REGULATORY IMPACT STATEMENT

FOR

THE NATIONAL HEALTH INSURANCE FUND ACT, REGULATIONS,2022

APRIL 2022

This Regulatory Impact Assessment (RIA) has been prepared by the National Health Insurance Board in Consultation with the Ministry of Health pursuant to Section 6 and 7 of the Statutory Instruments Act (No. 23 of 2013).

ABBREVIATIONS

CHPMS	Centralised Healthcare Provider Management System
CHMT	County Health Management Teams
HEFREP	Health Financing Reforms Experts Panel
ICT	Information, Communication and Technology
FY	Financial Year
NHIF	National Health Insurance Fund
OOP	Out-of-pocket (expenses)
RIA	Regulatory Impact Assessment
UHC	Universal Health Coverage

TABLE OF CONTENT

CHAPTER ONE: INTRODUCTION AND BACKGROUND

1.1 INTRODUCTION

This Regulatory Impact Assessment concludes that the proposed the National Health Insurance Fund Amendment Act, Regulations, 2022 are necessary to operationalize of the National Health Insurance Fund Act. The proposed Regulations will accelerate the realization of Universal Health Coverage in Kenya by making the Fund a strategic purchaser of health services with a sustainable revenue base.

1.2 REGULATORY-MAKING AUTHORITY AND THE LEGAL MANDATE

The Board in consultation with the Cabinet Secretary is empowered to make Regulations in respect to areas which are key in enabling the National Health Insurance Fund to fulfil its mandate as provided in the Act. The regulatory authority of the National Health Insurance Fund emanates from different provisions of the National Health Insurance Fund Act. In this regard, the Board in consultation with the Cabinet Secretary has developed regulations on five key areas to necessitate the operationalization of the Act. These include:

a) Claims and Benefits
b) Contributions
c) Contributor Registration
d) Empanelment and Contracting
e) Beneficiary Identification

The Regulations are made pursuant to the following relevant sections to the NHIF Act: -

Section 14A: the cabinet secretary shall, in consultation with the Board, make regulations for contributions to regulate contributions and benefits in the Act.

Section 15 (6): the cabinet secretary shall, in consultation with the Board, make regulations for contributions.

Section 20: The Board may make regulations in respect of voluntary contributions by unemployed persons, prescribing the manner of making such contributions, the procedure to be followed and the forms to be used.

Section 21 (1): The Board shall prescribe the mode of identification of beneficiary, considering the existing legal framework for national registration.

Section 23 (2): The Board shall, make regulations in relation to standard and matching contributions.

Section 27: The National Health Insurance Fund Act also provides that the Board may, in consultation with the Cabinet Secretary, make regulations prescribing the amount of any benefits and the period within which any benefits shall be payable out of the Fund for the time being.

Section 29 of the National Health Insurance Fund Act provides that the Board may, in consultation with the Cabinet Secretary, make regulations facilitating the implementation of this Act, including, regulations—

a) prescribing anything required to be prescribed under this Act.
b) prescribing the particulars, information, proof, or evidence to be furnished as to any question or matter arising under this Act, including any question or matter relevant to the payment of contributions by or in respect of any person, or the making or validity of any claim or application for the payment of any benefit under this Act.
c) prescribing, in respect of any action required or permitted to be taken under this Act, the time and manner of taking that action, the procedure to be followed and the forms to be used.

Section 31 of the National Health Insurance Fund Act provides that the Board may, in consultation with the Cabinet Secretary may make regulations for the determination by the Board or by any officer thereof, or by a person or body of persons appointed or constituted in accordance with the regulations, of any questions arising under or in connection with this Act, including any claim for benefit.

In exercise of the above powers, the Board in consultation with to Cabinet Secretary has drafted the National Health Insurance Fund Act, Regulations 2022. This RIA has been prepared and undertaken public consultations and in partial fulfilment of the requirements of the Statutory Instruments Act.

1.3 REQUIREMENTS OF THE STATUTORY INSTRUMENTS ACT

The Statutory Instruments Act, No. 23 of 2013 is the legal framework governing the conduct of RIA in Kenya. Sections 6 and 7 require that if a proposed statutory instrument is likely to impose significant costs on the community or a part of the community, the regulation-making authority shall, prior to making the statutory instrument, prepare a regulatory impact statement about the instrument. The Act further sets out certain key elements that must be contained in the RIA namely:

a) a statement of the objectives of the proposed legislation and the reasons.

b) a statement explaining the effect of the proposed legislation.

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; and

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

Section 5 of the Act requires that a regulation-making authority to conduct 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.

1.4 WHAT IS A REGULATORY IMPACT STATEMENT?

RIA is a systematic policy tool used to examine and measure the likely benefits, costs, and effects of new or existing regulation. RIA is an analytical report to assist decision makers. As an aid to decision making RIA includes an evaluation of possible alternative regulatory and non-regulatory approaches with the overall aim of ensuring that the final selected regulatory approach provides the greatest net public benefit. Typically, the structure of an RIA should contain the following elements:

a) title of the proposal.

b) the objective and intended effect of the regulatory policy.

c) an evaluation of the policy problem.

d) consideration of alternative options.

e) assessment of all their impacts distribution.

f) results of public consultation.

g) compliance strategies, and

h) processes for monitoring and evaluation.[1]

RIA is usually conducted before a new government regulation is introduced to provide a detailed and systematic appraisal of the potential impact of a new regulation to assess whether the regulation is likely to achieve the desired objectives. RIA promotes evidence-based policymaking as new regulations typically lead to numerous impacts that are often difficult to foresee.

From a societal viewpoint, RIA should confirm whether a proposed regulation is welfare-enhancing, in that, the benefits will surpass costs. RIA therefore has objectives of improving understanding of the real-world impact of regulatory action, including both the benefits and the costs of action, integrating multiple policy objectives, improving transparency and consultation; and enhancing governmental accountability.

[1] Regulatory Policy Division Directorate for Public Governance and Territorial Development: Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers. OECD, 2008

CHAPTER 2: OBJECTS OF THE NATIONAL HEALTH INSURANCE FUND ACT, REGULATIONS, 2022

2.1 GENERAL OBJECTIVE

The objective of the National Health Insurance Fund Act, Regulations, 2022 Regulations is to give full effect to the Act. In particular, these regulations have given a focus on key areas under the NHIF Act that must be operationalized as a matter of priority to facilitate the attainment of Universal Health Coverage (UHC).

These Regulations seek to:

a) prescribe the mode of identification of beneficiaries for purposes of fulfilling goals of the Fund.
b) ensure that every person who has attained the age of eighteen years and is a resident of Kenya is registered as a member of the Fund.
c) define the different types of contributions to be made to the Fund.
d) set out the criteria and process for application for empanelment and contracting process; and
e) provide for benefit entitlements to members and their beneficiaries and the payment of claims to healthcare providers.

2.2 SPECIFIC OBJECTIVES

These Regulations seek to fulfil the following specific objectives:

1. **The National Health Insurance Fund (Beneficiary Identification) Regulations, 2022**

This regulation provides for the documentation required for identification during registration of a member and his/her beneficiaries. It also provides for the documentation required for identification while accessing services at NHIF service points.

2. **The National Health Insurance Fund (Member Registration) Regulations, 2022**

These regulations set out the procedure for registration of members, amendment of beneficiary details and deregistration of a member. They also set out the penalties

for members who do not register as member. Furthermore, they provide for linkages with national databases for purposes of mobilizing registration

3. **The National Health Insurance Fund Contributions, 2022**

These regulations set out the rates for standard, matching, special and voluntary contributions. They also give detail on how indigent and vulnerable persons will be identified. Finally, they also set out the waiting periods for those who register for the first time or fail to make contributions.

4. **The National Health Insurance Fund Empanelment and Contracting Regulations, 2022**

These regulations set out the criteria and procedure for empanelment and contracting of healthcare providers. They also provide for the measures that the Fund 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.

5. **The National Health Insurance Fund Claims and Benefits 2022**

These regulations define the benefit package that NHIF will offer. They highlight the process of seeking treatment overseas. The regulations also stipulate the limits payable by the Fund with respect to members with a private insurance.

Finally, the regulations provide for establishment of a Centralized Healthcare Provider Management System for purposes of claims administration, recording beneficiaries' data, inputting health care service delivery data, and maintaining healthcare providers data.

CHAPTER 3: BACKGROUND AND CONTEXT

3.1 BACKGROUND

The right to health has been enshrined in Constitution of Kenya 2010 and Kenya's development agenda outlined in Vision 2030. The Constitution in the Bill of Rights chapter gives all citizens the right to the highest attainable standards of health as fundamental thereby committing the government to ensuring the highest attainable level of health care for all.

In pursuance of the right to health, the 58th World Health Assembly of 2005 (WHO, 2005) urged member countries to aim at providing universally accessible health care to all members of the population based on the principles of equity and solidarity. Further, Universal Health Coverage (UHC) has been adopted as Target 3.8 of the Sustainable Development Goals (SDGs), with a clear goal of ensuring that individuals and communities receive the health services they need without suffering financial hardship. This includes provision of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care.

Kenya has adopted UHC as one of the Big Four Agenda by His Excellency the President Uhuru Kenyatta, with an aspiration that by 2022, all persons in Kenya will be able to access essential health care services for their health and wellbeing through a single unified benefit package, without the risk of financial catastrophe.

About 5% of Kenyans incur catastrophic expenditures from out-of-pocket healthcare payments and many more do not seek care when they fall ill due to affordability barriers. Financial protection is therefore an intrinsic part of UHC together with service coverage. Financial protection is achieved when there are no financial barriers to access health care services and no direct payments are required to obtain health services (out-of-pocket health spending). This minimizes financial hardship to the population.

Out-of-pocket (OOP) health spending is an inefficient and inequitable way of financing health and should be reduced as much as possible in favour of pre-payment mechanisms such as health insurance. Therefore, the Kenyan government has made a policy decision to use the National Health Insurance Fund (NHIF) as the key driver for scaling up pre-payment financing of healthcare and purchasing of healthcare

services. Consequently, the NHIF Act No. 9 of 1998 was amended and assented to on the 10th of January 2022. The proposed Regulations are therefore meant to facilitate the operationalization of the NHIF Act No. 9 of 1998 (amended) towards attainment of UHC.

3.2 DOMESTIC CONTEXT

The government is committed to implementing UHC through inclusion of the "affordable care for all" in the Big 4 Agenda[2].UHC is expected to bring health and development efforts together and contribute to poverty reduction as well as building solidarity and trust, aspirations that are also enshrined in the government development agenda and the Kenya Vision 2030.

Over the years, the Government through the Ministry of Health has implemented policies and programs towards the realization of UHC. There policies and programmes implemented have been targeted towards increasing access to quality healthcare services and providing financial protection through the reduction of out-of-pocket payments when accessing care. The policies and programmes that have been implemented include:

1. The Free Maternity Services (Linda Mama Program) with over one million mothers getting free maternity services every year:
2. The removal of User Fees in primary care facilities where about 45 million free outpatient services are provided annually:
3. The Health Insurance Subsidy Program for the Orphans and Vulnerable Children; Health Insurance Subsidy Program for the Elderly persons and People with Severe Disabilities covering 181,968 households and 42,000 people respectively; and
4. *EduAfya* Medical Insurance Cover for public secondary school children. This is in addition to the primary and secondary level programs and projects that are providing access to essential health services to the public.

Despite these efforts, there are gaps that still exist hindering progress towards UHC. The insurance coverage is still low at approximately 19.1%, the OOP expenditure

[2] The other pillars of the Big Four include: Affordable housing; Enhancing Manufacturing; and Food security and Nutrition.

(household expenditure on health) as a total of health expenditure remains high at approximately 28% while catastrophic health expenditure is estimated at approximately 4.9% (40% threshold) leaving at least one million Kenyans at risk of falling into poverty every year as they seek health services due to medical bills. Further, approximately 28% of Kenyans do not seek health care services when unwell due to financial barriers. [3]

Kenya has continued to implement UHC using a phased approach with Phase 1 being a pilot in four counties namely Machakos, Nyeri, Kisumu and Isiolo. This was implemented in the financial year (FY) 2018/2019 through input financing. The pilot counties were supported through the exchequer with inputs to their health systems strengthening in health commodities, human resources for health, and basic equipment especially for primary health care services.

Further the County Health Management Teams (CHMT) were supported with financial resources towards activities that address the determinants of health and the management of the health system towards UHC. Resources were also directed towards community health services including establishing functional community units in the pilot counties while health facilities were supported to provide basic and specialized services and for operational and maintenance. The target population in the pilot counties were expected to access health services without paying for them in the public health facilities since user fee was removed in the public health facilities in the four pilot counties.

The main purpose of the pilot was to generate evidence in-order to inform the UHC plans and reforms i.e., enable the Government to rapidly test and draw lessons in preparation for the full UHC scale-up. This phase was expected to provide among others, specific lessons on:

i. The extent to which providing Government subsidies through user fee removal to the population enables improved utilization of health care services and financial risk protection.
ii. The costs of providing essential health services as well as their adequacy and affordability.

[3] Kenya Household Health Expenditure and Utilization survey (2018)

iii. The ability of the health system in counties to respond and adapt to an increase in demand for health services and the extent to which the health needs of the population are met.

iv. The effectiveness of the public health care providers management, including financial management and the implications on health service delivery.

The lessons from the pilot counties showed the need to focus to a more sustainable health financing model. The Government therefore has committed to scale up UHC through the more sustainable output-based financing with a national health insurance scheme nested in NHIF. This direction was not only informed by the lessons from the pilot counties but also by the recommendations of the Health Financing Reforms Experts Panel (HEFREP) that was appointed by the Cabinet Secretary for Health in 2018. The HEFREP mandate was to make recommendations towards the transformation and repositioning of NHIF as strategic purchaser of healthcare services towards attainment of UHC. HEFREP made recommendations for reforms in four main areas:

a) Healthcare Financing Reforms

The reforms panel recommended that the purchaser/provider relationships should be clearly stipulated regarding empanelment process, healthcare providers contracting, referral systems, quality assurance and provider payment mechanisms. In addition, to address the purchaser/government relationships reforms MOH should review and update the Kenya health policy, and health sector strategic plans to clearly articulate the role of the NHIF as a purchaser. Further, the panel recommended that NHIF should review its strategic plan to align with the MOH policies. In addressing purchaser relationships, HEFREP recommended reforms in Customer Complaints handling mechanisms as well as review of the benefits package to ensure it is harmonized by scrapping multiple benefit packages, and instead offer one benefit package for all.

The proposed NHIF Act Regulations have proposed the relationships that should be established between NHIF and healthcare providers, the Government especially the Ministry of Health and the beneficiaries who are the NHIF members and their

dependants. The Beneficiaries Identification Regulations and the Empanelment & Contracting regulations further spell the obligations of the parties involved.

b) Business Process Reengineering

The panel recommended that NHIF member and employer registration processes, healthcare provider empanelment, claims management processes as well as beneficiary relations regarding handling customer complains to be reviewed and automated as much as possible. Also, a mechanism for post-payment medical claims audit needs to be established. To enable this, the panel recommended upgrading of NHIF ICT infrastructure and transformation of NHIF organizational structure.

The proposed NHIF Act Regulations have made provisions to enable NHIF integration with relevant Government agencies such as Registrar of Persons to create convenience in identification and registration of members and their beneficiaries. The Regulations have also provided for operationalization of the Centralized Health Care Provider Management System established in Section 21A of the Act to process claims and benefits out of the Fund.

c) Financial Stability Reforms

The reforms panel made recommendations on financial stability which proposed the review of member enrolment trends, the Fund's financial viability in relation to contributions to the Fund and review of administrative/operational expenses to ensure they are maintained at the minimum.

The proposed NHIF Act Contributions Regulations 2022 have provided for operationalization of Sections 15(6), 20 and 23(2) of the NHIF Act which have stipulated different categories of contributions

d) Governance, Legal and Regulatory reforms

The panel proposed the need to strengthen NHIF's regulation, supervision, and governance capacity, enhance transparency and accountability. Further, HEFREP recommends reforms to augment NHIF's stakeholder engagement through establishment of the national NHIF stakeholder Advisory Committee. Reforms were also proposed in the NHIF legal framework through amendments of the NHIF Act.

Subsequently, the NHIF Act has been amended provided for a strengthened Board of Management to enhance governance of the Fund.

The government has implemented several reforms to enhance the capacity of the NHIF to effectively deliver on its mandate, namely:

1. Upward revision of premium contribution rates in 2015,
2. The expansion of the NHIF benefit package that previously offered inpatient care only, by the addition of outpatient care and several specialized services,
3. Human resource reforms to restructure the functional organization of the NHIF
4. Information Communication Technology (ICT) reforms to automate several core functions including claims management, member registration, and premium contributions, and
5. Amendment of the NHIF Act to ensure there is appropriate legal framework for UHC implementation.
6. Expansion of empanelled healthcare providers network to ensure that beneficiaries have access to affordable and quality healthcare services
7. Implementation of biometric registration and identification of NHIF beneficiaries not only to enhance convenience for members seeking services but also to reduce medical fraud.
8. Adoption of a paperless Electronic Claims Management System to enhance efficiency in submission and processing of hospital claims and reimbursements to the healthcare providers

3.3 AFRICA REGIONAL CONTEXT

Countries in Africa are at different levels in the implementation of UHC and with different financing approaches. While there is no one-size-fits-all approach to achieving UHC and that strategies adopted by different countries will depend on local circumstances and national dialogue, there is a common understanding of the urgent need to invest in UHC. Indeed, many governments in Africa are coming to the reality that it is not appropriate for some members of society to face death, disability, ill-health, and most often, impoverishment when accessing care, a matter that could be addressed sustainably at limited cost.

In this regard, different governments in Africa are now adopting different health financing models with the majority reviewing their health systems, financing

mechanisms, and budgets through transformational reforms geared towards the achievement of UHC.

Globally, a UHC index has been adopted to measure the level and progress of different countries toward UHC and to monitor the Sustainable Development Index 3.8. The index considers both health service coverage and health expenditures in relation to a household's budget have been utilized to appreciate the extent of service capacity and availability as well as to identify financial hardship caused by direct health care payments. Looking at the African Region, with an average UHC index score of 46% for 39 countries, Kenya was ranked as medium coverage with a score of 56% in 2019.

Comparatively, some of the other countries in Africa scored as follows; Botswana (54%), Eritrea (50%), Eswatini (58%), Rwanda (54%), Uganda (50%), Zambia (55%), and Zimbabwe (55%). Countries with the highest UHC coverage index in Africa included Algeria (75%), Cabo Verde (69%), Mauritius (65%), Namibia (62%), Sao Tome and Principe (60%), Seychelles (70%) and South Africa (67%)[4]

3.4 INTERNATIONAL CONTEXT

Impoverishing health spending continue to be a problem globally[5]. 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 OOP on health represented between 83% and 89% of the people incurring impoverishing health spending. This 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.

Between 2015 and 2017, the proportion of the population with OOPs exceeding 10% of their household budget rose from 12.7% of the population (940 million) to 13.2% (996 million) and was driven by:

i. An increase in the amount people spent per person OOP for health; and
ii. A higher rate of growth of OOP spending relative to growth in private consumption.

[4] Universal Health Coverage (UHC) Regional Fact Sheet, WHO / World Bank, 2020
[5] Global monitoring report on financial protection in health 2021 (WB and WHO)

These trends emphasize the need to focus urgent policy attention of how health systems are financed.

The United Nations 2030 Agenda for Sustainable Development identified 17 Sustainable Development Goals (SDGs), an intergovernmental set of aspirations towards improving sustainably the future we want. Attainment of good health and well-being is SDG 3, with required health actions reflected across all the other SDGs. SDG 3, Target 3.8 spells out the need to achieve UHC, including financial risk protection, access to quality essential health services, and medicines and vaccines for all.

Most low and middle-income countries are designing and implementing strategies that are accelerating progress toward UHC. At the first-ever UN High-Level Meeting on UHC in September 2019, member states reaffirmed their commitment to achieving UHC by 2030 and asserted the right of people to enjoy the highest attainable standard of physical and mental health as an integral part of the SDGs.[6]

According to The World Bank Group (WBG) and World Health Organization (WHO) report: -*Tracking Universal Health Coverage: 2021 Global Monitoring Report* showed that countries had made progress towards UHC. However, in 2020, the COVID-19 pandemic disrupted health services and stretched countries' health systems beyond their limits as they struggled to deal with the impact of the pandemic. Due to this, the report showed that health indices such as, immunization coverage dropped for the first time in ten years, and deaths from TB and malaria increased.[7]

The *2021 Global Monitoring Report on Financial Protection in Health* showed that even before the COVID-19 pandemic, the world was off-track to reduce financial hardship for poor people. While impoverishing health spending decreased between 2015 and 2017, the number of people impoverished or further impoverished by out-of-pocket health spending remained unacceptably high with about 1 billion people

[6] The World Bank (2021) Universal Health Coverage: (*www.worldbank.org/en/topic/universalhealthcoverage*)

[7] Tracking Universal Health Coverage: 2021 Global Monitoring Report (WBG and WHO)

paying catastrophically large portions of their household budgets on health out-of-pocket expenditure.

CHAPTER 4: EVALUATION OF THE PROBLEM

As demonstrated in Chapter 3, Kenya has undertaken the obligation to protect its citizens from severe financial hardship caused by out of pocket medical expenses through the realization of UHC. The Board of Management of NHIF in consultation with the Cabinet Secretary responsible for health has identified the following pertinent challenges facing the NHIF these are discussed in this Chapter.

4.1 IDENTIFIED CHALLENGES

4.1.1 FINANCIAL SUSTAINABILITY

NHIF premium contributions have increased significantly over the years with NHIF collecting Kes. 31.6 billion in FY 20/21 for the National Scheme. Whereas the contributions have increased, the pay-out to healthcare providers has also increased and with time the Fund may not be able to meet its financial obligations. The benefit pay-out ratio for FY 20/21 for the National Scheme was 89%. This means that the Fund's solvency needs to be monitored very closely. Solvency is supposed to take care of the risks that NHIF faces for example fraud risk, operation risk, disease outbreak, uncollected premium etc. The investment needed to achieve Universal Health Coverage is substantial and therefore voluntary contributions must be abolished. For contributors who cannot afford to make monthly contributions, the Government of Kenya will step in and sponsor them on a tax-funded model. The proposed regulations will guide on how contributions to the Fund will be made and the applicable rates depending on the contributor.

4.1.2 HIGH ATTRITION RATES

Attrition refers to a gradual but deliberate reduction in the number of members who make monthly contributions to the Fund. A high attrition rate means that more members are not consistently contributing to the Fund. The active membership is low compared to cumulative membership because of low retention rates caused by attrition by informal sector registered members. According to the NHIF 2020/21 financial statements, while the overall retention rate of the NHIF was 41%, that of the formal sector was 72% and that of the informal sector was 24%. This finding is consistent with international experience that shows that voluntary enrolment and contributions to health insurance schemes is plagued by high attrition rates and

hence difficult to scale up.[8] The aim of these regulations is to ensure members do not default on payment of contributions by introducing penalties to deter members from falling out.

4.1.3 ADVERSE SELECTION

Adverse selection refers to the scenario in which sick individuals, who have greater coverage needs, purchase health insurance, while healthy people delay or decide to abstain. NHIF has been exposed to adverse selection due to the voluntary nature of the informal sector scheme. When the benefit pay-out ratios are disaggregated for the national scheme, it reveals that the benefit pay-out ratio of the formal sector was 55% while that of the informal sector was 248% in FY 2020/21. This reveals that there is significant adverse selection among the informal sector; given that the national scheme was voluntary for the informal sector, high risk groups (those that know that they are likely to need to seek healthcare) register while healthy individuals are more likely not to register.[9] This is consistent with international best practice that shows that voluntary mechanisms are inefficient because of their susceptibility to adverse selection. The proposed regulations will cure the adverse selection experienced in the informal sector by making enrolment to the scheme mandatory.

4.1.4 FRAUD

Fraud and abuse are widespread and very costly to Kenya's healthcare system. Factors that contribute to occurrence of fraud include collusion between beneficiaries and health service providers, lack of sophisticated interrogation/detection software, poor internal controls and poorly trained claims processing staff.[10] Global studies indicate that errors and fraud can account for between 3% to 15% of claim costs.[11] The proposed regulations have stipulated the offences of a healthcare provider colluding with a patient, another healthcare

[8] Mcintyre, Diane & Obse, Amarech & Barasa, Edwine & Ataguba, John. (2018). Challenges in Financing Universal Health Coverage in Sub-Saharan Africa. May.10.1093/acrefore/9780190625979.013.28

[9] D. McIntyre, "Learning from experience: health financing in low- and middle-income countries," Geneva Switzerland, 2007.

[10] https://akinsure.com/content/uploads/documents/Medical_Insurance_Fraud_Survey_2013.pdf

[11] Gee, J., & Button, M. (2015). *The Financial Cost of Healthcare Fraud 2015: What Data from Around the World Shows*. PKF Littlejohn. https://www.pkf.com/media/31640/PKF-The-financial-cost-of-fraud-2015.pdf

provider, an officer of the Fund and falsifying or altering information with an aim of defrauding the Fund. The proposed regulations also provide for establishment of a centralized healthcare management system which will help to curb fraud.

4.1.5 OUT OF POCKET EXPENDITURE

One of the dimensions of UHC is to reduce cost sharing and fees. 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.[12] 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. This is both because they usually have a greater need for health services and because they lack financial resources.[13] The proposed regulations will cushion the members from out-of-pocket payments by ensuring enrolment to NHIF is mandatory and highlighting the benefits payable to healthcare providers.

4.1.6 WEAK HEALTH FINANCING MODEL

A good health financing system entails the expansion of sustainable mechanisms for raising revenue for health, optimizing on means of pooling resources together, and purchasing health services in the most efficient manner, however, the health system is characterized by mixed yet fragmented approaches.[14] There are revenues raised, pooled, and being utilized to purchase health services either independently or with very weak linkages and collaboration among players. This includes the government (both national and 47 counties) through taxes albeit with some inequitable subsidization of health services for some groups, donor funding that may be directed only to specific diseases or population groups, some populations covered by the National Health Insurance Fund (both individually and by the government), private health insurance coverage with overlaps and weak harmonization between the public and private insurance, as well as a large number of populations that are still paying for services through out-of-pocket spending at points of care. The proposed

[12] World Health Organization Global Health Expenditure database (apps.who.int/nha/database)
[13] World Health Organization. (2005). Designing health financing systems to reduce catastrophic health expenditure. World Health Organization. https://apps.who.int/iris/handle/10665/70005
[14] The Kenya Health Financing Strategy 2020-2030

regulation, therefore, streamlines revenue-raising through the prioritization of domestic resources that are more sustaining. Both the government and individuals shall contribute through mandatory health insurance with the government covering all vulnerable groups. The regulation also, as a policy, identifies NHIF as the key mechanism for pooling health resources and purchasing health services for all. This will eliminate overlaps and reduce inefficiencies leading to an adequate, efficient, and equitable health financing system for Kenyans.

4.1.7 LOW INSURANCE COVERAGE

Many Kenyans do not access health services due to cost factors and when they do, they access limited yet costly services through inadequate out-of-pocket spending capacity. The goal of the Universal Health Coverage under the Big Four Agenda has been to eliminate the social and economic challenges that Kenyans face due to the cost of health care by purposefully restructuring the health financing landscape. Prepayment for health services through insurance has been shown to cushion households from impoverishment when they fall ill. However, health insurance coverage in Kenya is generally low (19%). Additionally, community health insurance schemes and private health insurance schemes pool operate independently and are not linked to other insurance pools. To accelerate the achievement of UHC through health insurance, the regulations propose 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 accessible to all Kenyans irrespective of their ability to pay where the healthy persons will cross-subsidize the sick while the wealthy cross-subsidize the poor.

4.1.8 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 the increase in the number of motorcycles), unspecified soft tissue injuries (11%), cut-wounds, dog bites, falls, burns and poisonings each (< 10%). Up to 54% of Kenyans die due to a lack of optimal emergency care, yet this is their constitutional right [9].[15] This is attributed to a lack of access to the needed emergency health services due to weak financial protection. The proposed regulations guarantee covered 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.

4.1.9 SYSTEMS INEFFICIENCIES

NHIF has been identified as the vehicle to deliver UHC for Kenyans. In carrying out this mandate, the institution must improve service delivery efficiency to meet the needs of the entire sector. To mention a few, some of the challenges that require to be addressed include but are not limited to:[16]

a) The empanelment processes that have been lengthy, cumbersome, and biased towards curative services rather than preventive, favoured private healthcare facilities, larger healthcare facilities, and facilities in urban areas, with limited empanelling of healthcare facilities in poor, rural, and/or marginalized areas thus skewing the geographical distribution of empanelling healthcare facilities and compromising access and equity.
b) Contracting of individual healthcare facilities with no provision for contracting networks of healthcare facilities, an arrangement that has made it inefficient to contract many small healthcare facilities that typically provide primary healthcare services and misses the opportunity to purchase an integrated range of services.
c) Limited automation of NHIF processes hampers efficiency in provision of services and limits the ability of the Fund to collect and use data to improve service delivery.

[15] *The NHIF we want. Report of the Health Financing Reforms Expert Panel for The Transformation and Repositioning of National Hospital Insurance Fund (NHIF) as a strategic purchaser of health services* July 1, 2019.
[16] Ministry of Health. National Emergency Medical Care Treatment Guidelines, 2021

d) The need to strengthen monitoring and supervision of healthcare providers and impose sanctions and rewards for the quality of care provided including introducing a clinical audit mechanism that assesses the quality of care provided by contracted healthcare facilities to monitor and ensure adherence to clinical guidelines; The proposed regulations address automation of NHIF processes through a centralized healthcare provider management system, expansion from a 'hospital' to a health insurance Fund to enable engagement with more healthcare providers, and improvements in contracting and empanelment processes including timelines for these processes. Automation of the systems will be critical in not only improving efficiencies but also in being a valuable repository of the health sector data and information and facilitating the use of evidence in decision-making.

CHAPTER 5: POLICY AND LEGAL FRAMEWORK FOR HEALTH INSURANCE COVERAGE IN KENYA

BACKGROUND

An evaluation of the legal and policy frameworks related to the NHIF is intended to answer the question whether there is a legal basis for developing the proposed Regulations. It is also intended to bring out the context and legal environment within which the proposed NHIF Regulations,2022 are being developed. Regulatory processes should be structured so that all regulatory decisions rigorously respect the principles of 'rule of law' that is, responsibility should be explicit for ensuring that all regulations are authorized 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.

5.1 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[17].

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[18] and that the State shall provide appropriate social security to persons who are unable to support themselves and their dependents.

The Constitution obligates 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 realization of the rights guaranteed in Article 43. These measures include addressing the needs of vulnerable groups within society and the international obligations

[17] Article 10(2)(b)
[18] Article 43(2)

regarding those rights[19]. 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 right. These vulnerabilities are addressed in the Constitution which pays special attention to the health of children[20], minorities and marginalized groups[21] and the elderly[22]. 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 met. It is to fulfil these constitutional obligations that the NHIF Board in consultation with the Cabinet Secretary for Health has drafted these regulations.

5.2 INTERNATIONAL LAW CONTEXT

Kenya has ratified several international treaties that form a part of the legal and regulatory context of NHIF. Three treaties are particularly relevant:

a) The International Convention on Economic, Social and Cultural Rights (ICESCR)
b) The Convention on the Rights of the Child (CRC)
c) The African Charter on Human and Peoples' Rights (ACHPR)

These ratified treaties are part of the law of Kenya through Article 2(6) of the Constitution.

The ICESCR, in Article 12, recognizes the right to the highest attainable standard of physical and mental health. Article 12(d) requires state parties to create "conditions which would assure to all medical service and medical attention in the event of sickness". This has been interpreted to include providing financial aid for the most vulnerable and marginalised persons in society[23]. The 2022 amendments to the NHIF Act address this by providing for the national government's obligation to make contributions on behalf of indigent and vulnerable Kenyans and providing for all other Kenyans to make contributions to be assured of medical cover in the event of illness.

[19] Article 22
[20] Article 53(1)(c)
[21] Article 56(e)
[22] Article 57(d)
[23] United Nation High Commission on Human Rights, General Comment 14, paragraph 40

The ACHPR, Article 16 similarly sets out the right to the highest attainable standard of physical and mental health. It further requires state parties to ensure that "their people receive medical attention when they are sick". Kenya has opted to ensure this access through ensuring that all Kenyans will have access to medical care upon registration and contribution as members or beneficiaries of NHIF.

The Convention on the Rights of the Child provides both for the right of children to the highest standard of health[24] and obligates state parties to take special measures with respect to the health care of children with disabilities[25]. This is relevant to the NHIF Act as amended in 2022 because this Act exempts children with disabilities from the age limit for accessing cover under their parent/guardian (provided they are wholly dependent on such parents and guardians). It is also relevant to the draft regulations on registration which provide for access by children with disabilities to registration and medical care financed by NHIF.

In addition, there are a series on non-binding instruments that guide the interpretation and implementation of these health rights. Key amongst these is the Abuja Declaration on HIV, Tuberculosis and Other Infectious Diseases 2001 under which Kenya and other African Countries pledged to allocate at least 15% of their budgets to the improvement of the Health Sector.[26] The same provision also requires that states ensure that needed resources are made available from all sources and are efficiently and effectively used. This is relevant regarding NHIF's role in health financing based on NHIF's function of carrying out the government's policies on national health insurance.[27]

5.3 NATIONAL HEALTH INSURANCE FUND ACT NO.9 OF 1998

The principal statute that governs NHIF is the National Health Insurance Act (as amended in 2022). The Act provides for the Board of Management of NHIF.[28] It is this Board that is empowered by various provisions of the Act to make regulations to implement the Act.

[24] Article 24
[25] Article 23
[26] Abuja Declaration on HIV, Tuberculosis and Other Infectious Diseases 2001, paragraph 26
[27] NHIF Act Section 5(1)(f)
[28] NHIF Act, Section 4

The 2022 amendments to the Act gave the Board the mandate, to amongst other matters, to facilitate attainment of UHC with respect to health insurance.[29] The draft regulations are for the purpose of complying with this mandate and detail how the Board intends to accomplish this in the areas of registration of members, identification of beneficiaries, contributions to the Fund, claims and benefits and empanelment and contracting of Healthcare Providers.

The 2022 Amendments of the Act also provided for mandatory registration of members.[30] The implementation of this amendment is provided for in the draft regulations on registration of members which 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, NHIF has the mandate to pay for benefits provided by Health Care providers to its members and their dependents. The 2022 amendments implemented several reforms in this area; these included:

1. Providing for emergency treatment[31]
2. Providing for a centralized health care provider management system[32]
3. Requiring non-withdrawal of benefits for those with chronic illness[33]

The draft regulations will provide for the payment of claims (including those for emergency treatment), the functions and access to the centralized provider management system as well as the benefit package that NHIF will provide to its members under the statutory medical scheme.

The Act further provides for contributions to the Fund.[34] This section was amended in 2022 to further provide for matching contributions, contributions by the national government as well as voluntary contributions by the unemployed. The Regulations will implement these amendments by providing for how these contributions will be made and the rates of contribution for each category of contributor. The regulations

[29] NHIF Act Section 5
[30] NHIF Act, Section 14A
[31] NHIF Act, Section 22
[32] NHIF Act, section 21A
[33] NHIF Act, Section 22
[34] NHIF Act, Section 15

will also provide for how the unemployed shall be identified for purposes of voluntary contributions.

The empanelment and contracting of Healthcare Providers under Section 30 was another key area amended in 2022. The provision provides for empanelment in consultation with Health Regulatory bodies listed under Section 60 of the Health Act. It also sets out how revocation of empanelment will occur and the consequences of such revocation (for example the requirement of publication in at least 2 newspapers of nationwide circulation). The regulations contribute to the implementation of these provisions by providing for the minimum criteria for empanelment, the process of empanelment and strengthening the enforcement of the compliance by health care providers through the creation of criminal offences with respect to empanelled and contracted providers.

Other areas of the Fund's operations that are covered by the NHIF Act include the following:

1. the employees and officers of the Fund
2. the sources of revenue for the Fund
3. risk spreading and protection of the interests of contributors
4. penalties for breaches of the Act
5. the administration of the Fund including payment of the Fund's expenses
6. legal proceedings under the Act
7. reporting and auditing of the Fund's operations.

5.4 HEALTH ACT NO.21 OF 2017

NHIF operates within the health sector as a state corporation under the Ministry of Health. The Health Act is relevant to this regulatory environment with respect to national health insurance. It provides further detail to the constitutional obligations of the state to observe, respect, protect, promote, and fulfil the right of Kenyans to the highest attainable standard of health. This includes ensuring "financial access" to health care.[35]

[35] Health Act, Section 5

The Health Act also mandates that every person has a right to emergency medical care[36] which includes pre-hospital care, stabilization and arranging for referral of the patient. This impacts the benefits payable by NHIF and will be relevant in the draft claims and benefits 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 which requires the government to, among other things:

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

The amendments to the NHIF Act and the regulations thereunder are geared towards facilitating this financial access through UHC. In particular, the regulations on contributions and those on claims and benefits set out the rates for contributors to pay (the main source of revenue for social health insurance) and how NHIF will reimburse the medical benefits its members and their beneficiaries receive from healthcare providers.

The Health Ministry is also required under Section 86 to provide for vulnerable groups and indigents as well as to provide a framework for examining means of optimizing usage of private health services. This the Ministry has done through various instruments including the Universal Health Coverage Policy 2020-2030 which provides, amongst other matters, coverage for indigent Kenyans. This obligation also impacts NHIF contributions: the national government under the NHIF Act is required to contribute for vulnerable and indigent persons; the draft regulations on

[36] Health Act, Section 7

contributions would implement this aspect of the Health Act as they provide for the process of identifying indigent and vulnerable persons.

Section 86 of the Health Act also affects the empanelment, contracting and payment of benefits to private healthcare providers under Section 30 of the NHIF Act; these is covered in the regulations on empanelment and contracting which explain how such providers will be onboarded into the centralized healthcare provider management system.

Public health care providers are also critical in the provision of health care and the Health Act sets out the division of duties between national government and county governments (for example under Section 20 and 22) with respect to public health facilities. This impacts NHIF's draft regulations since the Fund must empanel and contract such public healthcare providers in line with the regulatory requirements under National and County Laws.

With respect to health regulators, the Health Act lists the relevant health sector regulators in Section 60. These bodies must be consulted by NHIF under Section 30 of the Amended Act in the empanelment of healthcare providers.

5.5 THE INSURANCE ACT (CAP 487)

The Insurance Act provides for, among other things the regulation of the business of insurance in Kenya.

NHIF is directly affected by the Insurance Act because of the Insurance Amendment Act No.11 of 2019 which amended the definition of "insurance schemes" under the Insurance Act to bring on board social insurance schemes.[37] This meant that since that Act governed "the business of insurance" it also covered NHIF. Another result of this amendment is that the Insurance Regulatory Authority established under Section 3 of the Insurance Act joined the bodies that have regulatory authority over NHIF.

The amendments to the NHIF Act that came into effect in 2022 provided that the Insurance Act shall only apply to the Fund with respect to risk spreading and claims administration services. Thus, sections of the Insurance Act that are most relevant to NHIF's regulatory context are those addressing the payment and reporting of

[37] Insurance Act, Section 2

claims (for example under Part VIII of the Insurance Act). These provisions will impact the draft regulations on claims and benefits.

Where NHIF seeks to use risk spreading mechanisms such as re-insurance and co-insurance, these will be subject to the approval and oversight of the IRA. These mechanisms must also comply with the provisions of the Insurance Act with respect to insurance risks and re-insurance treaties (for example Section 20 which prohibits the placing of risks with insurers or reinsurers not licensed by IRA and the power of the Commissioner General to examine re-insurance treaties under Section 8).

5.6 RETIREMENT BENEFITS ACT NO.3 OF 1997

The Retirement Benefits Act is now a critical piece in the legislative context under which NHIF operates. This is due to the amendments to the NHIF Act which permitted the Fund to receive funds from post-retirement medical schemes to offer medical benefits to retirees covered by such schemes.

The Retirement Benefits Act governs such post-retirement schemes and in particular sets up the Retirement Benefits Authority as the regulator of such schemes (Section 3). It requires retirement benefit schemes to be registered and to have appropriate scheme rules (Section 24). It also requires the CEO of RBA to maintain a register of such schemes (Section 30).

Currently post-retirement medical funds are government by the Retirement Benefits (Post-Retirement Medical Funds) Guidelines, 2018 which provides for access to NHIF medical benefits for retirees and how such medical funds are to be administered. However, the RBA is in the process of preparing draft Post-Retirement Medical Funds Regulations 2022 which will update this statutory regime and may facilitate the implementation of the NHIF amendments providing for post-retirement schemes.

5.7 THE CHILDREN'S ACT (CAP 141)

The Children's Act makes provision for parental responsibility, fostering, adoption, custody, maintenance, guardianship, care, and protection of children. It makes the both the parents of a child and the Government responsible for the health and medical care of children.[38]

[38] Children's Act, Section 9

The Act is important to NHIF 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 who are particularly vulnerable. These include the following:

a) orphan children
b) adopted children
c) children living with mental or physical disability
d) children in need of care and protection

The Act provides for the appointment of guardians for children through testamentary document, by deed or by a court of law.[39] The Act also provides for the responsibility of guardians including for medical treatment of these children.[40] This is important because the NHIF Act only recognizes that persons over the age of 18 will register as members and this may leave out orphaned children from access to affordable medical treatment unless a guardian can register them under his/her cover. 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's Act provides for eligibility to adopt a child and the adoption process. Such children can only benefit from NHIF if there is proof of adoption and the adopting parent registers them on his/her cover. The draft regulations provide for adopted children in line with the Children's Act: they can be registered for NHIF upon proof that they have formally completed the process of adoption.

The Children's Act requires that there should be no discrimination with respect to children with disabilities[41] and provides for their right to medical treatment[42]. The NHIF Act provides for this by ensuring such children to access cover without any age

[39] Children's Act, Section 102
[40] Children's Act, Section 24 read with Section 27
[41] Children's Act, Section 5
[42] Children's Act Section 12

limit provided they are wholly dependent on their parent/guardian.[43] The draft regulations will provide for such children's access to NHIF registration on provision of a birth certificate and a certification from the National Council of Persons Living with Disability.

5.8 THE EMPLOYMENT ACT NO.11 OF 2007

The Employment Act is the principal Act governing, among other matters, fundamental rights of employees and the basic conditions of employment of employees. It is relevant in this legislative context because it requires an employer to provide for medical care of employees, in particular medicine and medical attention for serious illness.[44]

However, were there is a statutory insurance scheme like NHIF, the employer is exempted from this provision.[45] This make NHIF's contributions and benefits duties a critical part of the architecture of fulfilling employees' rights under the Employment Act since all employers are required to deduction the standard contribution from their employees' remuneration and such employees are entitled to medical benefits under the statutory scheme set up by the NHIF Act.

The amendments to the NHIF Act support Section 34 of the Employment Act because they provide for matching contributions by employers. The proposed regulations will also provide for how employers will make such matching contributions. In addition, these regulations emphasise that this obligation (to make matching contributions) is upon the employer in line with section 34 of the Employment Act and will prohibit such an employer from deducting this contribution from their employee on pain of paying penalties.

5.9 OTHER LEGAL STATUTES

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

a. State Corporations Act
b. Public Finance Management Act

[43] NHIF Act, Section 2
[44] Employment Act, Section 34(1)
[45] Employment Act, Section 34(4)

c. Public Audit Act
d. Data Protection Act
e. Consumer Protection Act
f. Criminal Procedure Code
g. Public Procurement and Assets Disposals act

b) Work Injuries Benefits Act

POLICY FRAMEWORK FOR HEALTH INSURANCE IN KENYA

BACKGROUND

The right to health is set out in the Constitution of Kenya, however, the vision of how this will be progressively achieved is set out in various government policy documents. These policies these inform the legislative interventions that are taken to respect, protect, promote, and fulfil this right. With respect to implementing the amendments to the changes required under NHIF Act, the key policies are the following:

(a) Vision 2030
(b) The Kenya Health Policy 2014 – 2030
(c) The Universal Health Policy 2020-2030
(d) Sessional paper No 2 of 2017
(e) The Big 4 Agenda

It is also in line with Kenya's commitment to the Sustainable Development Goals (SDGs) which has already been discussed in Chapter 3.

5.10 VISION 2030

Vision 2030 is an over-arching national development policy that was unveiled in 2007 and has been implemented in rolling 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 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 2022 amendments to the NHIF 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 as well as the matching contributions that will be made by employers in addition to employee contributions.

5.11 KENYA HEALTH POLICY 2014-2030

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 NHIF because the policy orientation, among other things, targets investment targeted towards health financing to improved 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.

The regulations will achieve these policy aims by addressing the implementation of matching, special and voluntary contributions which will increase the financial resources available to the health sector to pay for NHIF beneficiaries' medical expenses. These regulations will also help ensure that indigent and vulnerable

persons have adequate financial risk protection and lower their financial barriers to accessing health care by implement national government contributions for these groups and obligating NHIF to make them aware of their coverage by the national government. The regulations on contributor registration will also enhance the number of persons registered with the fund by providing for mandatory registration of persons and penalties for failure to register.

5.12 THE UNIVERSAL HEALTH COVERAGE POLICY 2020-2030

UHC aims to move towards ensuring that the whole population shall progressively access a comprehensive package of quality health services, while expanding protection from financial catastrophe. The UHC policy gives direction towards ensuring significant improvement in the overall status of health in Kenya in line with the Big Four Agenda, the Constitution of Kenya 2010, Kenya Health Policy 2014-2030, Kenya Vision 2030, regional and global commitments.

The most relevant policy objective with respect to NHIF is policy objective 3: Protection from the financial risks of ill health. This aims to ensure Kenyans are protected from the financial risks of ill health. This means ensuring that the mechanisms for raising revenues for the health system are fair and sustainable. This shall include mandatory pre-paid sources. Efficiency in resources utilization should be improved to obtain the maximum possible level of health outputs or outcomes given the available quantity and mix of health system inputs.

The regulations on contributor registration will seek to ensure the widest possible coverage of Kenyans through mandatory registration. In addition, the regulations on contributions will raise the pool of resources (the pre-paid source of financing mentioned in the policy) to ensure adequate benefits to NHIF members and their families. The rates of contribution under the regulations are also set at levels designed to ensure both fairness and sustainability.

5.13 SESSIONAL PAPER NO.12 OF 2017 ON THE POLICY ON UNIVERSAL HEALTH CARE COVERAGE IN KENYA

Sessional Paper no.12 of 2017 was prepared to plan for the role of NHIF in the pursuit of UHC. Many of its recommendations centred on reviewing the legal framework of the Fund's operations and several the recommendations were implemented in the 2022 amendments to the NHIF Act and the proposed regulations.

For example, the policy recommended matching contributions by employers. This is being achieved by the amendments to Section 15 of the NHIF Act and by the regulations on contributions which provide for how such matching contributions will be made. A second recommendation was that NHIF should link with national databases for automatic update of member details. The regulations on contributor registration will implement this by requiring the Fund to link with national registration databases to mobilise registration. A third policy recommendation was that the national government subsidise indigent Kenyans' contributions. This has been implemented in the amendments to the NHIF Act as well as the regulation on contributions that provide the method of identifying these indigent individuals and the rate of their contributions.

5.14 BIG 4 AGENDA

The big 4 Agenda were launched in 2017 as a key policy direction for the Government of Kenya that prioritised goals centred on Food Security, achievement of UHC, affordable housing and industrialisation.[46] The specific UHC targets are achievement of 100% coverage for all Kenyans and to reduce out-of-pocket expenses as a percentage of household expenditure by 54%. In this regard, the health financing provided under NHIF is central to both ensuring this full coverage and in reducing the financial burden on Kenyan households.

The regulations achieve this by providing for the registration of all sectors of Kenyan society under the contributor registration regulations. The claims and benefits regulations also provide (in the schedule) the benefit package to be provided by NHIF in pursuit of UHC. It targets those medical expenses that are likely to cause severe financial hardship (including chronic illness and major surgical procedures)

[46] https://big4.delivery.go.ke/ (accessed on 20/04/2022)

CHAPTER 6: PUBLIC CONSULTATIONS

An evaluation of the public consultation process is necessary to ascertain whether all interested parties have had the opportunity to present their views. Regulations should be developed in an open and transparent fashion, with appropriate procedures for effective and timely input from interested parties such as affected businesses, interest groups, professional bodies and other government ministries, departments, and agencies.

6.1 LEGAL REQUIREMENTS RELATING TO PUBLIC PARTICIPATION AND CONSULTATION

Participation of the people, inclusivity, transparency, and accountability are a constitutional requirement whenever the State or Public Officer applies the Constitution, enacts any law or makes or implements a public policy[47]. This requirement is premised on the sovereignty principle[48] which vests all sovereign power to the people of Kenya. This power entitles the people to unfettered access to the process of making public decisions through their involvement.

Further, the objects of devolution[49] give 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. Finally, the values and principles of public service[50] require the involvement of the people in the process of policymaking and part, transparency, and provision to the public of timely and accurate information.

Regarding the subsidiary legislation making process, the Statutory Instruments Act requires that the regulatory making authority shall undertake public consultations before making statutory instruments (Regulations), and particularly, where the proposed Regulations are likely to have a direct or a substantial indirect effect on business or restrict competition. The Act provides that in determining whether any consultation that was undertaken is appropriate, the regulation making authority

47 Article 10 of the Constitution
48 Article 1 of the Constitution
49 Article 174(c) of the Constitution
50 Article 232 (1) of the Constitution

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 further requires that the persons to be consulted should either directly or by advertisement through representative organizations be invited to make submissions by a specified date, which should not be lesser than 14 days or be invited to participate in public hearings concerning the proposed instrument.

6.2 STAKEHOLDER MAPPING

The following stakeholders were identified for purposes of developing the National Health Insurance Fund Act, Regulations, 2022:

1. All members of the public
2. Parliamentary Committees.
3. Health Care Providers.
4. Ministries, Departments and Agencies (MDAs).
5. Development Partners.
6. County Governments.
7. Healthcare Provider Regulatory Bodies.
8. Healthcare Professional Associations.
9. Patient Support Groups.
10. Religious Groups.
11. Civil Society Groups.
12. Media.
13. Employer Associations.
14. Community Based Health Insurance Schemes (CBHIS).

6.3 THE PROCESS OF PUBLIC CONSULTATIONS

6.3.1 PUBLIC CONSULTATIONS ON THE NATIONAL HEALTH INSURANCE FUND ACT, REGULATIONS, 2022

Pursuant to section 5 of the Statutory Instruments Act,[51] the Board identified specific stakeholders whom it engaged in a consultative process. These include the main professional and specialist institutions and individuals who will be directly or indirectly affected by the proposed statutory instruments[52].

6.4 PUBLIC CONSULTATION APPROACH AND METHODOLOGIES

The Board opted to adopt the following methodology:

1. Publishing of the draft copy of the National Health Insurance Fund Act 2022 Regulations in the NHIF Website inviting representations generally and specifically from the identified stakeholders.
2. Stakeholder notification on the ongoing process through letters and follow-up emails inviting them to tender their submissions on the draft Regulations within a specified reasonable period.
3. Posting advertisements in newspapers of wide national circulation inviting any persons or institutions to make their submissions within a specified date and directing them on where they can get copies of the Regulations. *(Advertisements Attached to the report)*
4. Holding virtual/physical meetings with select stakeholders.
5. Requesting for written submissions on the draft regulations.
6. Based on the above approach, a total of four virtual meetings were held between the Board and key stakeholders and fifty-six (56) physical meetings comprising mostly of stakeholders in the forty- seven (47) Counties.

The following is the list of persons and institutions consulted between February 24th February and 2nd April 2022.

51 Institutions from where there can be drawn knowledge of persons having expertise in fields relevant to the proposed statutory instrument and persons likely to be affected by the proposed statutory instrument.
52 See list of consulted institutions below.

6.4.1 WRITTEN SUBMISSIONS

	STAKEHOLDERS	DATE
	Government Ministries, Departments and Agencies (MDAs).	15th March 2022
	Ministry of Health Ministry of Interior Ministry of Education Finance and National Treasury Ministry of Labour Ministry of Public Service and Gender State Department of Social Protection State Department of Public Service Kenya Medical Practitioners and Dentists Council (KMPDC) Kenya Health Professional Oversight Authority (KHPOA) Pharmacy and Poisons Board (PPB) Council of Clinical Officers (CCO) Nursing Council of Kenya (NCK) Kenya Medical Laboratory Technicians & Technologists Board (KMLTTB) Kenya Radiation Protection Board National Cancer Institute of Kenya (NCI)	

6.4.2 VIRTUAL MEETINGS

	STAKEHOLDERS	AGENCIES	DATE
	NHIF STAFF		24th and 25th February 2022

	Development Partners	World Bank ▪ Japan International Cooperation Agency (JICA) ▪ Pharm Access Kenya ▪ African Medical and Research Foundation (AMREF) ▪ Living Goods ▪ ThinkWell Kenya United Nations Children's Fund (UNICEF) German Corporation for International Cooperation (GiZ) KfW Development Bank United Nations High Commissioner for Refugees (UNHCR)	16th March 2022

6.4.3 PHYSICAL MEETINGS

	STAKEHOLDERS	AGENCIES	DATE
	Parliamentary Committees	Senate Delegated Legislation Committee	17th March 2022
		National Assembly Health Committee	21st March 2022
		National Assembly Delegated Legislation Committee	2nd April 2022
	County **Healthcare Professional Associations**	Council of Governors (COG) Kenya Medical Association (KMA) Kenya Union of Clinical Officers (KUCO) Kenya National Union of Nurses (KNUN) Kenya Dentists' Association (KDA) Kenya Cancer Association (KENCASA) KRPA Kenya Network of Women with Aids (KENWA)	24th March 2022

	Patient Support Groups	Kenya Medical Practitioners and Dentists Council (KMPDC) Kenya Health Professional Oversight Authority (KHPOA) SUPKEM Kenya Evangelical Alliance National Council of Churches of Kenya (NCCK)	
	Health Care Provider Regulatory Bodies	Hindu Association	
	Religious Groups	Muslims For Human Rights (MUHURI) Human Rights Watch Amnesty International	
	Civil Society Groups	Media Council of Kenya Editors' Guild Mainstream Media Digital platforms Community Media	
	Media	Central Organizations of Trade Unions (COTU) Federation of Kenya Employers (FKE) Kenya National Farmers Federation (KENAF)	

	Employer Associations **Informal Sector**		

6.4.4 COUNTY PUBLIC PARTICIPATION FORA

COUNTY PUBLIC PARTICIPATION FORUMS - 23RD MARCH 2022

CODE	COUNTY	VENUE
1.	Mombasa	Koblenz Hall, Moi Avenue
2.	Kwale	Ward Administrators Hall -Ukunda Show ground.
3.	Kilifi	Kibaoni Social Hall next to Kilifi and Mariakani Water Office
4.	Tana River	Laza Primary School Hall, Hola town
5.	Lamu	Huduma Centre Hall, Lamu
6.	Taita Taveta	Dan Mwanzo CDF Hall, Voi
7.	Garissa	Government Guest House Garissa
8.	Wajir	ICT Hall Wajir
9.	Mandera	Mandera Peace Hall, Mandera
10.	Marsabit	Catholic Hall, Marsabit
11.	Isiolo	C.D.F Hall, Isiolo
12.	Meru	Kamundi Hall
13.	Tharaka Nithi	C.D.F Hall, Chuka
14.	Embu	Upper Tana Management Project Hall Next to Embu University.
15.	Kitui	Kitui Multipurpose Hall, Kitui
16.	Machakos	Machakos Social Hall Opposite Machakos Stadium
17.	Makueni	County Green Park Social Hall, Wote
18.	Nyandarua	CDF Hall adjacent to Huduma Centre (Same Compound)
19.	Nyeri	Old Nyeri Municipal Hall, Nyeri

20	Kirinyaga	Kirinyaga Central NG-CDF Hall
21	Murang'a	County Conference Hall, Murang'a
22	Kiambu	Kiambu County Hall
23	Turkana	Bishop Mahon Teachers Training College, Lodwar
24	West Pokot	Yang'at Hall, Kapenguria
25	Samburu	Allamano Pastoral Centre, Maralal
26	Trans Nzoia	Kitale Museum Hall, Kitale
27	Uasin Gishu	Uasin Gishu County Hall, Eldoret.
28	Elgeyo Marakwet	Elgeyo Marakwet County Hall/ Treasury Hall, Iten
29	Nandi	Christ is the Answer Ministries (CITAM), Kapsabet
30	Baringo	Kabarnet Vocational Rehabilitation Centre, Kabarnet
31	Laikipia	Nanyuki vocational Training, Nanyuki
32	Nakuru	Shabab Social Hall, Nakuru
33	Narok	Narok North Youth Empowerment Centre, Narok
34	Kajiado	Masai Technical Training Institute, Kajiado
35	Kericho	Lytneys Hotel, Kelunet Plaza, Kericho
36	Bomet	AGC. Town Church, Bomet
37	Kakamega	Kakamega Regional Commissioners Hall- Magharibi Hall
38	Vihiga	Mutembe Friends Church opposite Vihiga County Referral Hospital
39	Bungoma	County Green Hotel Sikata Junction, Bungoma
40	Busia	Busia County Commissioner's Hall
41	Siaya	IEBC Hall behind the County Commissioner's Office.
42	Kisumu	Mama Grace Onyango Social Centre (formerly Kisumu Social Hall)
43	Homabay	Decce Hall at the County Commissioner's Office, Homa Bay
44	Migori	IFAD Hall, Migori
45	Kisii	Zonic Hotel, Kisii
46	Nyamira	Kenya Industrial Estates (KIE) Hall, Nyamira
47	Nairobi	KICC Amphitheatre

6.4.5 PUBLIC PARTICIPATION – HEALTHCARE PROVIDERS

	PARTICIPANTS	LOCATION	DATE
	MoH, SPARC	Virtual	17th February 2022
	COG's, CECs for Health, County Director's for Health, County Chief Officers.	Virtual	23rd February 2022
	Government National Referral Hospitals (Level 6)	NHIF Auditorium	8th March 2022
	County Referral Hospitals (Level 5)	NHIF Auditorium	9th March 2022
	KMA, KMPDU	NHIF Auditorium	10th March 2022
	RUPHA, KAPH, High-Cost Private Hospitals	NHIF Auditorium	15th March 2022
	Kenya Faith-Based Health Services Consortium (KFBHSC) and KAPH	NHIF Auditorium	18th March 2022
	Negotiations with all above stakeholders and specialists on the surgical benefit package	NHIF Auditorium	24th - 30th March 2022

Attached to the report is a detailed matrix indicating representations received from the Stakeholders, their comments and action taken in revising the Regulations.

CHAPTER 7: AN OVERVIEW OF THE PROPOSED NATIONAL HEALTH INSURANCE FUND ACT, REGULATIONS, 2022

SALIENT FEATURES

This overview is intended to assess whether the proposed regulation is clear, consistent, comprehensible, and comprehensive enough to address the identified problem. The regulations should be understood by likely users, and to that end the Regulator should take steps to ensure that the text and structure of regulations are as clear as possible.

7.1. CLAIMS AND BENEFITS

The draft National Health Insurance Fund regulations provides for a Centralized Health Care Provider Management System 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 authorized persons and apply to the board for rights and access to the system in line with data protection Act 2019. There is provision for the system to maintain to an audit trail of all process and have the capability of data retrieval.

Under the regulations, beneficiaries with a private health insurance cover have their private health insurance liable for payment up to the limits the beneficiary is covered, and the Fund shall pay the daily rebate, for inpatient. The Fund shall cover the outstanding bill where private insurance cover's limits for various benefits have been exhausted subject to the Fund's applicable limits with respect to each benefit.

Moreover, beneficiaries undergoing treatment for a chronic illness shall access service and shall be limited to benefits that have been specified by the Fund. The Fund shall provide the benefits provided in the schedules provided that the Beneficiary's contribution is up to date.

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.

7.2 REGISTRATION OF MEMBERS

The National Health Insurance Fund regulations provide that a person 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 utilize existing National Population Data Bases to enable actualization of mandatory registration

7.3. EMPANELMENT AND CONTRACTING

The National Health Insurance Fund regulations have given guidelines on the relationship between the Fund and healthcare providers through the process of empanelment and provision of contracts. This will assure the provision and access of safe and quality services offered by qualified and licensed healthcare providers.

The regulations stipulate the requirements for empanelment and contracting of healthcare providers. The healthcare providers who meet these requirements shall be empanelled and contracted by the Fund and there after onboarded on to the Centralised Healthcare Provider Management System.

Failure to meet the requirements provided for by these regulations will lead to rejection of the application by the board.

Provision for an annual inspection have been spelled out in these regulations to ensure compliance with the Act and the Board may revoke empanelment of a healthcare provider in accordance with the Act.

7.4. CONTRIBUTIONS

The National Health Insurance Fund regulations has provided for Standard contributions; Matching contributions; Voluntary contributions and Special Contributions. The Standard contribution is derived from the monthly gross pay of the members and where the member is employed the employer shall match the contributions in accordance with the rate of gross salary.

The identification of a voluntary contributor has been specified by the regulations as a person who has obtained a recommendation from the National Employment

Authority stating that they are unemployed; are not categorized as an indigent by State Department for Social Protection; and are not a beneficiary under any member. These contributors have their monthly contribution rates set at five hundred shillings.

On the provision for special contributions, the regulation provides for the State department for social protection to provide a list of indigents and vulnerable persons to the Fund, which will in turn notify the persons covered of their eligibility as a beneficiary. The monthly rate of contribution for special contributions have been set at five hundred shillings.

These regulations provide for the review of benefits every two years

CHAPTER 8: COST-BENEFIT ANALYSIS

8.1 COSTS AND BENEFITS GENERALLY

The analysis of the expected costs and benefits of the proposed National Health Insurance Fund Amendment Act, Regulations, 2022 contained in this part seeks to answer the question 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. This will in turn inform the decision makers since the cost of government action should be justified by its benefits before action is taken.

Table1:

8.2 MATRIX OF BENEFITS AND COSTS ON THE NATIONAL HEALTH INSURANCE FUND AMENDMENT ACT, REGULATIONS, 2022

Problem	**Proposed Reform**	**Benefits**	**Cost**
Inadequate Financial Sustainability of the Fund	Mandatory contributions	**Benefits to the Fund** Assured premiums/revenue of Ksh. 81.0 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%	**Cost to the Govt** Indigents Cover - Ksh. 30.7 billion **Cost to the Citizens** Informal sector Cost - Ksh.13.5 billion
	Employer/Employee Matching	**Benefits to the Fund** Increased revenue base of Ksh. 31.2 billion Financial Sustainability	**Cost to employers** Matching contributions of Ksh. 31.2 billion
High Attrition Rate/Low Retention among	Mandatory contributions for Informal Sector and Indigents with	**Benefit to the Fund**	As above

voluntary contributors	payment of premiums for indigents by the national government	Improved retention of informal sector from **24%** to 100% **Benefit to Govt**	
	Lowered penalty rates for defaulters	**Benefit to the Fund** Increased retention **Benefit to the Citizens** Reduced expenditure from 500% to 10% of principal amount	**Cost to the Fund** Reduced collections of penalties by **490%**
Fraud	Enhanced fines for defrauding the fund	**Benefit to the Fund** Reduced losses at approximately 10% – 20% of total pay-out **Benefits to Beneficiaries** Enhanced benefits	
	Biometric registration of beneficiaries	**Benefit to the Fund** Reduced losses at approximately 10% – 20% of total pay-out **Benefits to Beneficiaries** Enhanced benefits from savings made	
	Automation through the Centralized Healthcare Provider Management System (CHPMS)	**Benefit to the Fund** Reduced losses at approximately 10% – 20% of total pay-out **Benefits to Beneficiaries** Increased transparency	**Cost to the Fund** Acquisition and Countrywide roll-out of CHPMS – Ksh. 5 billion Maintenance – Ksh. **Cost to Healthcare Providers** ICT Infrastructure acquisition and maintenance

Adverse Selection in the Informal Sector	Mandatory Contributions by/for all Kenya residents	**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 19.1 billion per annum **Benefits to the Govt** Healthy work force **Benefit to Citizens** Reduced OOP expenditure by 15%	**Cost to the Govt** Indigents Cover – Ksh. 30.7 billion **Cost to the Citizens** Informal sector Cost – Ksh.13.5 billion
Low Health Insurance Coverage	Mandatory Registration of all Kenya Residents Modalities for optimizing and standardizing coverage and reimbursements for efficiency under both the private sector and NHIF	**Benefits to the Fund** Growth in revenue to Ksh. 81.0 billion from all Kenyan residents Clarity on apportioning reimbursements with private insurers **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%	**Cost to the Govt** Indigents Cover – Ksh. 30.7 billion **Cost to the Citizens** Informal sector Contributions – Ksh.13.5 billion **Cost to private insurers** Payment of reimbursements up to the limit individual is covered before NHIF funds can be utilized.
High out of the pocket expenditure	Mandatory registration of all Kenya residents	**Benefits to the citizens** Reduced out of pocket payments for health Government subsidy of 30.7 billion for indigents	**Cost to the Govt** Indigents Cover – Ksh. 30.7 billion **Cost to the Citizens**

	National government payment of premiums for the indigents and the vulnerable		Informal sector Contributions – Ksh.13.5 billion
Limited access to emergency services	Coverage of emergency services by the Fund	**Benefits to the citizens** Assured access to emergency health services to all Kenyans Reduced mortality and disability-adjusted Life Years arising from medical emergencies **Benefits to healthcare providers** Assured reimbursements for health emergency services provided to clients who would not have otherwise paid	**Cost to the Govt** Indigents Cover – Ksh. 30.7 billion **Cost to the Citizens** Informal sector Contributions – Ksh.13.5 billion
Weak health financing models	Mandatory registration to NHIF for all Kenyans as the key financing mechanism for health services	**Benefit to Government** Strengthened health financing systems **Benefits to the Fund** Growth in revenue to Ksh. 81.0 billion from all Kenyan residents	**Cost to the Govt** Indigents Cover – Ksh. 30.7 billion Reorganization of financial resources for health **Cost to the Citizens** Informal sector Contributions – Ksh.13.5 billion

System inefficiencies	Improvement in timelines for empanelment of providers, increased scope and geographical spread of health care providers engaged including for primary healthcare and the provision of a centralized healthcare providers' management system	**Benefit to the Fund** Reduced losses at approximately 10% – 20% of total pay-out Increased provider choices for its members **Benefits to Beneficiaries** Access and equity with a wider geographical spread for available healthcare providers Increased transparency **Benefits to the Govt** Achievement of UHC in a primary healthcare approach **Benefits to the HC providers** Improved efficiency Assured reimbursement for primary healthcare service providers	**Cost to the Fund** Acquisition and Countrywide roll-out of CHPMS – Ksh. 5 billion Maintenance **Cost to Healthcare Providers** ICT Infrastructure acquisition and maintenance

CHAPTER 9: CONSIDERATION OF ALTERNATIVES TO THE NATIONAL HEALTH INSURANCE FUND AMENDMENT ACT, REGULATIONS, 2022

This Part considers the question whether the proposed regulations is the best form of government action. The Statutory Instruments Act requires a regulator to carry out, early in the regulatory process, an informed comparison of a variety of regulatory and non-regulatory policy measures, considering relevant issues such as costs, benefits, distributional effects, and administrative requirements.

Regulation should be the last resort in realizing policy objectives. There are alternatives, which could come in handy in dealing with certain aspects of the insurance industry. The options considered under this part are the following:

9.1 OPTION ONE: MAINTENANCE OF THE STATUS QUO

Maintaining the status quo means that no regulations will be developed and therefore the National Health Insurance Act will not get 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. Key aspects of the Regulations which may impact on the implementation of the Act include: -

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

i. Non achievement of the UHC state in Kenya, this means that the Fund will not be able to ensure that all Kenyans from the age of 18 years and above are duly registered as NHIF members and by virtue of this will contribute to the Fund and enjoy accessible, affordable health care
ii. The Fund will not be financially sustainable noting that now, the funds payment of claims is calculated at approximately 3 shillings for every shilling collected and this brings about concerns on the Fund's sustainability in the future.
iii. Currently there are high attrition rates in terms of reduced member contributions towards the scheme noting that this is a worldwide phenomenon

that voluntary contributions are not maintainable thus the need to implement the regulations to improve and maintain the same.

iv. NHIF has been exposed to adverse selection due to the voluntary nature of the informal sector scheme. When the benefit pay-out ratios are disaggregated for the national scheme, it reveals that the benefit pay-out ratio of the formal sector was 55% while that of the informal sector was 248% in FY 2020/21. This reveals that there is significant adverse selection among the informal sector; given that the national scheme was voluntary for the informal sector, high risk groups (those that know that they are likely to need to seek healthcare) register while healthy individuals are more likely not to register [2].

v. Fraud and abuse are widespread and very costly to Kenya's healthcare system. Factors that contribute to occurrence of fraud include collusion between beneficiaries and health service providers, lack of sophisticated interrogation/detection software, poor internal controls, and poorly trained claims processing staff. Need to implement the regulations to prevent this.

vi. 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 [5]. 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. Implementation will address this.

9.2 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, this must be done in law. This therefore necessitates the need the include all these information in regulations to ease and improve implementation and achievement of UHC.

9.3 OPTION THREE: DEVELOPING THE NATIONAL HEALTH INSURANCE FUND AMENDMENT ACT, REGULATIONS,2022

The development of the five regulations on beneficiary identification, member registration, member contributions; empanelment and contracting and on benefits and claims shall ensure that the implementation of the National Health Insurance Fund Act will affect a much more practicable aspect towards the attainment of Universal Health Coverage. These regulations will in effect allow the Fund to implement the amended areas of the Act and thus ease attainment of UHC.

9.4 IMPACT ANALYSIS OF THE OPTIONS

9.4.1 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 register for NHIF A burdened nation crippled by debilitating and expensive medical bills	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 years to be registered as an NHIF 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

Impact on sectors	Option one: Maintaining the Status quo	Option two: Administrative measures	Option three: Developing the National Health Insurance Act Regulations
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 poverty because of catastrophic health expenditures	Administrative measures are not sufficient to address out of pocket expenditure	Improved access to healthcare services across the population 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 existing legal frameworks	The existing legal gaps will not be addressed	Regulatory concerns will remain un-addressed	Addresses all the identified gaps Provides harmony with related legal frameworks

Impact on sectors	Option one: Maintaining the Status quo	Option two: Administrative measures	Option three: Developing the National Health Insurance Act Regulations
			No further legal amendments or enactments will be required

9.5 PREFERRED OPTION

The preferred option would be the implantation of the drafted regulations with a view to ensure that universal health coverage was attained and that all Kenyans received accessible, affordable, and quality health care without suffering financial constraints.

CHAPTER 10: COMPLIANCE AND IMPLEMENTATION

As different aspects of the proposed Regulations are evaluated and analysed, it is important to determine how compliance and implementation of the actual provisions will be achieved. It is the duty of the regulator to assess the adequacy of the institutional framework and other incentives through which the regulation will take effect, and design responsive implementation strategies that make the best use of them.

The implementation and enforcement of the NHIF Regulations 2022 will be undertaken through the existing legal and institutional framework at the national level, the Board of NHIF in consultation with the Cabinet Secretary responsible for matters relating to Health.

10.1 CONFORMING TO LEGAL REQUIREMENTS IN DEVELOPING THE PROPOSED REGULATIONS

Based on the above analysis, the following matters are apparent:

a) **Regulatory-Making Authority and the legal mandate:** Section 14A, 20,21(1),23(2)27,29 and 31 of the National Health Insurance Act empowers the Board in collaboration with Cabinet Secretary responsible for Health to make regulations generally to give effect to the Act. The Board in collaboration with the Cabinet Secretary responsible for Health therefore have the required legislative powers to propose the Regulations.

b) **Requirements of the Statutory Instruments Act:** Section 5 requires that a regulation-making authority to conduct public consultations and to drawing on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument; and to ensure that persons likely to be affected by the proposed statutory instrument had an adequate opportunity to comment on its proposed content. Sections 6 and 7 require that an RIA be prepared where a statutory instrument is likely to impose significant costs on the community. The RIA must contain certain key elements namely:

i. a statement of the objectives of the proposed legislation and the reasons,

ii. a statement explaining the effect of the proposed legislation,

iii. a statement of other practicable means of achieving those objectives, including other regulatory as well as non-regulatory options

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

v. the reasons why the other means are not appropriate.

The public consultation and RIA structure requirements have been fully met.

a) **Other existing legal frameworks**: The proposed Regulations does not propose to have any new legislation to be enacted or any of the existing laws to be amended. It harmonizes with other laws making their implementation more effective.

b) The proposed Regulations as drafted are clear, consistent, comprehensive, and comprehensible enough to cover all matters.

10.2 CONCLUSION AND RECOMMENDATION

This Regulatory Impact Assessment concludes that the proposed the National Health Insurance Fund Regulations, 2022 are necessary to operationalize the National Health Insurance Fund Act. It is recommended that the proposed Regulations be adopted.