

REPUBLIC OF KENYA




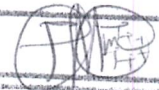
THE NATIONAL ASSEMBLY



TWELFTH PARLIAMENT
THIRD SESSION

THE DEPARTMENTAL COMMITTEE ON HEALTH
REPORT ON THE PRESIDENTIAL MEMORANDUM ON THE HEALTH LAWS
(AMENDMENT) BILL, (NATIONAL ASSEMBLY BILL NO. 14 OF 2018)

DIRECTORATE OF COMMITTEE SERVICES
THE NATIONAL ASSEMBLY
PARLIAMENT BUILDINGS
NAIROBI

 THE NATIONAL ASSEMBLY PAPERS LAID	
DATE: 05 FEB 2019	DAY: TUESDAY
TABLED BY:	HON. JAMES K. MURGOR
CLERK AT THE TABLE:	

FEBRUARY, 2019

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CHAIRMAN'S FOREWORD

The Health Laws (Amendment) Bill No. 14 of 2018 was read a First Time on 26th April, 2018. Pursuant to the provisions of Standing Order 127(1) the Bill was committed to the Departmental Committee on Health for consideration. The Committee tabled its report on 7th August, 2018.

The Bill proposes to amend various sections of the following thirteen Acts of Parliament;


- i. The Pharmacy and Poisons Act (Cap. 244)
- ii. The Medical Practitioners and Dentists Act (Cap. 253)
- iii. The Nurses Act (Cap. 257)
- iv. The Kenya Medical Training College Act (Cap. 261)
- v. The Nutritionists and Dieticians Act (No. 18 of 2007)
- vi. The Kenya Medical Supplies Authority Act (No. 20 of 2013)
- vii. The Counsellors and Psychologists Act (No. 14 of 2014)
- viii. Physiotherapists Act (No. 20 of 2014)
- ix. The Health Records and Information Managers Act (No. 15 of 2016)
- x. Clinical Officers (Training, Registration and Licensing) Act (No. 20 of 2017)

The House duly considered the report and passed it with amendments, on 7th November, 2018. The Bill was presented to H.E The President on 31st December, 2018. In exercise of powers under Article 115(1)(b) of the Constitution, the President vide a memorandum dated 9th January, 2019 referred the Bill back to the National Assembly for reconsideration of certain sections in five Acts. This report is a culmination of this exercise.

The Committee sincerely thanks the Offices of the Speaker and the Clerk of the National Assembly for the immense and timely technical and logistical support accorded to it in the execution of its mandate. I also thank all the Members of the Committee and the secretariat for their commitment and hard work which enabled us to complete the tasks related to the scrutiny of the proposed amendments and compilation of this report.

The Committee reiterates its gratitude to stakeholders who made submissions in relation to the Consideration of the Bill, and especially the Ministry of Health that subsequently appeared to consider the contents of the memorandum.

On behalf of the Departmental Committee on Health and pursuant to provisions of Standing Order 127 (4), it is my pleasant privilege and honor to present the Report of the Committee on its consideration of the Presidential memorandum on the Health Laws (Amendments) Bill No. 18 of 2018.


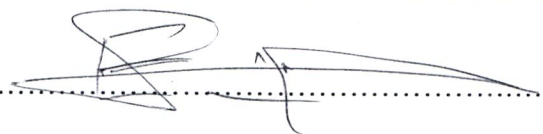
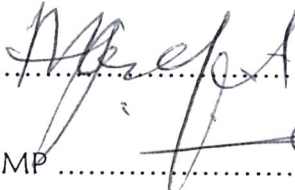
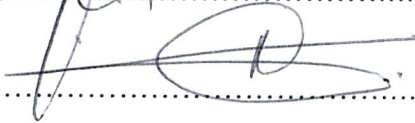

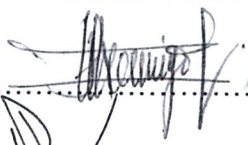
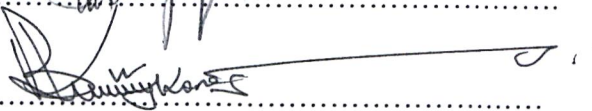
SIGNED


HON. SABINA CHEGE, MP
(CHAIRPERSON)

DATE 26/2/19

ADOPTION OF REPORT OF THE COMMITTEE ON HEALTH ON THE
CONSIDERATION OF THE PRESIDENTIAL MEMORANDUM ON THE HEALTH LAWS
(AMENDMENT) BILL NO. 14 OF 2018

We, the Honourable Members of the Departmental Committee on Health, do hereby affix our signatures to this report on the Presidential memorandum on the Health Laws (Amendment) Bill No. 14 of 2018, to affirm our approval and confirm its accuracy, validity and authenticity;

1. Hon. Sabina Chege, MP 
2. Hon. SwarupRanjan Mishra, MP
3. Hon. (Dr.) EseliSimiyu, MP 
4. Hon. (Dr.) James Nyikal, MP
5. Hon. Alfred AgoiMasadia, MP 
6. Hon. (Dr.) James KipkosgeiMurgor, MP 
7. Hon. MuriukiNjagagua, MP
8. Hon. (Dr.) Mohamed DahirDuale, MP
9. Hon. Stephen Mule, MP.....
10. Hon. Chris Karan, MP 
11. Hon. Esther M. Passaris, MP
12. Hon. Gladwell JesireCheruiyot 
13. Hon. KipsengeretKoros, MP 

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14. Hon. Martin Peters Owino, MP

15. Hon. Mercy WanjikuGakuya, MP

16. Hon. Prof. Mohamud Sheikh Mohamed, MP

[Signature]

17. Hon. Patrick MuneneNtwiga, MP

[Signature]

18. Hon. Tongoyo Gabriel Koshal, MP

[Signature]

19. Hon. Zachary KwenyaThuku, MP

COMMITTEE MANDATE

Mr. Speaker Sir,

The Departmental Committee on Health is established pursuant to the provisions of Standing Order No. 216(5) of the National Assembly and in line with Article 124 of the Constitution which provides for the establishment of the Committees by Parliament. The mandate and functions of the Committee is to;

- a) *Investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned Ministries and departments;*
- b) *Study the programme and policy objectives of the Ministries and departments and the effectiveness of the implementation;*
- c) *Study and review all legislation referred to it;*
- d) *Study, assess and analyze the relative success of the Ministries and departments as measured by the results obtained as compared with its stated objectives;*
- e) *Investigate and inquire into all matters relating to the assigned Ministries and departments as they may deem necessary, and as may be referred to them by the House;*
- f) *Vet and report on all appointments where the constitution or any law requires the National Assembly to approve, except those under Standing Order 204; and*
- g) *Make reports and recommendations to the House as often as possible, including recommendation of proposed legislation.*

The Departmental Committee is mandated to cover the functions of the Ministry of Health alongside its Semi-autonomous Government Agencies.

Committee Membership

The Committee comprises the following Honourable Members;

1. Hon. Sabina Chege, MP – **Chairperson**

2. Hon. SwarupRanjan Mishra, MP – Vice Chairperson
3. Hon. (Dr.) EseliSimiyu, MP
4. Hon. (Dr.) James Nyikal, MP
5. Hon. Alfred AgoiMasadia, MP
6. Hon. (Dr.) James KipkosgeiMurgor, MP
7. Hon. MuriukiNjagagua, MP
8. Hon. (Dr.) Mohamed DahirDuale, MP
9. Hon. Stephen Mule, MP
10. Hon. Chris Karan, MP
11. Hon. Esther M. Passaris, MP
12. Hon. Gladwell JesireCheruiyot
13. Hon. KipsengeretKoros, MP
14. Hon. Martin Peters Owino, MP
15. Hon. Mercy WanjikuGakuya, MP
16. Hon. Prof. Mohamud Sheikh Mohamed, MP
17. Hon. Patrick MuneneNtwiga, MP
18. Hon. Tongoyo Gabriel Koshal, MP
19. Hon. Zachary KwenyaThuku, MP

The Committee is supported by the following members of the Secretariat;

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|---------------------------------|------------------------------|
| 1. Mr. Victor Weke | - Clerk Assistant I |
| 2. Mr. MuyodiMeldaki Emmanuel - | Clerk Assistant III |
| 3. Mr. Ahmed Hassan Odhowa | - Principal Research Officer |
| 4. Ms. Christine Odhiambo | - Legal Counsel I |
| 5. Mr. Eric Kanyi | - Fiscal Analyst |
| 6. Ms. Winnie Kiziah | - Media Officer |
| 7. Ms. Catherine Wangui | - Serjaent-at-Arms |
| 8. Ms. Rahab Chepkilim | - Audio Officer |

EXECUTIVE SUMMARY

Mr. Speaker Sir,

This report details the Consideration of the Presidential memorandum on his refusal to assent to the Health Laws (Amendment) Bill No. 14 of 2018. The Bill was read a First Time on 26th April, 2018 with the Committee tabling its report on 7th August, 2018. The House passed the Bill with amendments on 7th November, 2018. On 12th February, 2019, the House committed the reconsideration of the Bill to the Committee, to table its recommendations before 28th February, 2019, in line with the strict timelines of Standing Order 154.

The memorandum affected five Acts of Parliament, namely;

- i) The Pharmacy and Poisons Act (Cap 244)
- ii) The Medical Practitioners and Dentists Act (Cap 253)
- iii) The Nurses Act (Cap 257)
- iv) The Counsellors and Psychologists Act (No. 14 of 2014)
- v) The Clinical Officers Act (No. 20 of 2017)

The Committee began this exercise with a briefing from the secretariat on 14th February, 2019, and subsequently held a meeting with the Ministry of Health on 19th February 2019.

The Ministry submitted that upon further interrogation of the proposed amendments by the MOH it emerged that some were not in keeping with international definition of terms, current government policy and the Constitution. Consequently His Excellency, the President of Kenya signed a Memorandum of Refusal in a bid to have the National Assembly readdress these proposed amendments.

The Committee observes that the Ministry ought to have pursued these matters with the Committee before the Bill was passed. While most of the recommendations contained in the memorandum are beneficial, some are contrary to what the Committee agreed upon

with the Ministry and other stakeholders. Further, if the Ministry hastens full operationalization of the Health Act, 2017, a lot of these matters will be ironed out.

1.0 INTRODUCTION

The recommittal of Health Laws (Amendment) Bill No. 14 of 2018 done on 12th February, 2019 affects five statutes. The table below contrasts the various sections of the Bill in contrast to the President's reservations/ recommendations, and the resultant effect;

Act	Section	Amendment in Health Laws Bill	President's Amendment	Effect
The Pharmacy and Poisons Act, (Cap 244)	2	“pharmaceutical device” includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, blood products, therapeutic feeds, nutritional formulations, beauty products and related products;	Delete.	The term “pharmaceutical device” is similar to the definition of the term “health product”. Further, the term “pharmaceutical device” has not been used in the Bill, therefore a deletion of the same would be necessary.
		“pharmaceutical equipment” means equipment used in the manufacture and quality control of pharmaceutical products;	Delete.	The term “pharmaceutical equipment” has not been used in the Bill, therefore a deletion of the same would be necessary.
		“pharmaceutical product” means any material or product intended for human or veterinary use presented in its finished dosage or form, that is subject to control by or under this Act;	Delete.	According to the WHO, the term “pharmaceutical product” refers to medicines or drugs, and the term “drug” has already been defined in the Bill.
		“Good Manufacturing Practice” also known as “GMP” means a system for ensuring that products	Delete and substitute with— “Good Manufacturing	The amendment seeks to align the definition of the term to the WHO meaning

	<p>are consistently produced and controlled according to quality standards, and is designed to minimise risks involved in any pharmaceutical production that cannot be eliminated through testing the final product;</p>	<p>Practice”, also referred to as “GMP”, “cGMP” or “current Good Manufacturing Practice” is the part of quality management which ensures that products are consistently produced and controlled according to their intended use as required by the marketing authorization, clinical trial authorization or product specification;</p>	<p>so as to avoid ambiguities.</p>
<p>3</p>	<p>(1) There is established a Board which shall consist of—</p> <p>(a) a Chairperson who shall be appointed by the President and who shall—</p> <p>(i) be a registered pharmacist of good standing with a degree in pharmacy; and</p> <p>(ii) have at least ten years’ experience in the pharmaceutical sector;</p> <p>(b) the Director of pharmaceutical services;</p> <p>(c) the Principal Secretary in the ministry for the time being responsible for matters relating to finance or his or her representative;</p> <p>(d) one enrolled pharmaceutical technologist with expertise in community pharmacy appointed by the Cabinet Secretary;</p> <p>(e) two persons representing the pharmacy training institutions, of which one shall be a pharmacist and one shall be a pharmaceutical technologist;</p>	<p>-Delete paragraph (d).</p> <p>-Delete paragraph (f) and substitute therefor the following new paragraph—</p> <p>“(f) three other persons appointed by the Cabinet Secretary, of whom—</p> <p>(i) one person shall be a pharmacist representing institutions of higher learning;</p> <p>(ii) one person shall be a pharmaceutical technologist representing mid-level colleges; and</p> <p>(iii) one person shall be</p>	<p>To reduce the size of the Board members so as to align it with the recommendations of the Mwongozo Code.</p> <p>However the amendment as contained in the President’s memoranda has the effect of deleting only paragraph (d). No amendment is proposed in paragraph (e), which provide for the representatives of the pharmacy training institutions. The new paragraph (f) as proposed will introduce 2 more representatives of the training institutions</p>

		<p>(f) three persons appointed by the Cabinet Secretary, of whom—</p> <p>(i) one shall be an enrolled pharmaceutical technologist nominated by the Kenya Pharmaceutical Association; and</p> <p>(ii) two shall be registered pharmacists nominated by the Pharmaceutical Society of Kenya, and one of whom shall have expertise in industrial pharmacy;</p> <p>(g) the Chief Executive Officer, who shall be an ex officio member; and</p> <p>(h) one medical practitioner nominated by the Kenya Medical Association and appointed by the Cabinet Secretary.</p> <p>(2) The persons appointed under subsection (1)(f) shall be appointed by the Cabinet Secretary from among members nominated by their relevant professional associations, each of which shall nominate two candidates in each category taking into consideration gender, ethnicity and regional balance.</p> <p>(3) A person shall not qualify for appointment as a member of the Board under subsection (1)(e) and (f) unless such person is the holder of a minimum of a diploma in the relevant field from an institution recognized in Kenya and has at least five years managerial experience.</p>	<p>an enrolled pharmaceutical technologist with expertise in community pharmacy nominated by the Kenya Pharmaceutical Association;”</p>	<p>into the Board. The overall membership of the Board would reduce from 11 to 10 members.</p>
3B	Functions of the Board.		Delete paragraph 3B(3)(g) and	

		<p>3B. (1)The Board shall be responsible for the regulation of health products, technologies and the profession of pharmacy.</p> <p>(2) The Board shall perform the following functions in relation to regulation of health products and technologies—</p> <p>(a) advise the national and county governments in all matters relating to the safety, packaging and distribution of medicines;</p> <p>(b) ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality safety and efficacy;</p> <p>(c) ensure that the personnel, premises and practices employed in the manufacture, storage, marketing, distribution and sale of medicinal substances comply with the defined codes of practice and other prescribed requirements;</p> <p>(d) enforce the prescribed standards of quality, safety and efficacy of all medicinal substances manufactured, imported into or exported out of the country;</p> <p>(e) grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances;</p> <p>(f) maintain a register of all authorized medicinal substances;</p> <p>(g) publish, at least once in every three months, lists of authorized or registered medicinal substances and of products with marketing</p>	<p>substitute therefor the following new paragraph—</p> <p>“(g) approve institutions to be established or accredited under the Universities Act, training pharmacists and mid-level institutions and training pharmaceutical technologists”</p>	
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		<p>authorizations;</p> <p>(h) regulate licit use narcotic, psychotropic substances and precursor chemical substances in accordance with either the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988;</p> <p>(i) consider applications for approval and alterations of dossiers intended for use in marketing authorization of medicinal substances;</p> <p>(j) inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, and other retail outlets;</p> <p>(k) prescribe a system for sampling, analysis and other testing procedures of finished medicinal products released into the market to ensure compliance with the labeled specifications;</p> <p>(l) conduct post-market surveillance of safety and quality of medical products;</p> <p>(m) monitor the market for the presence of illegal or counterfeit medicinal substances;</p> <p>(n) regulate the promotion, advertising and marketing of medicinal substances in accordance with approved product information;</p> <p>(o) approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use;</p> <p>(p) approve and regulate clinical trials on</p>		
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		<p>medicinal substances;</p> <p>(q) disseminate information on medical products to health professionals and to the public in order to promote their rational use;</p> <p>(r) collaborate with other national, regional and international institutions on medicinal substances regulation;</p> <p>(s) advise the Cabinet Secretary on matters relating to control, authorization and registration of medicinal substances; and</p> <p>(t) perform any other function relating to regulation of medicinal substances.</p> <p>(3) The Board shall perform the following functions in relation to regulation of the profession of pharmacy—</p> <p>(a) promote the practice of pharmacy that complies with universally accepted norms and values;</p> <p>(b) prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be registered as pharmacists under this Act;</p> <p>(c) prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be enrolled as pharmaceutical technologists under this Act;</p> <p>(d) maintain a register of all persons registered or enrolled under this Act;</p> <p>(e) prescribe and conduct examinations for purposes of recognition, registration or enrolment under this Act;</p>		
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	<p>(f) establish or prescribe the different categories of pharmacy business and the scope of practice of persons registered or enrolled in terms of this Act, or the services or acts which shall for purposes of this Act be deemed to be services or acts specially pertaining to pharmacists or pharmaceutical technologists, and the conditions under which those services may be provided or the acts which may be performed;</p> <p>(g) approve institutions to be established or accredited under the Universities Act for the training of pharmacy practitioners;</p> <p>(h) license the practice of pharmacists and pharmaceutical technologists under this Act;</p> <p>(i) approve and license the premises for the practice by pharmacists and pharmaceutical technologists under this Act;</p> <p>(j) regulate the professional conduct of pharmacists and pharmaceutical technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards and ethics;</p> <p>(k) establish, approve and accredit continuing professional educational programs for pharmacists and pharmaceutical technologists;</p> <p>(l) establish and maintain a professional code of conduct for pharmacists and pharmaceutical technologists; and</p> <p>(m) perform any other function relating to regulation of the profession of pharmacy.</p>
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	24	<p>Delete the words “a pharmacist” and substitute therefor the words “pharmaceutical practice”.</p> <p>24. Authorized seller of poisons Any person lawfully carrying on the business of a pharmacist in accordance with the provisions of this Part shall be an authorized seller of poisons.</p>	Delete.	The effect of the amendment is to retain the provision as currently contained in the Act, which authorizes only pharmacists to be authorized sellers of poisons. The amendment in the Bill sought to expand the provision to allow any person who engages in pharmaceutical practice to be an authorized seller of poisons.
<p>The Medical Practitioners and Dentists Act, (Cap 253)</p>	4B	<p>Powers of the Council</p> <p>4B. The Council shall have all powers necessary for the proper performance of its functions under this Act and in particular, but without prejudice to the generality of the foregoing, shall have power to—</p> <ul style="list-style-type: none"> (a) control, supervise and administer the assets of the Council in such manner and for such purpose as best promotes the purpose for which the Council is established; (b) determine the provisions to be made for capital and recurrent expenditure and for the reserves of the Council; (c) receive any grants, gifts, donations or endowments and make legitimate disbursements therefrom; (d) enter into an association with other bodies or organizations within or outside Kenya as the 	Delete paragraph (f) and substitute therefor the following new paragraph— “(f) invest any funds of the Council not immediately required for its purposes, in accordance with the Public Finance Management Act and other relevant laws”	The amendment serves to introduce the reference to the Public Finance Management Act which serves to guide the manner in which public funds may be invested.

<p>The Nurses Act, (Cap 257)</p>	<p>4</p>	<p>Council may consider desirable or appropriate and in furtherance of the purpose for which the Council is established;</p> <p>(e) open a bank account or banking accounts for the funds of the Council; and</p> <p>(f) invest any funds of the Council not immediately required for its purposes.</p>	<p>Insert the following new paragraph immediately after paragraph (i)–</p> <p>“(j) the Director General of health or a representative appointed in writing by the Director General of health”</p>	
	<p>Membership of the Council</p> <p>(1) The Council shall consist of the following persons appointed by the Cabinet Secretary–</p> <p>(a) a chairperson who shall–</p> <p>(i) be a holder of a diploma or Bachelor’s degree in nursing from a university or college recognized in Kenya; and</p> <p>(ii) have at least ten years’ experience in leadership and management;</p> <p>(b) the Director of Nursing Services or a representative appointed in writing by the Director of Nursing Services;</p> <p>(c) one person nominated by the National Nurses Association of Kenya;</p> <p>(d) one person nominated by other professional associations of Kenya representing nurses and midwives;</p> <p>(e) one representative of midwives involved in clinical practice;</p> <p>(f) one representative of accredited mid-level institutions involved in the training of nurses</p>			

		<p>and midwives in Kenya;</p> <p>(g) one representative of accredited universities involved in training of nurses and midwives in Kenya;</p> <p>(h) two persons nominated by the Cabinet Secretary to represent the public;</p> <p>(i) the Chief Executive Officer who shall be the Registrar and shall be appointed in accordance to section 11 of this Act and shall be an ex officio member of the Council.</p>		
9		<p>Amendment in original Bill deleted.</p> <p>9. Functions of Council and annual report</p> <p>(1) The functions of the Council shall be—</p> <p>(a) to establish and improve standards of all branches of the nursing profession in all their aspects and to safeguard the interests of all nurses;</p> <p>(b) to establish and improve the standards of professional nursing and of health care within the community;</p> <p>(c) with the approval of the Minister, to make provision for the training and instruction for persons seeking registration or enrolment under this Act;</p> <p>(d) with the approval of the Minister, to prescribe and regulate syllabuses of instruction and courses of training for persons seeking registration or enrolment under this Act;</p> <p>(e) to recommend to the Minister institutions to be approved institutions for training of persons seeking registration or enrolment under this Act;</p>	Delete the words “nursing commodities” in paragraph (i)	<p>The amendment was contained in the original Bill.</p> <p>The rationale for the President’s proposal is to align the provision with the current policy of separating the regulation of commodities from the regulation of health professionals to increase efficiency, effectiveness and reduce the cost of doing business.</p> <p>It also seeks to implement section 62 of the Health Act which provides for the establishment of a single regulatory body to regulate health products and health technologies.</p>

	<p>(f) with the approval of the Minister, to prescribe and conduct examinations for persons seeking registration or enrolment under this Act;</p> <p>(g) to prescribe badges, insignia or uniforms to be worn by persons registered, enrolled or licensed under this Act;</p> <p>(h) to have regard to the conduct of persons registered, enrolled or licensed under this Act, and to take such disciplinary measures as may be necessary to maintain a proper standard of conduct among such persons;</p> <p>(i) to have regard to the standards of nursing care, qualified staff, nursing commodities, facilities, conditions and environment of health institutions, and to take such disciplinary or appropriate measures as may be necessary to maintain a proper standard of nursing care in health institutions;</p> <p>(j) to direct and supervise the compilation and maintenance of registers, rolls and records required to be kept under sections 12, 14 and 16;</p> <p>(k) to advise the Minister on matters concerning all aspects of nursing.</p>		
11	<p>Delete subsection (5) and substitute therefor the following new subsection—</p> <p>“(5) The officers appointed under this section shall be paid such remuneration and allowances as the Council may from time to time determine.”</p>	<p>Delete and substitute therefor the following new subsection—</p> <p>“(5) The officers appointed under this section shall be paid such remuneration and allowances as the Council may, on the advice of the</p>	<p>The amendment seeks to introduce the requirement that the Council, in determining the remuneration of the officers of the Council, must do so in consultation with the Salaries and Remuneration</p>

<p>Salaries and remuneration Commission, determine.”</p>	<p>Commission, in line with Article 230(4) (b) of the Constitution.</p>			
<p>The Counsellors and Psychologists Act, 2014, of (No. 14 of 2014)</p>	<p>15</p>	<p>No amendment.</p> <p><i>B—Counsellors and Psychologists Society of Kenya</i></p> <p>15. Establishment of the Society</p> <p>(1) There is established a Society to be known as the Counsellors and Psychologists Society of Kenya.</p> <p>(2) The Society—</p> <p>(a) is a body corporate, capable of suing and being sued in its corporate name;</p> <p>(b) shall have a common seal which shall be kept in such manner as the Council may direct;</p> <p>(c) may borrow, lend or otherwise raise money in such usual manner, including by way of executing securities and guarantees, as it may from time to time determine;</p> <p>(d) may acquire, hold, develop and dispose of movable or immovable property;</p> <p>(e) may acquire, hold and dispose of investments in other enterprises.</p> <p>(3) All courts, judges and other persons acting judicially shall take judicial notice of the seal of the Society affixed to a document and shall presume that it was duly affixed.</p> <p>(4) The provisions of the Third Schedule shall have effect with respect to the Society.</p>	<p>Delete section 15.</p>	<p>The Counsellors and Psychologists Society of Kenya is a welfare organization that is independent of the CS of Health. The society should therefore be established under the Societies Act, Cap. 108.</p>
<p>16</p>	<p>No amendment.</p>	<p>Delete section 16.</p>	<p>The section provides that every person registered</p>	

		<p>Membership of the Society Each person who is registered under this Act is a member of the Society.</p>		<p>under the Act shall be a member of the Society, and this goes against Article 36(2) of the Constitution which provides that a person shall not be compelled to join an association of any kind.</p>
17		<p>No amendment.</p> <p>Chairperson of the Society (1) There shall be a chairperson of the Society who shall be elected in the manner provided in the Third Schedule. (2) A member seeking election as chairperson shall be a person who— (a) has been a member of the Society for a continuous period of not less than five years; (b) has served on the Council or its Committees for at least one year; and (c) has not been disqualified under the provisions of the Fourth Schedule.</p>	Delete section 17.	<p>Deletion of section 17 is a consequential necessity arising out of the deletion of section 15 which establishes the Society.</p>
18		<p>No amendment.</p> <p>Functions of the Society The functions of the Society shall be to— (a) establish standards of professional competence and practice amongst members of the Society;</p>	Delete section 18.	<p>Deletion of section 18 is a consequential necessity arising out of the deletion of section 15 which establishes the Society. Further, this section provides that the Society</p>

		<p>(b) protect, assist and educate the public in Kenya in all matters touching, ancillary or incidental to the professions of counselling and psychology;</p> <p>(c) represent, protect and assist members of the professions of counselling and psychology in Kenya in respect of conditions of practice and otherwise;</p> <p>(d) promote the international recognition of the Board and the Society;</p> <p>(e) advise the Board on matters relating to examination standards and policies;</p> <p>(f) carry out any other functions prescribed for it under any of the other provisions of this Act or under any other written law.</p>		<p>shall establish standards of professional competence and practice among the members of the Society. However this is a regulatory function which should be the mandate of the Counsellors and Psychologists Board.</p>
19	<p>No amendment.</p> <p>The Council of the Society</p> <p>(1) The Society shall be governed by a Council to be known as the Council of the Society.</p> <p>(2) Subject to this Act, all acts and things done in the name of, or on behalf of, the Society, by the Council or with the authority of the Council shall be deemed to have been done by the Society.</p> <p>(3) The Council shall issue standards of professional practice which shall form the basis of practice of counselling and psychology for members of the Society.</p> <p>(4) The Council may with the approval of the Cabinet Secretary, issue by-laws, regulations and guidelines to govern matters affecting the operations of the Society and practice by members of the Society.</p>	<p>Delete section 19.</p>	<p>Delete section 19 is a consequential necessity arising out of the deletion of section 15 which establishes the Society.</p>	

20	<p>No amendment.</p> <p>Committees of the Council (1) The Council may establish such committees as are necessary for the performance of the functions of the Society and may, subject to the provisions of this Act, delegate powers conferred on it to such committees. (2) The provisions of the Fourth Schedule shall have effect with respect to the Council.</p>	Delete section 20.	Deletion of section 20 is a consequential necessity arising out of the deletion of section 15 which establishes the Society, and section 20 which establishes the Council of the Society.
21	<p>No amendment.</p> <p>Membership of the Council The Council shall consist of a chairperson and ten other members elected every two years in the manner prescribed in the Fourth Schedule.</p>	Delete section 21.	Deletion of section 21 is a consequential necessity arising out of the deletion of section 15 which establishes the Society, and section 20 which establishes the Council of the Society.
22	<p>No amendment.</p> <p>Secretary to the Council (1) There shall be a Secretary to the Council who shall be appointed by the Council through an open and competitive process. (2) The Secretary to the Council shall hold and vacate the office of Secretary in accordance with the terms of the instrument of appointment to that office. (3) In addition to the functions which he or she is required to exercise and perform by or under this Act, the Secretary to the Council shall exercise and perform such other functions as the Council may, from time to time, determine.</p>	Delete section 22.	Deletion of section 22 is a consequential necessity arising out of the deletion of section 15 which establishes the Society, and section 20 which establishes the Council of the Society.

			No amendment. (The Third Schedule provides for the Chairperson and members of the Society.)	Delete the Third Schedule.	This is a consequential amendment arising out of the deletion of the provisions establishing the Society.
			No amendment. (The Fourth Schedule provides for the members of the Council)	Delete the Fourth Schedule.	Deletion of the Fourth Schedule is a consequential necessity arising out of the deletion of section 15 which establishes the Society, and section 20 which establishes the Council of the Society.
Clinical Officers (Training, Registration and Licensing) Act, 2017, (No.20 of 2017)	4(1)(a)	Delete and substitute therefor the following new subsection— (1) The Council shall consist of the following persons— (a) a chairperson appointed by the President and who shall have— (i) a relevant bachelors' degree from a recognised university; and (ii) at least ten years' relevant experience;	Delete and substitute therefor the following new paragraph immediately after paragraph (a)(ii)— “(iii) be registered as a clinical officer under this Act”	Insert the following new paragraph immediately after paragraph (a)(ii)— “(iii) be registered as a clinical officer under this Act”	The provision as contained in the Bill does not stipulate that the chairperson of the Clinical Officers Council shall be a clinical officer. In common practice, the legislations that establish regulatory bodies within the health sector require chairpersons to have the respective disciplines.

- (b) the Director General for health or his or her designated representative;
- (c) the Chief Clinical Officer;
- (d) one clinical officer elected by members of faculty of Clinical Medicine from Kenya Medical Training College;
- (e) one clinical officer representing the Kenya Clinical Officers Association who shall be nominated by the Association and appointed by the Cabinet Secretary;
- (f) two clinical officers representing universities training clinical officers elected amongst the teaching staff;
- (g) the Registrar who shall be an ex-officio member and secretary to the Council;
- (h) two clinical officers, one in public practice and the other in private practice from each gender nominated by the Cabinet Secretary;

		<p>(i) one person with knowledge and expertise in finance or audit appointed by the Cabinet Secretary; and</p> <p>(j) one person representing the public nominated by consumer organisations and appointed by the Cabinet Secretary.</p>		
4(1)(f)		<p>(f) two clinical officers representing universities training clinical officers elected amongst the teaching staff;</p>	<p>Delete and substitute therefor the following new paragraph—</p> <p>(f) one clinical officer representing universities training clinical officers elected by the teaching staff from among their number;</p>	<p>The inclusion of two representatives of university level leads to an over-representation of the university level of training institutions since most clinical officers are educated to the diploma level.</p>

2.0 SUBMISSION FROM THE MINISTRY OF HEALTH

The Ministry of Health appeared before the Committee on 19th February, 2019 and submitted as follows;

The Health Laws Bill seeks to make wide-ranging amendments to various health-related statutes on the Health Policy. Further, the amendments seek to align the existing laws to the Constitution 2010, Health Act of 2017 and facilitate implementation of Universal Health Coverage. The Bill was published and tabled before the National Assembly in April 2018. Following Parliament's ensuing deliberations, amendments were proposed to the Bill and passed by the Committee of the Whole House in November 2018.

Upon further interrogation of the proposed amendments by the MOH it emerged that some were not in keeping with international definition of terms, current government policy and the Constitution. Consequently His Excellency, the President of Kenya signed a Memorandum of Refusal in a bid to have the National Assembly readdress these proposed amendments.

The Memorandum contains proposed amendments to the following laws;

A. Pharmacy and Poisons Act Cap 244

The Bill proposes to amend the Pharmacy and Poisons Act to align the statutes with the current laws, strengthen regulation of health products, health devices and pharmaceutical practice.

1. *Interpretation: Section 2*

The Memorandum recommends changes in the following various provisions:-

i. Deletion of newly defined terminologies

The Memo proposes the deletion of the following terminologies to increase clarity of terminology and enhance international collaboration and trade:-

- a. "Pharmaceutical device". The new terminology is identical to the already given definition of 'health product'.

- b. "Pharmaceutical equipment". This term has not been used in either the Bill of the Act and therefore, the definition is redundant.
 - c. "Pharmaceutical product". This term normally refers to medicines or drugs. However the definition of the term "drug" has already be defined in the Act as *'any medicine, medicinal preparation or therapeutic substance'*.
- ii. New definition of the term "Good Manufacturing Practice"
- Good manufacturing practice is really a part of quality management of health products and technologies as opposed to an entire 'system' as alluded to in the proposed amendments. As such, the Memo recommends use of the definition that is recognized by the World Health Organization to avoid confusion in the application of the term and enhance international collaboration.

2. Establishment of the Pharmacy and Poisons Board: Section 3

The effect of the proposed amendments on the composition of the Board is the establishment of a large Board, which is contrary to Government policy, Code of Governance, and best practice that enhances effectiveness and efficiency.

As such the Memo, recommends that one person be dropped without losing the intended skill in community pharmacy that they would represent. This skill will be represented by a pharmaceutical technologist nominated by Kenya Pharmaceutical Association. Further, there was need to clarify the representation of training institutions to expressly include those mid-level colleges as they train pharmaceutical technologists.

3. Functions of the Pharmacy and Poisons Board: Section 3B.

In the proposed amendments paragraph (3) (g) includes a function for the Board to approve University level training institutions for training pharmacy practitioners.

In view of this, the Memo recommends that the paragraph to be replaced by one that ensures the Board has oversight of Universities training pharmacists and mid-level institutions training pharmaceutical technologists. This will increase clarity and take into

account oversight of mid-level institutions that offer training for pharmaceutical technologists.

Further, the term ‘pharmacy practitioners’ is not used in the law or Bill and in fact it does not describe any known cadre.

4. Qualifications for Registration: Section 8 (2)

The Memo recommends that the proposed amendments be changed to provide for qualified pharmaceutical technologists to be included in a ‘Roll’ as opposed to a ‘Register’ in line with section 6(2) of the Act, thereby enhancing congruence.

5. Authorized sellers of Poisons: Section 24.

The proposed amendment provides for any person undertaking ‘*pharmaceutical practice*’ to sell poisons. The effect of the amendment is that poisons may be handled by persons who do not possess the requisite training and competencies to deal with them, putting the public at grave risk. As such, the Memo recommends the deletion of the amendment.

B. The Medical Practitioners and Dentists Act, (Cap. 253)

Powers of the Council: Section 4B

The proposed amendment introduces powers to invest surplus funds without qualifying the guiding regulations, thus giving the Council unlimited power to invest. The Memo recommends that investments be done with reference to the Public Finance Management Act, 2012 and other relevant laws which provide for the manner in which public funds may be invested. This will ensure prudent management of public funds.

C. The Nurses Act (Cap 257)

1. Membership of the Council: Section 4

The Memo recommends for the inclusion of the Director General of Health, as a member of the Council as in the original Bill, in line with current policy with respect to regulatory bodies in the sector and ensuring skills mix in governing bodies. The inclusion of this policy maker would also seek to improve oversight and governance of the regulatory body.

2. *Functions of Council and Annual Report: Section 9 (1) (i)*

The Memo recommends the deletion of the words 'nursing commodities' as per the original Bill. The proposal was intended to implement section 62 of the Health Act, 2017, which requires that a single regulatory body regulate health products and health technologies. It is intended that this latter regulatory body should have a multidisciplinary staff complement, including nurses.

Additionally the Memo's proposal will serve to increase efficiency, effectiveness and reduce the cost of doing business in respect to commodity regulation.

3. *Appointment of The Registrar and other officers: Section 11 (5)*

The proposed amendment gives the Council powers to determine the remuneration and allowances of its recruited officers, without reference to the Salaries and Remuneration Commission (SRC), which is mandated by Article 230(4) (b) of the Constitution to advise on the remuneration of public officers. As such, the provision contravenes the Constitution. Hence the Memo recommends that the provision be qualified to include the consultation and advice from SRC.

D. The Counselors and Psychologists Act, 2014, (No. 14 of 2014). Sections: 15, 16, 17, 18

The original Bill sought to amend the Counselors and Psychologists Act, 2014, (No. 14 of 2014) to streamline the regulation, operations and practice of counselors and psychologists in line with Article 43(1)(a) of the Constitution, Government policy and health professional regulation in the Sector.

1. *Section 15. Establishment of the Counselors and Psychologists Society of Kenya:* The original Bill included provisions that deleted the establishment of the Society, since the latter ought to have been established under the Societies Act (Cap. 108).

2. *Section 16 Member of the Society:* The Act provides that each person registered under the Act be a member of the Society. Mandatory membership to a Society is unconstitutional as it goes contrary to Article 36 (2) of the Constitution which provides for voluntary membership in associations of any kind.

3. *Section 17 Election of the chairperson of the Society:* The Act provides for the election of a Chairperson. The Memo recommends deletion of the proposed amendment as a consequence to the proposed deletion of Section 15.

4. *Section 18 Functions of the Society:* The section provides for a function which is regulatory in nature. Specifically, 18(a) mandates the Society to establish standards of professional competence and practice among the members of the Society, which ought to be a function of the regulating body.

5. *Section 19 and 20: Council and Committees of the Society:* These sections provide for the Council and its committees. The Memo recommends the deletion of these sections as a consequence to the proposed deletion of Section 15.

6. *Section 21 Membership of the Council of the Society:* The Section provides for election of the Council Members in the manner prescribed in the Fourth Schedule. The Memo recommends the deletion of this section as a consequence to the proposed deletion of Section 15 and 19.

7. *Section 22 Secretary to the Council of the Society:* The Section provides for the Secretary. The Memo recommends the deletion of this section as a consequence to the proposed deletion of Section 15 and 19.

8. *Third and Fourth Schedule: Election of the chairperson and members of the Council of the Society:* The Schedule provide for the manner of elections. The Memo recommends the deletion of this section as a consequence to the proposed deletion of Section 15, 19 and 21.

E. The Clinical Officers (Training, Registration and Licensing) Act, 2017, (No.20 of 2017).

The proposed amendments to the Clinical Officers (Training, Registration and Licensing) Act, 2017 provide for the composition of the Council as follows:-

1. *The qualification of the Chairperson: Section 4 (1) (a).* The proposed provision does not stipulate that the chairperson of the Clinical Officers Council shall be

a clinical officer. This is unlike other similar legislation that require that the chairpersons of the respective regulators come from their respective disciplines.

As such, in a bid to clarify the appointment of the chairperson, the Memo recommends an additional subparagraph (a) (iii) which articulates that the Chair be a registered Clinical Officer.

Two representatives from Universities training clinical officers: Section 4(1) (f).
The Memo recommends deletion of one position to avoid over-representation from Universities since most clinical officers are trained in mid-level colleges.

3.0 OBSERVATIONS

The Committee made the following observations;

1. The Speaker in a ruling made on 28th July, 2015 guided the House on the procedure for processing of Presidential Memoranda by the House including, inter alia, that the President is not prohibited from including his preferred text of the particular clause, section, subsection or paragraph of the Bill. Further these texts need not be subjected to other stages of a Bill;
2. It is on this basis that the Committee, already constrained by the strict timelines, could not open up the process to views from other stakeholders. The Committee is however open to further consultations on any future proposed amendments;
3. The Ministry submitted proposed amendments to Section 8 (2) of the Pharmacy and Poisons Act. This specific section was not part of the President's memorandum and were therefore rejected;
4. Most of the reservations by the H.E The President were sound, as they kept with international best practices, and in line with efforts to streamline the health sector in the country;
5. The Committee however observes that the matters were not fundamental and may not have warranted a rejection at assent. The Ministry which was given ample time, severally, before the Bill went to second reading should have diligently pursued these matters with the Committee;
6. Further, the Health Act 2017 would streamline many of the issues raised in the Presidential memorandum and the Ministry should expedite its full operationalization;
7. The proposal to Section 9 (1) (i) of the Nurses Act by H.E The President is contrary to what the Committee had agreed on unanimously with the stakeholders, and most importantly the Ministry of Health.

4.0 RECOMMENDATIONS

The Committee having considered the President's reservations and recommendations makes the following recommendations;

- THAT, the following amendments as proposed in the Presidential memorandum be Agreed to—

(1) in the proposed amendments to the Pharmacy and Poisons Act, Cap. 244—

(a) in section 2, by—

- (i) deleting the definition of the term “pharmaceutical device”;
- (ii) deleting the definition of the term “pharmaceutical equipment”;
- (iii) deleting the definition of the term “pharmaceutical product”;
- (iv) deleting the definition of the term “Good Manufacturing Practice” and substituting therefor the following new definition—

“Good Manufacturing Practice”, also referred to as “GMP”, “cGMP” or “current Good Manufacturing Practice” is the part of quality management which ensures that products are consistently produced and controlled according to their intended use as required by the marketing authorization, clinical trial authorization or product specification;

(b) in section 3(1), by—

- (i) deleting paragraph (d);
- (ii) deleting paragraph (f) and substituting therefor the following new paragraph—

“(f) three other persons appointed by the Cabinet Secretary, of whom—

- (i) one person shall be a pharmacist representing institutions of higher learning;
 - (ii) one person shall be a pharmaceutical technologist representing mid-level colleges;
- and

(iii) one person shall be an enrolled pharmaceutical technologist with expertise in community pharmacy nominated by the Kenya Pharmaceutical Association;”

(c) in section 3B, by deleting paragraph (3)(g) and substituting therefor the following new paragraph–

“(g) approve institutions to be established or accredited under the Universities Act, training pharmacists and mid-level institutions training pharmaceutical technologists”

(d) by deleting the proposed amendment to section 24;

(2) in section 4B of the proposed amendments to the **Medical Practitioners and Dentists Act, Cap 253**, by inserting the words “in accordance with the Public Finance Management Act and other relevant laws” immediately after the words “its purposes” appearing in paragraph (f);

(3) in the proposed amendments to the **Nurses Act, Cap 257**–

(a) in section 4(1), by inserting the following new paragraph immediately after paragraph (i)–

“(j) the Director General of health or a representative appointed in writing by the Director General of health”

(b) in section 11, by deleting subsection (5) and substituting therefor the following new subsection–

“(5) The officers appointed under this section shall be paid such remuneration and allowances as the Council may, on the advice of the Salaries and remuneration Commission, determine.”

(4) by inserting the following new amendments in the Schedule to the proposed amendments to the **Counsellors and Psychologists Act, 2014, No. 14 of 2014**—

s.15	Delete.
s.16	Delete.
s.17	Delete.
s.18	Delete.
s.19	Delete.
s.20	Delete.
s.21	Delete.
s.22	Delete.
Third	Delete.
Schedule.	
Fourth	Delete.
Schedule.	

(5) in section 4(1) of the proposed amendments to the **Clinical Officers (Training, Registration and Licensing) Act, No. 20 of 2017**, by—

(a) inserting the following new sub-paragraph immediately after sub-paragraph

(a)(ii)—

“(iii) be registered as a clinical officer under this Act”

(b) deleting paragraph (f) and substituting therefor the following new paragraph—

“(f) one clinical officer representing universities training clinical officers elected by the teaching staff from among their number;”

- THAT, the following amendment as proposed in the Presidential memorandum be **Rejected**—

Section 9(1) of the Nurses Act, Cap 257, be amended by deleting the words “nursing commodities” appearing in paragraph (i);

Justification

The regulation of the standards of nursing commodities is a function that should be retained by the Nursing Council until such time as Parliament enacts a single regulatory body for the regulation of health products and health technologies, as provided in section 62 of the Health Act, No. 21 of 2017.

- THAT, the following new amendments be incorporated in the Presidential memorandum–

1) Section 3(1) of the Pharmacy and Poisons Act, Cap. 244 be amended by deleting paragraph (e);

Justification

The new paragraph (f) as contained in the Presidential memorandum provides for the appointment of two representatives of training institutions into the Pharmacy and Poisons Board. This new paragraph introduces the appointment of a pharmacist representing institutions of higher learning as well as a pharmaceutical technologist representing mid-level colleges.

Paragraph (e) as contained in the Bill also provides for the appointment of two persons representing pharmacy training institutions into the Board. It is therefore necessary to delete paragraph (e) so as to avoid the over-representation of training institutions in the Board.

2) Section 4(1) of the Nurses Act, Cap. 257 be amended by deleting the word “two” appearing in paragraph (h) and substituting therefor the word “one”;

Justification

The Presidential memorandum introduces the Director General of health in the membership of the Nursing Council, thereby increasing the total membership of the Council. The Committee is therefore of the view that to retain the membership at eleven,

it is necessary to reduce the number of persons nominated by the Cabinet Secretary to represent the public, from two people to one person.

