCTION

Generally, Social Health Insurance would radically reform how health is accessed and financed. These reforms provide both opportunities and risks to the entire health system architecture. Lessons from the UHC pilot in 4 counties in Kenya reveals that increasing access comes with a tendency of over-utilisation of insurance visits. The high utilisation puts significant strain on the pool thus challenging its sustainability. Consequently, enforcing mandatory health insurance contributions will create both positive and negative incentives. Also, to ensure *"no one is left behind"* significant investments are required at the different levels of the health system to ensure the availability of better healthcare services to beneficiaries. Further, enrolment of informal groups will be an expensive and challenging task.

8.2. IMPACT OF THE REGULATION ON COUNTY GOVERNMENTS

- Any delays in exchequer releases of funds earmarked to Primary Healthcare Fund will result in disruption in provision of healthcare particularly in the procurement and dispensing of medical commodities.
- A mandatory Social Health Insurance means an Increased number of people seeking care at health facilities (short-term) implying that counties would need to invest more across all health pillars to ensure that the demand of members are met

- The Social Health Insurance combined with Facilities Improvement Financing reforms would see public health facilities increase their own resources and consequently improving their purchasing capacity and medical stock.
- The gate-keeping mechanism envisioned under the Primary Care Networks would enhance efficiency by reducing unnecessary self referrals and ensure better distribution of the SHI funds thus improving the financial status of facilities.
- The comprehensive requirements for contracting and empanelling health facilities will standardise service quality and improve health outcomes.
- Likely to be stiff competition from the private health providers who now have a level playing field.
- Likely conflict of interest by HCWs referring high net worth patients to private health facilities.
- Reduction in the cost of care due to economies of scale.

8.3. IMPACT OF THE REGULATION ON PRIVATE SECTOR

- Opportunity to expand coverage including to rural communities given the harmonised tariffs / level playing field
- Cost escalation mainly in hiring HCWs. Private facilities rely on public health workers for some specialised services. They would need to hire own HCWs especially specialists (if the government ones are 'tied' to government facilities) which implies additional operational costs
- Increased appetite to charge clients for co-payment over and above the SHA rebates.

8.4. IMPACT OF THE REGULATION ON INDIVIDUALS

- Reduced out-of-pocket health expenditure given all households would have a pre-payment mechanism

- In the short to medium term put significant strain on household income especially for formal employees who will pay more to the SHA than their current obligations.
- Disruptions in access to government services during the transition process (mainly during the registration)
- Inequitable access especially for specialised services. People in deprived communities will have limited access to all the services they are entitled to.
- Increased options between public and private health facilities and also access to services from individual providers.
- Improved access to health services for the indigent and vulnerable groups including access to emergency, chronic and critical services that is currently limited.

8.5 IMPACT ANALYSIS OF THE OPTIONS

Matrix of impact of options on key sectors

Impact on sectors	Option one: Maintaining the Status quo	Option two: Administrative measures	Option three: Developing the National Health Insurance Act Regulations
Impact on Public sector	• Non-attainment of UHC • Low registration by persons (over 18 years) who are qualified to	• Difficulty in enforcement.	• The proposed measures in the Regulations will not only address the challenges but also create an enabling environment for investors. • Allow registration of all persons over the age of 18

Impact on sectors	Option one: Maintaining the Status quo	Option two: Administrative measures	Option three: Developing the National Health Insurance Act Regulations
	register for Social Health Insurance. ● A burdened nation crippled by debilitating and expensive medical bills		years to be registered as a member, ● allow members to access quality and affordable health care without suffering financial constraints
Impact on Private sector	● The private sector will largely remain unaffected.	● There is no guarantee that administrative measures will address private sector concerns	● Ease the burden of health care
Economic Impact	● Cost of healthcare services will continue to rise	● Administrative measures are inadequate to contain costs of healthcare	● Reduce the debilitating cost of health care
Social Impact	● families will continue being pushed to	● Administrative measures are not sufficient	● Improved access to healthcare services across the population

Impact on sectors	Option one: Maintaining the Status quo	Option two: Administrative measures	Option three: Developing the National Health Insurance Act Regulations
	poverty because of catastrophic health expenditures	to address out of pocket expenditure	Will address out of pocket through pre-payment mechanism [Social Insurance]
Human Rights Impact	• Attainment of socio-economic rights on health will be slowed down.	• Administrative measures do not have the force of law necessary for guaranteeing human rights	• The regulations will assist in the achievement of highest attainable standards of healthcare for citizens
Impact on business	• Largely no impact	• Lack the force of law for full implementation of the Act.	• creates framework for enterprises to contribute to attainment of UHC
Impact on environment	• Will be generally unaffected	•	• Will facilitate investment in health infrastructure leading to a better environment for all
Impact on taxes	• Largely no impact	•	•

Impact on sectors	Option one: Maintaining the Status quo	Option two: Administrative measures	Option three: Developing the National Health Insurance Act Regulations
Impact on existing legal frameworks	• The existing legal gaps will not be addressed	• Regulatory concerns will remain unaddressed	• Addresses all the identified gaps • Provides harmony with related legal frameworks • No further legal amendments or enactments will be required

CHAPTER 9

CONSIDERATION OF ALTERNATIVES FOR THE PROPOSED SOCIAL HEALTH INSURANCE (GENERAL)REGULATIONS,2024

9.1 INTRODUCTION

The Statutory Instruments Act requires a regulator to carry out an informed evaluation of a variety of regulatory and non-regulatory policy measures by considering relevant issues such as costs, benefits, distributional effects and administrative requirements. Regulations or regulations should be the last resort in realising policy objectives. The options considered under this part are: maintenance of the status quo, administrative measures and developing the proposed Social Insurance Health (General) Regulations.

9.2 OPTION ONE: MAINTENANCE OF THE STATUS QUO

Maintaining the status quo means that no regulations will be developed and therefore the Social Health Insurance Act will not be fully implemented. The development of these Regulations is a requirement of the Act which seeks to address the problems and challenges that have faced the sector since inception. As enacted, the Act requires these Regulations for its full implementation.

Effect of non-implementation of the Act will include amongst others-

i. Non achievement of the UHC state in Kenya, this means that the Authority will not be able to ensure that all Kenyans from the age of 18 years and above are duly registered as members in order to contribute to the Social Insurance Fund and enjoy accessible, affordable health care

ii. The Social Health Insurance Fund will not be financially sustainable and this brings about concerns on the Fund's sustainability in the future.

iii. The out-of-pocket expenditure in Kenya as a percentage of the total health expenditure as of 2019 was 24.3%. Although out-of-pocket expenditure has gradually reduced over the years, from 47.1% in the year 2000 to 24.3% in the year 2019, Kenyans are still at risk of being exposed to catastrophic health expenditures . When out-of-pocket payments are required, households with elderly, handicapped, or chronically ill members are generally more likely to be confronted with catastrophic health spending than others.

The full Implementation of the proposed regulations will address the above highlighted challenges.

9.3 OPTION TWO: ADMINISTRATIVE MEASURES

This is a non-regulatory measure which, if applied, will depend on the good will of public officers to implement the provision of the new Act. Administrative measures involve issuance of directives and circulars to the various departments hoping that they will be implemented. Administrative measures do not have the force of law and may be challenged in court of law. These Regulations seek to impose payment of mandatory fees in terms of contribution to the fund and this must be done in law. This therefore necessitates the need to include all this information in regulations to streamline implementation and achievement of UHC.

Furthermore, changes to the benefits payable cannot be done administratively as the stakeholders have a legitimate right to incorporate their views on the same and to give their recommendations since they will be affected by these changes.

9.4 OPTION THREE: DEVELOPING THE SOCIAL HEALTH INSURANCE FUND (GENERAL) ACT, REGULATIONS, 2024

The development of the regulations on beneficiary identification, member registration, member contributions; empanelment and contracting and on benefits and claims shall ensure that the full implementation of the Social Health Insurance Fund Act. This will affect a much more practicable aspect towards the attainment of Universal Health Coverage.

9.5 PREFERRED OPTION

The preferred option would be the implementation of the drafted regulations with a view to ensure that universal health coverage is fully attained and that all Kenyans receive accessible, affordable, and quality health care without suffering financial constraints as envisioned.

CHAPTER 10

COMPLIANCE AND IMPLEMENTATION

10.1 INSTITUTIONS

It is the duty of the regulator to assess the adequacy of the institutional framework and other incentives through which the regulations will take effect and design responsive implementation strategies that make the best use of them[18].

The implementation and enforcement of these proposed regulations will be undertaken through the existing institutional framework at National level (Ministry of Health) and the County level (County Governments).

10.2 CONCLUSION

Based on the analysis in this report, the proposed Social Health Insurance (General) Regulations,2024 are extremely necessary.

10.3 RECOMMENDATION

In view of the above conclusion, it is recommended that the proposed Social Health Insurance (General) Regulations be adopted.

[18] Source: OECD (1995), the 1995 Recommendation of the Council of the OECD on Improving the Quality of Government Regulation, Paris.

Annexure 2

Problem	Proposed Reform	Cost	Benefits
Inadequate Financial Sustainability of the Social Health Insurance Fund	Mandatory contributions.	**Cost to the Govt** • Indigents Cover – Ksh. 45 billion **Cost to the Citizens** • Informal sector Cost – Ksh.56 billion	**Benefits to the Fund** • Assured premiums/revenue of Ksh. 133 billion from all Kenyan residents **Benefits to the Govt** • Reduced cost of hospital bills waivers of 30% – 40% of FIF • Achievement of UHC **Benefit to Citizens** Reduced OOP expenditure by 15% to less than 10% of total health expenditure.
Weak Funding Model	Mandatory contributions for Informal Sector and Indigents with payment of premiums for indigents by the	As above	**Benefit to the Fund** • Improved retention of informal sector from **24%** to 100% **Benefit to Govt** **Cost to Government for means testing**

	national government; Payments for non-salaried persons to be determined through means testing instrument.		
	Compliance mechanism introduced to support mandatory registration.	**Cost to the Fund** ● Reduced collections	**Benefit to the Fund** ● Increased retention **Benefit to the Citizens** Reduced expenditure from 500% to 10% of principal amount
	Automation through the Centralized Healthcare Provider Management System (CHPMS)	**Cost to the Fund** ● Acquisition and Countrywide roll-out of CHPMS – Ksh. 5 billion ● Maintenance – Ksh. **Cost to Healthcare Providers**	**Benefit to the Fund** ● Reduced losses at approximately 10% – 20% of total pay-out **Benefits to Beneficiaries** Increased transparency

		• ICT Infrastructure acquisition and maintenance	
Adverse Selection in the Informal Sector	Mandatory Contributions by/for all Kenya residents	**Cost to the Govt** • Indigents Cover – Ksh. 45 billion **Cost to the Citizens** • Informal sector Cost – Ksh.56 billion	**Benefits to the Fund** • Reduced pay-out ratio from the current 280% to at most 85% • Increased Informal Sector Revenue from the current approximately 5.5 billion to approximately 56 billion per annum **Benefits to the Government** • Healthy workforce **Benefit to Citizens** Reduced OOP expenditure by 15% to less than 10% of total health expenditure.
Low Health Insurance Coverage	Mandatory Registration of all Kenya Residents	**Cost to the Govt** • Indigents Cover – Ksh. 45 billion	**Benefits to the Fund** • Growth in revenue to Ksh. 133 billion from all Kenyan residents

		Cost to the Citizens ● Informal sector Contributions – Ksh. 56 billion ●	**Benefits to the Govt** ● Reduced cost of hospital bills waivers of 30% – 40% of FIF ● Healthy workforce ● Achievement of UHC **Benefit to Citizens** Reduced OOP expenditure by 15% to less than 10% of total health expenditure.
High out of the pocket expenditure.	Mandatory registration of all Kenya residents National government payment of premiums for the indigents and the vulnerable	**Cost to the Govt** ● Indigents Cover – Ksh. 45 billion **Cost to the Citizens** ● Informal sector Contributions – Ksh.56 billion	**Benefits to the citizens** ● Reduced out of pocket payments for health ● Elimination of the practice of hospital detention due Government subsidy of Ksh. 45 billion for indigents
Limited access to emergency services, and premium chronic	Expanded Coverage for emergency services by the	**Cost to the Govt** ● Ksh. 46 billion	**Benefits to the citizens** ● Assured access to emergency and premium chronic and critical illness health services to all Kenyans.

and critical illness services.	Emergency ,Chronic and Critical illness Fund		• Reduced mortality and disability-adjusted Life Years arising from medical emergencies, some chronic and critical illnesses. **Benefits to healthcare providers** Assured reimbursements for health emergency, premium chronic and critical illness health services provided to clients who would not have otherwise paid.
Weak health financing models	Improved Health Financing Model. Mandatory registration for all Kenyans as the key financing mechanism for health services	**Cost to the Govt** • Indigents Cover – Ksh. 45 billion • Reorganization of financial resources for health **Cost to the Citizens** • Informal sector Contributions – Ksh.56 billion	**Benefit to Government** • Strengthened health financing systems **Benefits to the Fund** • Growth in revenue to Ksh. 133 billion from all Kenyan residents

Weak primary healthcare services	Primary healthcare Fund	Cost to the Government Kshs. 58 billion	**Benefits to the citizens** Improved access to primary health care services for free. **Benefits to the Government** Long term reduction in cost of care accrued from gradual decline in diseases through preventive and health promotion services. **Benefits to the facilities and providers** Assured reimbursements for primary healthcare services provided. Availability of financial resources for facility improvement.

System inefficiencies	Change in the manner used for empanelment of providers. Increased scope and geographical spread of health care providers engaged including for primary healthcare . Centralized healthcare providers' management system	**Cost to the Fund** ● Acquisition and Countrywide roll-out of CHPMS – Ksh. 5 billion ● Maintenance **Cost to Healthcare Providers** ● ICT Infrastructure acquisition and maintenance	**Benefit** Improved transparency for clients, providers, facilities, and the Government.
