



**Rt. Hon. Speaker**  
You may approve for tabling  
J. M. Nyegenye, C.B.S.,  
Clerk of the senate/secretary, PSC  
Date: 03/07/24

**THE SENATE**  
**THIRTEENTH PARLIAMENT | THIRD SESSION**

**SELECT COMMITTEE ON DELEGATED LEGISLATION**

**REPORT ON THE CONSIDERATION OF THE SOCIAL HEALTH INSURANCE**  
**(GENERAL) REGULATIONS, 2024**  
**LEGAL NOTICE NUMBER 49 OF 2024**  
**AND**  
**THE SOCIAL HEALTH INSURANCE (TRIBUNAL PROCEDURE) RULES, 2024,**  
**(LEGAL NOTICE NUMBER 48 OF 2024)**

PAPERS LAID	
DATE	3/7/2024
TABLED BY	Majority Leader
COMMITTEE	Delegated Legislation
CLERK AT THE TABLE	Njatu



Clerk's Chambers,  
The Senate,  
Parliament Buildings  
**NAIROBI**

**JULY 2024**

## **TABLE OF CONTENTS**

<b>ABBREVIATIONS AND ACRONYMS</b>	<b>3</b>
<b>CHAIRPERSON'S FOREWORD</b>	<b>4</b>
<b>CHAPTER ONE</b>	<b>14</b>
<b>INTRODUCTION</b>	<b>14</b>
<b>1.1 BACKGROUND</b>	<b>14</b>
<b>1.2 SCRUTINY OF THE REGULATIONS</b>	<b>15</b>
<b>1.2.1 Conformity with the Constitution of Kenya, 2010</b>	<b>18</b>
<b>1.2.2 Compliance with the Statutory Instruments Act, 2013.</b>	<b>19</b>
<b>CHAPTER TWO</b>	<b>22</b>
<b>COMMITTEE OBSERVATIONS AND RECOMMENDATIONS</b>	<b>22</b>
<b>2.1 COMMITTEE OBSERVATIONS</b>	<b>22</b>
<b>2.2 COMMITTEE RECOMMENDATIONS</b>	<b>29</b>
<b>ANNEXURES</b>	<b>31</b>

## **ABBREVIATIONS AND ACRONYMS**

CS	Cabinet Secretary
CoG	Council of Governors
KMA	Kenya Medical Association
KMPDU	Kenya Medical Practitioners, Pharmacists and Dentists Union
MoH	Ministry of Health
MDAs	Ministries, Departments and Agencies
NHIF	National Health Insurance Fund
PSC	Parliamentary Service Commission
RIA	Regulatory Impact Assessment
RMA	Regulation Making Authority
Sen	Senator
SHIF	Social Health Insurance Fund

## **CHAIRPERSON'S FOREWORD**

**Mr. Speaker,**

### **Establishment of the Committee**

The Senate Select Committee on Delegated Legislation is established under Standing Order 195 (1) of the Senate Standing Orders. The Committee is mandated to scrutinize statutory instruments to ensure that they are consistent with the provisions of the Statutory Instruments Act, 2013.

### **Membership of the Committee**

The Select Committee on Delegated Legislation is comprised of the following members: -

- |  |                    |
|--|--------------------|
| 1. Sen. Mwenda Gataya Mo Fire, MP      | - Chairperson      |
| 2. Sen. Danson Buya Mungatana, MGH, MP | - Vice-Chairperson |
| 3. Sen. Joyce Chepkoech Korir, MP      | - Member / VC, PSC |
| 4. Sen. Mohamed Mwinyihaji Faki, MP    | - Member           |
| 5. Sen. Agnes Kavindu Muthama, MP      | - Member           |
| 6. Sen. Daniel Kitonga Maanzo, MP      | - Member           |
| 7. Sen. Julius Murgor Recha, MP        | - Member           |
| 8. Sen. Betty Batuli Montet, MP        | - Member           |
| 9. Sen. Gloria Orwoba, MP              | - Member           |



**Mr. Speaker,**

In line with its mandate, the Committee received the Social Health Insurance (General) Regulations, 2024, (Legal Notice No. 49 of 2024) and the Social Health Insurance (Tribunal Procedure) Rules, 2024, (Legal Notice No. 48 of 2024) (“the two instruments”) for parliamentary scrutiny pursuant to Part IV of the Statutory Instruments Act, 2013.

These two instruments were both prepared by the Ministry of Health and published by the Cabinet Secretary on 8<sup>th</sup> March 2024. The regulations were forwarded to the Senate by the Cabinet Secretary, Ministry of Health, pursuant to section 11(1) of the Statutory Instruments Act, 2013. The regulations were tabled before the Senate on 20<sup>th</sup> March, 2024 and subsequently stood committed to the Senate Committee on Delegated Legislation. Pursuant to section 15(2) of the Statutory Instruments Act, the Committee was required to scrutinize the regulations up until 4<sup>th</sup> July 2024, after which the stipulated twenty-eight (28) sitting days from 20<sup>th</sup> March 2024 would have lapsed. The Regulations were drafted pursuant to Section 50 of the Social Health Insurance Act which states that—

*“The Cabinet Secretary shall, in consultation with the Board, make Regulations for the better carrying out of the provisions of this Act.”*

**Mr. Speaker,**

In scrutinising the statutory instruments, the Committee was guided by the Constitution of Kenya, the Social Health Insurance Act (Act No. 16 of 2023) and the Statutory Instruments Act (Cap 2, Laws of Kenya).

**Mr. Speaker,**

The Committee has considered the two instruments and resolved to annul the Social Health Insurance (General) Regulations, 2024, (Legal Notice No. 49 of 2024) and the Social Health Insurance (Tribunal Procedure) Rules, 2024, (Legal Notice No. 48 of 2024). Kindly allow me to inform this Honourable House of the reasons why the Committee has reached a resolution to annul the two instruments. At the time of presentation before the Senate, the Regulation Making Authority, in this case the Cabinet Secretary for Health, provided the Committee with the

Regulatory Impact Statement, the Explanatory Memorandum, and a matrix detailing the public participation undertaken and the result of the consultations.

In the usual manner and pursuant to section 16 of the Statutory Instruments Act, the Committee invited the Cabinet Secretary for Health, the Council of Governors, the Kenya Medical Practitioners, Pharmacists and Dentists Union, alongside the Kenya Medical Association for a meeting on Thursday, 23<sup>rd</sup> May, 2024 to discuss the two regulations. Out of the invitees, only the Council of Governors and the Kenya Medical Association (KMA) attended the meeting. The Cabinet Secretary informed the Committee that she was away on official duty and therefore requested for another meeting date. The Committee agreed to meet with the Cabinet Secretary on another date but resolved to continue with the meeting with invited stakeholders.

The Committee invited the Cabinet Secretary for a second meeting on 19<sup>th</sup> June, 2024. On that date, the Cabinet Secretary did not attend the meeting but delegated the attendance to the Principal Secretary, State Department for Medical Services where various issues with regard to the Regulations were raised particularly on the lack of detailed evidence of public participation and the unavailability the tariffs. During this meeting the Principal Secretary did not satisfactorily address the issues raised by the stakeholders and the Committee.

The Committee invited the Cabinet Secretary for the third time for a meeting to be held on 25<sup>th</sup> June, 2024. The Cabinet Secretary neither attended this meeting nor issued a written response to the Committee's concerns.

**Mr. Speaker,**

During this meeting with the Council of Governors and the Kenya Medical Association, concerns were raised surrounding the readiness of the Ministry of Health to implement the Regulations by the commencement date i.e. 1<sup>st</sup> July, 2024.

Some of the concerns raised by the two stakeholders were that while it was a few weeks before the commencement of the Regulations—

- (i) the implementation of the Act and the Regulations required a highly digital environment.

The Social Health Authority is expected to host a centralised digital platform that will on board all services and service providers. As at the date of this report, the system had not



been procured. It was the opinion of the stakeholders that operationalisation of the Digital Health Act, 2023 ought to have preceded that of the Social Health Insurance Act, 2023 in order to provide an infrastructure on which the latter would be based on;

- (ii) the Authority had not carried out means testing to determine contributions that will be paid by households whose income is not derived from salaried employment;
- (iii) Regulation 18(4) of the Social Health Insurance (General) Regulations requires the Social Health Authority in consultation with the Cabinet Secretary responsible for cooperatives, micro, small and medium enterprises development and other financing institutions to provide premium financing to non-salaried people to enable them pay the annual contributions within intervals under which their income becomes available. This provision makes an assumption that non-salaried people will get an income to pay off the loan. The Regulation Making Authority did not clarify how this provision will be implemented;
- (iv) the Authority had not conducted nationwide registration of contributors and beneficiaries;
- (v) the procedure of empanelment and accreditation of healthcare providers was not clear. Section 33 of the Social Health Act provides that the accreditation of healthcare providers under the Act shall be done by a body responsible for accreditation to be established under the Act. This body has not been established. In addition, Regulation 31 of the Social Health Insurance (General) Regulations contradicts section 33 of the Act by providing that the accreditation shall be done by the Social Health Authority;
- (vi) the Committee was concerned about the membership of the Benefits Package and Tariffs Advisory Panel. The membership of the Panel includes a chairperson nominated by the local public university, one person nominated by the Health Non-Governmental Organisations Network (HENNET) and one person nominated by development partners involved in health matters. There is a lack of clarity on the following matters—
  - the local public university to nominate the chairperson;
  - the rationale of having a public university nominating the chairperson;
  - the inclusion of development partners in a legal body to determine benefits under the Funds from Kenyan contributions raising the issues of sovereignty and conflict of interest between the development partners' mother states and Kenya;
  - the rationale of including HENNET, a non-governmental body with voluntary membership;

- the rationale of including the local public university instead of the Authority in the joint secretariat together with the Ministry of Health. There is no clarity on which public university is being referred to;

The establishment of the Benefits Package and Tariffs Advisory Panel in Regulation 41(2) of the Social Health Insurance (General) Regulations appears to make some unexpected or unusual use of powers conferred under the Act and ought to have been established in the Social Health Insurance Act and not subsidiary legislation;

- (vii) the tariffs to determine the benefits to be enjoyed by contributors and beneficiaries were not provided for in the Regulations and upon further inquiry, the Committee was informed that the tariffs had not been published;
- (viii) the stakeholders raised issue with the cross referencing in the Regulations with provisions that did not exist in the parent Act that is the Social Health Insurance, 2023. For instance, Primary Care Network is in the Regulations and not in the parent Act.
- (ix) on biometric registration, the stakeholders questioned the rationale behind registration of minors which in their opinion was unnecessary being that they are already dependants. The Social Health Authority in their opinion ought to use data already captured by the National Health Insurance Fund (NHIF).
- (x) the stakeholders further observed that the Regulations did not provide for verification of Doctor's registration details. There was need therefore to provide a portal for doctors to verify their details.

**Mr. Speaker,**

The Committee made further observations on the Social Health Insurance (General) Regulations as follows—

### **1) Public Participation**

Public participation is the bedrock of Kenya's legislative process. Contrary to Article 10 and 118 of the Constitution of Kenya and Section 5A. (1)(d) and (e) of the Statutory Instruments Act, the Regulatory Making Authority did not submit evidence of an adequate post-drafting public participation for the Regulations that satisfactorily considered the issues from the public and stakeholders involved.



## **2) Inconsistency with the Social Health Act**

Regulation 31 of the Social Health Insurance (General) Regulations is *ultra vires* to section 33 of the Social Health Insurance Act. Section 33 of the Social Health Act provides that the accreditation of healthcare providers under the Act shall be done by a body responsible for accreditation to be established under the Act while Regulation 31 provides that the accreditation shall be done by the Social Health Authority.

## **3) Scope of the Regulations**

The Social Health Insurance Act, 2023 establishes a three-tier approach to funding health care that is the Primary Healthcare Fund, the Social Health Insurance Fund and the Emergency, Chronic and Critical Illness Fund. In its explanatory memorandum, the Regulatory Making Authority explained the rationale of the three-tier approach which is a departure from the National Health Insurance Fund that was one fund financing all categories of health care. It also highlighted additional benefits to patients under the three-tier model and how the out-patient services will be covered.

Regulation 27(1) and (2) of the Social Health Insurance (General) Regulations provide for the transition from Social Health Insurance Fund to the Emergency, Chronic and Critical Illness Fund after depletion of the benefits package under the Social Health Insurance Fund.

The Regulatory Making Authority however failed to explain the benefit package of the fund, as well as elaborating the process of transiting from one fund to another upon depletion of benefits in one fund, that is, the notification, approval timelines and in instances where the approval could be declined, the appeals mechanism, and the way forward in case of an emergency where a patient has depleted benefits from one fund.

## **4) Means Testing**

Regulation 21 of the Social Health Insurance (General) Regulations provides for means testing which is a method that uses a means testing instrument to determine whether an individual or a household has the ability to pay for their social health insurance premium. The means testing



instrument, as highlighted in the regulations, was to be used to collect data from households. The instrument shall be developed by the Cabinet Secretary for Health in collaboration with the Cabinet Secretary responsible for matters relating to social protection.

The Regulatory Making Authority however, could not elaborate on this instrument as a method of determining a households' ability to pay their premiums. The Regulatory Making Authority could neither explain the formula that was used to come up with the 2.75 % annual contribution per household income, nor how the means testing instrument could be challenged.

### **5) Transitional Provisions**

The first schedule of the Social Health Insurance Act, 2023 on Transitional Provisions envisions a seamless transition from the National Health Insurance Fund (NHIF) to the Social Health Authority.

The Regulatory Making Authority could not highlight the measures that have been put in place to ensure services are not interrupted in the transition. There was no clarity on how the issue of timely reimbursements to health facilities had been dealt with in the Regulations.

### **6) Data Protection**

The Social Health Authority intended to migrate a lot of data from NHIF as well as link personal data from the National Registration Bureau. Healthcare data is sensitive and attractive to cyber-criminals because they contain financial, health status and personal data which can be used in blackmail and fraudulent activities. Health data is also remarkably vulnerable to penetration because of the fluid and always-evolving nature of a patient's medical care and because of the number of clinicians, facilities and transactions required to connect patient care across multiple settings. The Regulatory Making Authority could not explain the measures it would take to ensure security of its systems from cyber-attack, considering the fact that the right to privacy and data protection is a constitutional right to every Kenyan.

Mr. Speaker,

After careful consideration of the Social Health Insurance (General) Regulations, 2024 and the Social Health Insurance (Tribunal Procedure) Rules, 2024 , pursuant to section 15 (1) of the Statutory Instruments Act and Standing Order 195(4)(b), the Select Committee on Delegated Legislation recommends that the Senate resolves that the Social Health Insurance (General) Regulations, 2024 (Legal Notice Number 49 of 2024), and the Social Health Insurance (Tribunal Procedure) Rules, 2024 ( Legal Notice Number 48 of 2024) be annulled for the following reasons—

- (i) Contrary to Article 10 and 118 of the Constitution of Kenya and Section 5A. (1)(d) and (e) of the Statutory Instruments Act, the Regulatory Making Authority did not submit evidence of an adequate post-drafting public participation for the Regulations that satisfactorily considered the issues from the public and stakeholders involved.
- (ii) The Social Health Insurance (General) Regulations contained a matter which ought to have been dealt with by an Act of Parliament. The membership of the Benefits Package and Tariffs Advisory Panel established under Regulation 41(2) ought to have been established under the Social Health Insurance Act.
- (iii) Regulation 31 of the Social Health Insurance (General) Regulations is *ultra vires* to section 33 of the Social Health Insurance Act. Section 33 of the Social Health Act provides that the accreditation of healthcare providers under the Act shall be done by a body responsible for accreditation to be established under the Act while Regulation 31 provides that the accreditation shall be done by the Social Health Authority.
- (iv) The Regulatory Making Authority could not clarify the issues around the means testing instrument, the annual contribution formula per household income, the scope of the Regulations as well as data protection, role of counties, and the transitional provisions, as envisaged in the Regulations.

Mr. Speaker,

**Acknowledgement**

I wish to thank the members of the Committee for their unwavering commitment to scrutinizing this statutory instrument. I also wish to thank the Offices of the Speaker and the Clerk of the Senate as well as the Secretariat for the support extended to it in fulfilling its mandate. Additionally, I extend my appreciation to representatives from the Ministry of Health and the stakeholders who appeared before the Committee and made their submissions.

Mr. Speaker,

It is now my duty, pursuant to section 15 (1) of the Statutory Instruments Act and standing order 195 (4) (b) of the Senate Standing Orders, to present the report of the Select Committee on Delegated Legislation on the consideration of the Social Health Insurance (General) Regulations, 2024, *Legal Notice Number 49 of 2024*, and the Social Health Insurance (Tribunal Procedure) Rules, 2024, *Legal Notice Number 48 of 2024*

Signed.....

Date.....

SEN. MWENDA GATAYA MO FIRE, MP

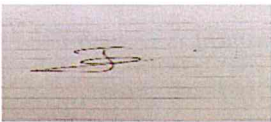

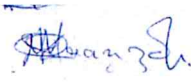

CHAIRPERSON

SELECT COMMITTEE ON DELEGATED LEGISLATION



**ADOPTION OF THE REPORT OF THE SELECT COMMITTEE ON DELEGATED  
LEGISLATION ON THE CONSIDERATION OF THE SOCIAL HEALTH INSURANCE  
(GENERAL) REGULATIONS, 2024, AND THE SOCIAL HEALTH INSURANCE  
(TRIBUNAL PROCEDURE) RULES, 2024**

We, the undersigned Members of the Select Committee on Delegated Legislation, do hereby append our signatures to adopt the Report to annul the Social Health Insurance (General) Regulations, 2024 (*Legal Notice Number 49 of 2024*) and the Social Health Insurance (Tribunal Procedure) Rules, 2024, (*Legal Notice Number 48 of 2024*)

1. Sen. Mwenda Gataya Mo Fire, MP – Chairperson
2. Sen. Danson Buya Mungatana, MGH, MP – Vice-Chairperson
3. Sen. Joyce Chepkoech Korir, MP – Member / VC, PSC
-   
4. Sen. Mohamed Mwinyihaji Faki, MP – Member
5. Sen. Agnes Kavindu Muthama, MP  – Member
6. Sen. Daniel Kitonga Maanzo, MP – Member
-   
7. Sen. Julius Murgor Recha, MP – Member
8. Sen. Betty Batuli Montet, MP  – Member
9. Sen. Gloria Orwoba, MP – Member

## CHAPTER ONE

### INTRODUCTION

#### 1.1 BACKGROUND

1. Section 2 of the Statutory Instruments Act defines a statutory instrument as follows—

*“statutory instrument” means any rule, order, regulation, direction, form, tariff of costs or fees, letters patent, commission, warrant, proclamation, by-law, resolution, guideline or other statutory instrument issued, made or established in the execution of a power conferred by or under an Act of Parliament under which that statutory instrument or subsidiary legislation is expressly authorized to be issued.*
2. Section 11 of the Statutory Instruments Act provides as follows-

**11. Laying of statutory instruments before Parliament**

  - (1) *Every Cabinet Secretary responsible for a regulation-making authority shall within seven (7) sitting days after the publication of a statutory instrument, ensure that a copy of the statutory instrument is transmitted to the responsible Clerk for tabling before the relevant House of Parliament.*
  - (2) *Notwithstanding subsection (1) and pursuant to the legislative powers conferred on the National Assembly under Article 109 of the Constitution, all regulation-making authorities shall submit copies of all statutory instruments for tabling before the National Assembly.*
  - (3) *The responsible Clerk shall register or cause to be registered every statutory instrument transmitted to the respective House for tabling or laying under this Part.*
  - (4) *If a copy of a statutory instrument that is required to be laid before the relevant House of Parliament is not so laid in accordance with this section, the statutory instrument shall cease to have effect immediately after the last day for it to be so laid but without prejudice to any act done under the statutory instrument before it became void.*
3. In line with its mandate, the Committee received the Social Health Insurance (General) Regulations 2024, (Legal Notice Number 49 of 2024) and the Social Health Insurance



(Tribunal Procedures) 2024, (Legal Notice Number 48 of 2024) for parliamentary scrutiny pursuant to Part IV of the Statutory Instruments Act.

4. The Regulations were published by the Cabinet Secretary in charge of Health, pursuant to Section 50 of the Social Health Insurance Act, 2023 which empowers the Cabinet Secretary, in consultation with the Board, to make Regulations for the better carrying out of the provisions of the Act; while the Rules were published pursuant to section 44(6) of the Social Health Insurance Act which empowers the Cabinet Secretary to prescribe procedures for the operationalization of the tribunal.
5. The Social Health Insurance (General) Regulations, 2024, and the Social Health Insurance (Tribunal Procedure) Rules, 2024 were prepared by the Ministry of Health and published by the Cabinet Secretary on 8<sup>th</sup> March 2024.
6. The regulations were forwarded to the Senate pursuant to section 11(1) of the Statutory Instruments Act. The Regulations were tabled before the Senate on 20<sup>th</sup> March 2024 and subsequently stood committed to the Senate Committee on Delegated Legislation. Pursuant to section 15(2) of the Statutory Instruments Act, the Committee was required to scrutinize the regulations up until 4<sup>th</sup> July, 2024, after which the stipulated twenty-eight (28) sitting days from its referral date would have lapsed.

## **1.2 SCRUTINY OF THE REGULATIONS**

7. In scrutinizing the statutory instruments, the Committee considered whether the instruments conforms—
  - i) to the letter and spirit of the Constitution;
  - ii) the Social Health Insurance Act (Act No. 16 of 2023)
  - iii) with the Statutory Instruments Act, 2013(Cap 2, Laws of Kenya)
8. Pursuant to section 16 of the Statutory Instruments Act, the Committee invited the Cabinet Secretary for Health, the Council of Governors, the Kenya Medical Practitioners, Pharmacists and Dentists Union, alongside the Kenya Medical Association for a meeting on 23<sup>rd</sup> May, 2024 to discuss the two regulations.

9. Out of the invitees, only the Council of Governors and the Kenya Medical Association (KMA) attended the meeting. The Cabinet Secretary informed the Committee that she was away on official duty and therefore requested for another meeting date. The Committee agreed to meet with the Cabinet Secretary on another date but resolved to continue with the meeting with invited stakeholders.
10. Some of the concerns raised by the stakeholders and observed by the Committee were that while it was a few weeks before the commencement of the Regulations—
  - (a) the implementation of the Act and the Regulations required a highly digital environment. The Social Health Authority is expected to host a centralised digital platform that will on board all services and service providers. As at the date of this report, the system had not been procured. It was the opinion of the stakeholders that operationalisation of the Digital Health Act, 2023 ought to have preceded that of the Social Health Insurance Act, 2023 in order to provide an infrastructure on which the latter would be based on;
  - (b) the Authority had not carried out means testing to determine contributions that will be paid by households whose income is not derived from salaried employment;
  - (c) Regulation 18(4) of the Social Health Insurance (General) Regulations requires the Social Health Authority in consultation with the Cabinet Secretary responsible for cooperatives, micro, small and medium enterprises development and other financing institutions to provide premium financing to non-salaried people to enable them pay the annual contributions within intervals under which their income becomes available. This provision makes an assumption that non-salaried people will get an income to pay off the loan. The Regulation Making Authority did not clarify how this provision will be implemented;
  - (d) the Authority had not conducted nationwide registration of contributors and beneficiaries;
  - (e) the procedure of empanelment and accreditation of healthcare providers was not clear. Section 33 of the Social Health Act provides that the accreditation of healthcare providers under the Act shall be done by a body responsible for accreditation to be established under the Act. This body has not been established. In addition, Regulation



- 31 of the Social Health Insurance (General) Regulations contradicts section 33 of the Act by providing that the accreditation shall be done by the Social Health Authority;
- (f) the Committee was concerned about the membership of the Benefits Package and Tariffs Advisory Panel. The membership of the Panel includes a chairperson nominated by the local public university, one person nominated by the Health Non-Governmental Organisations Network (HENNET) and one person nominated by development partners involved in health matters. There is a lack of clarity on the following matters—
- the local public university to nominate the chairperson;
  - the rationale of having a public university nominating the chairperson;
  - the inclusion of development partners in a legal body to determine benefits under the Funds from Kenyan contributions raising the issues of sovereignty and conflict of interest between the development partners' mother states and Kenya;
  - the rationale of including HENNET, a non-governmental body with voluntary membership;
  - the rationale of including the local public university instead of the Authority in the joint secretariat together with the Ministry of Health. There is no clarity on which public university is being referred to;
- (g) The establishment of the Benefits Package and Tariffs Advisory Panel in Regulation 41(2) of the Social Health Insurance (General) Regulations appears to make some unexpected or unusual use of powers conferred under the Act and ought to have been established in the Social Health Insurance Act and not subsidiary legislation;
- (h) the tariffs to determine the benefits to be enjoyed by contributors and beneficiaries were not provided for in the Regulations and upon further inquiry, the Committee was informed that the tariffs had not been published;
- (i) the stakeholders raised issue with the cross referencing in the Regulations with provisions that did not exist in the parent Act that is the Social Health Insurance, 2023. For instance, Primary Care Network is in the Regulations and not in the parent Act.
- (j) on biometric registration, the stakeholders questioned the rationale behind registration of minors which in their opinion was unnecessary being that they are already

dependants. The Social Health Authority in their opinion ought to use data already captured by the National Health Insurance Fund (NHIF).

(k) the stakeholders further observed that the Regulations did not provide for verification of Doctor's registration details. There was need therefore to provide a portal for doctors to verify their details.

11. The Committee invited the Cabinet Secretary for a second meeting on 19<sup>th</sup> June, 2024. On that date, the Cabinet Secretary did not attend the meeting but delegated the attendance to the Principal Secretary, State Department for Medical Services where various issues with regard to the Regulations were raised particularly on the lack of detailed evidence of public participation and the unavailability of the tariffs. During this meeting the Principal Secretary did not satisfactorily address the issues raised by the stakeholders and the Committee.
12. The Committee invited the Cabinet Secretary for the third time for a meeting to be held on 25<sup>th</sup> June, 2024. The Cabinet Secretary neither attended this meeting nor issued a written response to the Committee's concerns.

#### **1.2.1 Conformity with the Constitution of Kenya, 2010**

13. Article 10 of the Constitution of Kenya states that the national values and principles of governance bind all State organs, State officers, public officers and all persons whenever they enact any law or make public policy decisions. Article 10(2)(a) further lists public participation as being one of the national values and principles of governance. In the explanatory memorandum forwarded to the Committee, the Cabinet Secretary stated that the Ministry called for submissions from public, and stakeholders from private entities as well as public officers and members of the public.
14. Article 43 (1) of the Constitution of Kenya, 2010, provide for the right of every person to the highest attainable standard of health, which includes the right to health care services, including reproductive health care; to accessible and adequate housing, and to reasonable standards of sanitation; to be free from hunger, and to have adequate food of acceptable quality; to clean and safe water in adequate quantities; to social security; and to education. Article 43 (2) and (3) provides that every person shall not be denied emergency medical treatment; and that State shall provide appropriate social security to persons who are unable



to support themselves and their dependants. The regulations were intended to create a framework for the implementation of the Social Health Insurance Act, to advance the realisation of social and economic rights under Article 43(1) of the Constitution of Kenya.

15. The legislative power was delegated under an Act of Parliament i.e., the Social Health Insurance Act, 2023 which delegates the regulation making power to the Cabinet Secretary dealing with matters of health in the country.
16. The Fourth Schedule of the Constitution indicates that provision of primary healthcare is a devolved function of county governments, while the national government, through the Ministry of Health, retains the role of policy making and implementation, under its mandate. The regulations are limited the implementation of the Social Health Insurance Act.
17. Based on this reason, there was need for the regulations and rules to take notice of the importance of the county government as key pillars for implementation of such regulations to the public, at the county level. The role of the counties in relation to these regulations and rules, was not clear. Moreover, the Committee could not ascertain and verify from the documentary responses submitted by the Ministry, the extent to which the input from the counties, through the Council of Governors submissions during public participation and stakeholder engagements were considered and incorporated into the final regulations.

## **1.2.2 Compliance with the Statutory Instruments Act, 2013.**

### **1.2.2.1 Explanatory Memorandum**

18. Sections 5 and 5A of the Act requires the regulation-making body to consult persons who are likely to be affected by an instrument. It ought to explain in detail in an explanatory memorandum that consultations were carried out, the scope, the outcome of such consultations, the changes made on the legislation after the public consultations and an explanation on the lack of public consultation if none was done.
19. The explanatory memorandum that had been provided to the Committee by the Cabinet Secretary stated that the primary cause for the proposed regulations is that the Social Health Insurance Act, 2013 requires frameworks for the implementation of the Primary Healthcare Fund, the Social Health Insurance Fund and the Emergency, Chronic and Critical Illness Fund established in the Act. It further requires the mandatory registration of every person resident



in Kenya pursuant to section 26(1) of the Act and the mode of payment of contributions pursuant to section 27(1) and (2) of the Act.

20. The memorandum also stated that the purpose of the Social Health Insurance (Tribunal Procedures) Rules, 2024 is the need for a Dispute Resolution Tribunal as established under section 44 of the Social Health Insurance Fund Act, 2023 for the purpose of hearing and determining complaints, disputes and appeals arising from the Act.
21. The Cabinet Secretary stated that the Regulations were not amending another statutory instrument, and thus they did not require consolidation as required by the Statutory Instruments Act.
22. Contrary to Section 5A.(1)(d) and (e) of the Statutory Instruments Act, 2013 the regulatory making authority did not submit evidence of an adequate post-drafting public participation for both the Regulations and the Rules that satisfactorily considered the issues from the public and stakeholders involved.

#### **1.2.2.2 Regulatory Impact Statement**

23. Sections 6, 7 and 8 of the Statutory Instruments Act provides for the need for the regulation making authority to prepare a regulatory impact statement if a statutory instrument is likely to impose significant costs on the community or a part of the community. The regulatory impact statement should explain the objectives of the statutory rule, the effect of the proposed regulation, a statement of other practicable means of achieving those objectives, an assessment of the cost and benefits of the proposed rules and reasons why other means are not appropriate.
24. The Regulatory Impact Statement ("RIS") was provided to accompany the regulations for parliamentary scrutiny. However, the Ministry in its submissions failed to explain the financial implication of the application of the Rules and the Regulations to the public, and why other means for achieving the objectives of the instruments were not considered.



## CHAPTER TWO

### COMMITTEE OBSERVATIONS AND RECOMMENDATIONS

#### 2.1 COMMITTEE OBSERVATIONS

25. The Committee made the following observations—

##### **(a) Public Participation**

26. The Committee received the Explanatory Memorandum explaining the nature and extent of public participation undertaken. The Committee also received and considered the matrix of comments received from stakeholders that were consulted.

27. Public participation, as the bedrock of Kenya's legislative process, has been entrenched in the Constitution under Article 10 as a national value and principle of governance and is binding on all persons whenever any of them applies or interprets the Constitution, enacts, applies or interprets any law or makes or implements public policy decisions.

28. The Supreme Court in *British American Tobacco Kenya, PLC (formerly British American Tobacco Kenya Limited) v Cabinet Secretary for the Ministry of Health & 2 others* laid down the following guiding principles for public participation—

- (a) as a constitutional principle under Article 10(2) of the Constitution, public participation applies to all aspects of governance;
- (b) the public officer and or entity charged with the performance of a particular duty bears the onus of ensuring and facilitating public participation;
- (c) the lack of a prescribed legal framework for public participation is no excuse for not conducting public participation; the onus is on the public entity to give effect to this constitutional principle using reasonable means;
- (d) public participation must be real and not illusory. It is not a cosmetic or a public relations act. It is not a mere formality to be undertaken as a matter of course just to 'fulfill' a constitutional requirement. There is need for both quantitative and qualitative components in public participation;
- (e) public participation is not an abstract notion; it must be purposive and meaningful;
- (f) public participation must be accompanied by reasonable notice and reasonable opportunity. Reasonableness will be determined on a case to case basis;



- (g) public participation is not necessarily a process consisting of oral hearings, written submissions can also be made. The fact that someone was not heard is not enough to annul the process;
- (h) allegation of lack of public participation does not automatically vitiate the process. The allegations must be considered within the peculiar circumstances of each case: the mode, degree, scope and extent of public participation is to be determined on a case to case basis;
- (i) components of meaningful public participation include the following:
  - (i) *clarity of the subject matter for the public to understand;*
  - (ii) *structures and processes (medium of engagement) of participation that are clear and simple;*
  - (iii) *opportunity for balanced influence from the public in general;*
  - (iv) *commitment to the process;*
  - (v) *inclusive and effective representation;*
  - (vi) *integrity and transparency of the process;*
  - (vii) *capacity to engage on the part of the public, including that the public must be first sensitized on the subject matter.*

29. Additionally, the High Court in *Mui Coal Basin Local Community & 15 others v Permanent Secretary Ministry of Energy & 17 others [2015] eKLR* held that—

*“First, it is incumbent upon the government agency or public official involved to fashion a programme of public participation that accords with the nature of the subject matter. It is the government agency or Public Official who is to craft the modalities of public participation but in so doing the government agency or Public Official must take into account both the quantity and quality of the governed to participate in their own governance...*

*Second, public participation calls for innovation and malleability depending on the nature of the subject matter, culture, logistical constraints, and so forth. In other words, no single regime or programme of public participation can be prescribed and the Courts will not use any litmus test to determine if public participation has been achieved or not. The only test the Courts use is one of effectiveness...*

*Third, whatever programme of public participation is fashioned, it must include access to and dissemination of relevant information....*

*Fourth, public participation does not dictate that everyone must give their views on an issue... To have such a standard would be to give a virtual veto power to each individual in the community to determine community collective affairs. A public participation programme... must, however, show intentional inclusivity and diversity. Any clear and intentional attempts to keep out bona fide stakeholders would render the public participation programme ineffective and illegal by definition. In determining inclusivity in the design of a public participation regime, the government agency or Public Official must take into account the subsidiarity principle: those most affected by a policy, legislation or action must have a bigger say in that policy, legislation or action and their views must be more deliberately sought and taken into account.*

*Fifth, the right of public participation does not guarantee that each individual's views will be taken as controlling; the right is one to represent one's views – not a duty of the agency to accept the view given as dispositive. However, there is a duty for the government agency or Public Official involved to take into consideration, in good faith, all the views received as part of public participation programme. The government agency or Public Official cannot merely be going through the motions or engaging in democratic theatre so as to tick the Constitutional box."*

30. From the above judgments from the Courts, it is apparent that public participation must be real and not illusory. This is why section 5A(1)(e) provides that the explanatory memorandum should explain any changes made to the legislation as a result of the public participation.

31. From the engagement with the stakeholders and from the Committee's own observations, serious matters arose namely—

(a) the implementation of the Act and the Regulations required a highly digital environment. The Social Health Authority is expected to host a centralised digital



platform that will on board all services and service providers. As at the date of this report, the system had not been procured. It was the opinion of the stakeholders that operationalisation of the Digital Health Act, 2023 ought to have preceded that of the Social Health Insurance Act, 2023 in order to provide an infrastructure on which the latter would be based on;

- (b) the Authority had not carried out means testing to determine contributions that will be paid by households whose income is not derived from salaried employment;
- (c) Regulation 18(4) of the Social Health Insurance (General) Regulations requires the Social Health Authority in consultation with the Cabinet Secretary responsible for cooperatives, micro, small and medium enterprises development and other financing institutions to provide premium financing to non-salaried people to enable them pay the annual contributions within intervals under which their income becomes available. This provision makes an assumption that non-salaried people will get an income to pay off the loan. The Regulation Making Authority did not clarify how this provision will be implemented;
- (d) the Authority had not conducted nationwide registration of contributors and beneficiaries;
- (e) the procedure of empanelment and accreditation of healthcare providers was not clear. Section 33 of the Social Health Act provides that the accreditation of healthcare providers under the Act shall be done by a body responsible for accreditation to be established under the Act. This body has not been established. In addition, Regulation 31 of the Social Health Insurance (General) Regulations contradicts section 33 of the Act by providing that the accreditation shall be done by the Social Health Authority;
- (f) the Committee was concerned about the membership of the Benefits Package and Tariffs Advisory Panel. The membership of the Panel includes a chairperson nominated by the local public university, one person nominated by the Health Non-Governmental Organisations Network (HENNET) and one person nominated by development partners involved in health matters. There is a lack of clarity on the following matters—
  - the local public university to nominate the chairperson;
  - the rationale of having a public university nominating the chairperson;

- the inclusion of development partners in a legal body to determine benefits under the Funds from Kenyan contributions raising the issues of sovereignty and conflict of interest between the development partners' mother states and Kenya;
- the rationale of including HENNET, a non-governmental body with voluntary membership;
- the rationale of including the local public university instead of the Authority in the joint secretariat together with the Ministry of Health. There is no clarity on which public university is being referred to;

The establishment of the Benefits Package and Tariffs Advisory Panel in Regulation 41(2) of the Social Health Insurance (General) Regulations appears to make some unexpected or unusual use of powers conferred under the Act and ought to have been established in the Social Health Insurance Act and not subsidiary legislation;

- (g) the tariffs to determine the benefits to be enjoyed by contributors and beneficiaries were not provided for in the Regulations and upon further inquiry, the Committee was informed that the tariffs had not been published;
- (h) the stakeholders raised issue with the cross referencing in the Regulations with provisions that did not exist in the parent Act that is the Social Health Insurance, 2023. For instance, Primary Care Network is in the Regulations and not in the parent Act.
- (i) on biometric registration, the stakeholders questioned the rationale behind registration of minors which in their opinion was unnecessary being that they are already dependants. The Social Health Authority in their opinion ought to use data already captured by the National Health Insurance Fund (NHIF).
- (j) the stakeholders further observed that the Regulations did not provide for verification of Doctor's registration details. There was need therefore to provide a portal for doctors to verify their details.

32. The Committee observed that these issues ought to have been addressed at the public participation stage. The existence of such matters after the Regulations had been published raised the question of whether the public participation was qualitative. There was no explanation from the Regulation Making Authority on how the Regulations changed after the



public participation. As such, the Committee observed that public participation was not qualitative and was therefore contrary to Article 10 of the Constitution.

**(b) Inconsistency with the Social Health Act**

33. The Committee observed that Regulation 31 of the Social Health Insurance (General) Regulations is *ultra vires* to section 33 of the Social Health Insurance Act. Section 33 of the Social Health Act provides that the accreditation of healthcare providers under the Act shall be done by a body responsible for accreditation to be established under the Act while Regulation 31 provides that the accreditation shall be done by the Social Health Authority.

34. Subsidiary legislation cannot override an Act of Parliament. This is provided for in section 31(b) of the Interpretations and General Provisions Act (Cap. 2, Laws of Kenya) which states that—

*“31. Where an Act confers power on an authority to make subsidiary legislation, the following provisions shall, unless a contrary intention appears, have effect with reference to the making of the subsidiary legislation—*

*....*

*(b) no subsidiary legislation shall be inconsistent with the provisions of an Act”*

**(c) Compliance with the Statutory Instruments Act**

35. Section 13 of the Statutory Instruments Act contains relevant considerations to be applied by the Committee in the scrutiny of statutory instruments.

36. The Social Health Insurance (General) Regulations appears to make some unexpected or unusual use of powers conferred under the Social Health Act. Specifically, the Benefits Package and Tariffs Advisory Panel established under Regulation 41(2) of the Social Health Insurance (General) Regulations is a significant matter which ought to have been established in the Social Health Insurance Act and not subsidiary legislation. This is contrary to section 13(c) of the Statutory Instruments Act.



37. Additionally, section 13 (q) of the Statutory Instruments Act allows the Committee to consider any other reasons discussed in the following paragraphs—

**(i) Scope of the Regulations**

38. The Social Health Insurance Act, 2023 establishes a three-tier approach to funding health care that is the Primary Healthcare Fund, the Social Health Insurance Fund and the Emergency, Chronic and Critical Illness Fund. In its explanatory memorandum, the Regulatory Making Authority explained the rationale of the three-tier approach which is a departure from the National Health Insurance Fund that was one fund financing all categories of health care. It also highlighted additional benefits to patients under the three-tier model and how the out-patient services will be covered.
39. Regulation 27(1) and (2) of the Social Health Insurance (General) Regulations provide for the transition from Social Health Insurance Fund to the Emergency, Chronic and Critical Illness Fund after depletion of the benefits package under the Social Health Insurance Fund.
40. The Regulatory Making Authority however failed to explain the benefit package of the fund, as well as elaborating the process of transiting from one fund to another upon depletion of benefits in one fund, that is, the notification, approval timelines and in instances where the approval could be declined, the appeals mechanism, and the way forward in case of an emergency where a patient has depleted benefits from one fund.

**(ii) Means Testing**

41. Regulation 21 of the Social Health Insurance (General) Regulations provides for means testing which is a method that uses a means testing instrument to determine whether an individual or a household has the ability to pay for their social health insurance premium. The means testing instrument, as highlighted in the regulations, was to be used to collect data from households. The instrument shall be developed by the Cabinet Secretary for Health in collaboration with the Cabinet Secretary responsible for matters relating to social protection.
42. The Regulatory Making Authority however, could not elaborate on this instrument as a method of determining a households' ability to pay their premiums. The Regulatory Making Authority could neither explain the formula that was used to come up with the 2.75 % annual

contribution per household income, nor how the means testing instrument could be challenged.

**(iii) Transitional Provisions**

43. The first schedule of the Social Health Insurance Act, 2023 on Transitional Provisions envisions a seamless transition from the National Health Insurance Fund (NHIF) to the Social Health Authority.
44. The Regulatory Making Authority could not highlight the measures that have been put in place to ensure services are not interrupted in the transition. There was no clarity on how the issue of timely reimbursements to health facilities had been dealt with in the Regulations.

**(iv) Data Protection**

45. The Social Health Authority intended to migrate a lot of data from NHIF as well as link personal data from the National Registration Bureau. Healthcare data is sensitive and attractive to cyber-criminals because they contain financial, health status and personal data which can be used in blackmail and fraudulent activities. Health data is also remarkably vulnerable to penetration because of the fluid and always-evolving nature of a patient's medical care and because of the number of clinicians, facilities and transactions required to connect patient care across multiple settings. The Regulatory Making Authority could not explain the measures it would take to ensure security of its systems from cyber-attack, considering the fact that the right to privacy and data protection is a constitutional right to every Kenyan.

## **2.2 COMMITTEE RECOMMENDATIONS**

46. Based on the observations made, the Committee therefore makes the following recommendations—

**After careful consideration of the Social Health Insurance (General) Regulations, 2024 and the Social Health Insurance (Tribunal Procedure) Rules, 2024 , pursuant to section 15 (1) of the Statutory Instruments Act and Standing Order 195(4)(b), the Select Committee on Delegated Legislation recommends that the Senate resolves that the Social Health Insurance (General) Regulations, 2024 (Legal Notice Number 49 of 2024), and the Social Health**

Insurance (Tribunal Procedure) Rules, 2024 ( Legal Notice Number 48 of 2024) be annulled for the following reasons—

- (i) Contrary to Article 10 and 118 of the Constitution of Kenya and Section 5A. (1)(d) and (e) of the Statutory Instruments Act, the Regulatory Making Authority did not submit evidence of an adequate post-drafting public participation for the Regulations that satisfactorily considered the issues from the public and stakeholders involved.
- (ii) The Social Health Insurance (General) Regulations contained a matter which ought to have been dealt with by an Act of Parliament. The membership of the Benefits Package and Tariffs Advisory Panel established under Regulation 41(2) ought to have been established under the Social Health Insurance Act.
- (iii) Regulation 31 of the Social Health Insurance (General) Regulations is *ultra vires* to section 33 of the Social Health Insurance Act. Section 33 of the Social Health Act provides that the accreditation of healthcare providers under the Act shall be done by a body responsible for accreditation to be established under the Act while Regulation 31 provides that the accreditation shall be done by the Social Health Authority.
- (iv) The Regulatory Making Authority could not clarify the issues around the means testing instrument, the annual contribution formula per household income, the scope of the Regulations as well as data protection, role of counties, and the transitional provisions, as envisaged in the Regulations.



## ANNEXURES

Annex 1	Social Health Insurance (General) Regulations, 2024, (Legal Notice Number 49 Of 2024)
Annex 2	The Social Health Insurance (Tribunal Procedure) Rules, 2024, (Legal Notice Number 48 Of 2024)
Annex 3	Minutes of the Select Committee on Delegated Legislation

