

Approved for tabling *[Signature]*

30/9/15

PARLIAMENT OF KENYA LIBRARY

REPUBLIC OF KENYA



KENYA NATIONAL ASSEMBLY

*Paper laid  
By the Vice  
Chairperson of  
the Departmental  
Committee on Health  
Hon. James Mwangi  
on Wednesday  
30/9/2015  
[Signature]*

ELEVENTH PARLIAMENT – THIRD SESSION

THE DEPARTMENTAL COMMITTEE  
ON  
HEALTH

REPORT ON THE CONSIDERATION OF  
THE HEALTH RECORDS AND INFORMATION MANAGERS BILL, 2015

DIRECTORATE OF COMMITTEE SERVICES  
CLERK'S CHAMBER  
PARLIAMENT BUILDINGS  
NAIROBI

OCTOBER, 2015

## Contents

1.0 PREFACE .....	4
1.1 Committee Mandate .....	4
1.2 Committee Membership .....	5
1.3 Consideration of the Health Records and Information Managers Bill, 2015 .....	5
1.4 Public Memoranda /Views .....	5
1.5 Committee Observations and Recommendations.....	6
1.6 Acknowledgement.....	6
2.0 BACKGROUND.....	7
2.1 Situational Review .....	7
2.1.1 How Legal Frameworks Ought to Regulate the Health Professions:-.....	7
2.1.2 Regulating Health Professionals: Underpinning Policy Frameworks .....	8
3.0 COMPARATIVE ANALYSIS: REGULATION OF HEALTH CARE PROFESSIONALS .....	8
3.1 Unite Kingdom .....	8
3.2 South Africa .....	9
3.3 British Columbia .....	9
3.4 The Government of Dubai.....	9
3.5 Australia .....	9
4.0 CONSIDERATION OF THE HEALTH RECORD AND INFORMATION MANAGERS BILL, 2015.....	10
5.0 PUBLIC PARTICIPATION.....	11
5.1 The Ministry of Health Submissions on the Bill.....	11
5.2 Submission by Mr. Robert Wamalwa .....	11
6.0 COMMITTEE RECOMMENDATIONS.....	12
7.0 CLAUSES OF THE HEALTH RECORD AND INFORMATION MANAGERS BILL, 2015. ...	13

## **1.0 PREFACE**

It is my pleasant duty and pleasure, on behalf of the Committee on Health to present to the House the Report of the Committee on the Health Records and Information Managers Bill, 2015 pursuant to Standing Order 127. The Health Records and Information Managers Bill, 2015 seeks to make provision for training, registration and licensing of the health records and information managers; to regulate their practice; to provide for the establishment, powers and functions of the Health Records and Information Managers Board.

The specific objects which the Bill seeks to achieve include the following:

- i) Establishment of the Health Records and Information Managers Board..
- ii) To provide on the training and registration of health records and information managers.
- iii) To provide for private practice of health records and information and their licensing.
- iv) To provide for offences and penalties to the registration, enrolment, licensing and training of health records and information managers.
- v) To provide for the discipline of health records and information managers.
- vi) Establish National Research for Health Committee as advisory body for research for health and Kenya National Blood Transfusion Services.
- vii) To provide for e-Health and use of technological approaches to advance health objectives.

## **1.1 Committee Mandate**

The Committee on Health is one of the Departmental Committees of the National Assembly established under Standing Order 216 and mandated to, inter alia;

- (i) investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned Ministries and departments;
- (ii) study the programme and policy objectives of Ministries and Departments and the effectiveness of the implementation;
- (iii) study and review all legislation referred to it;
- (iv) study, assess and analyze the relative success of the Ministries and Departments as measured by the results obtained as compared with their stated objectives;
- (v) investigate and inquire into all matters relating to the assigned Ministries and Departments as they may deem necessary, and as may be referred to it by the House;
- (vi) vet and report on all appointments where the Constitution or any law requires the National Assembly to approve, except those under Standing Order 204 (Committee on Appointments) ; and
- (vii) make reports and recommendations to the House as often as possible, including recommendation of proposed legislation.

## **1.2 Committee Membership**

The Committee comprises the following Members:-

1. The Hon. Dr. Rachel Nyamai, M.P. - Chairperson
2. The Hon. Dr. Robert Pukose, MP - Vice Chairperson
3. The Hon. Alfred Agoi, M.P.
4. The Hon. Christopher Nakuleu, M.P.
5. The Hon. David Karithi, M.P.
6. The Hon. Dr. Dahir Duale Mohamed, M.P.
7. The Hon. Dr. David Eseli, M.P.
8. The Hon. Dr. Enoch W. Kibunguchy, M.P.
9. The Hon. Dr. James Murgor, M.P.
10. The Hon. Dr. James Nyikal, M.P.
11. The Hon. Dr. James O. Gesami, M.P.
12. The Hon. Dr. Naomi Shaban, M.P.
13. The Hon. Dr. Patrick Musimba, M.P.
14. The Hon. Dr. Stephen Wachira, M.P.
15. The Hon. Dr. Susan Musyoka, M.P.
16. The Hon. Eng. Stephen Mule, M.P.
17. The Hon. Fred Outa, M.P.
18. The Hon. Hassan Aden Osman, M.P.
19. The Hon. James Gakuya, M.P.
20. The Hon. John Nyaga Muchiri, M.P., HSC
21. The Hon. Joseph O. Magwanga, M.P.
22. The Hon. Kamande Mwangi, M.P.
23. The Hon. Leonard Sang, M.P.
24. The Hon. Masoud Mwahima, M.P.
25. The Hon. Michael Onyura, M.P.
26. The Hon. Mwinga Gunga, M.P.
27. The Hon. Paul Koinange, MP
28. The Hon. Raphael Milkau Otaalo, M.P.
29. The Hon. Zipporah Jesang Kering, M.P.

## **1.3 Consideration of the Health Records and Information Managers Bill, 2015**

On 17<sup>th</sup> June 2015, the Health Records and Information Managers Bill, 2015 was read a First Time and thereafter committed to the Departmental Committee on Health for consideration pursuant to Standing Order No. 127. The Committee held two sittings to consider the Bill.

## **1.4 Public Memoranda /Views**

On 17<sup>th</sup> July, 2015, the Committee placed advertisements on the Local Dailies calling for views from the general public on the Bill pursuant to Article 118 of the Constitution. The Committee received submissions from the Ministry of Health and Mr. Robert Wamalwa, a Lecturer in the Department of Health records and Information at Kenya Medical Training College.

**1.5 Committee Observations and Recommendations**

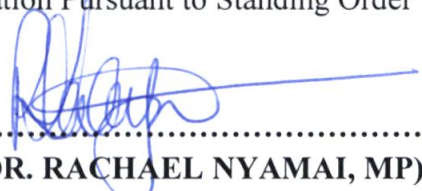
The Committee observed among other things that although the Bill proposes private practice for health records and information, the general trend for health records and information management is provided as a secondary service and is confidential in nature. Further, the Committee noted that there is no definition of the qualifications of the health record information managers.

The Committee will therefore be proposing various amendments to the Bill during the Committee Stage in the House to address areas of concern.

**1.6 Acknowledgement**

The Committee is thankful to the Offices of the Speaker and the Clerk of the National Assembly for the logistical and technical support accorded to it during its sittings. Further, I wish to express my appreciation to the Committee for the immense contributions towards the preparation and production of the report.

It is therefore my pleasant duty and privilege, on behalf of the Departmental Committee on Health, to table its report in the House on the consideration of the Health Bill, 2015 for consideration Pursuant to Standing Order 127

Signed..........Date.....26/8/2015.....  
(HON. DR. RACHAEL NYAMAI, MP)

**CHAIRPERSON,  
DEPARTMENTAL COMMITTEE ON HEALTH**

## **2.0 BACKGROUND**

1. The objective and purpose of the Bill is to provide for the training, registration and licensing of health records and information managers. The bill further seeks to regulate the practice of health records and information managers and to provide for the establishment powers and functions of the Health Records and Information Managers Board.
2. The Bill clearly defines the Health Records and Information Managers Board with its powers, functions and composition. The Bill also provides for training and registration of Health Records and Information Managers, their private practice, general licencing, disciplinary actions for offences and boards finances.
3. The Bill concerns County Governments.

## **2.1 Situational Review**

While regulating a Health Profession such as the Health Records and Information Managers, it is necessary to consider the following:-

- i. The likelihood of harm, and the likely extent of harm, to the health and safety of the public if a health service ordinarily provided by the profession is not provided properly,
- ii. Whether there is likelihood to be an increase in the quality of the services provided, to the benefit of the public, if the profession is regulated,
- iii. Whether the profession would operate appropriately if it were not regulated,
- iv. Whether the profession can be regulated. As such a profession can be regulated if:
  - a. The profession has a distinct area of practice,
  - b. There exists an objective basis for assessing the competence of members of the profession,
  - c. Significant training and education is needed to become a competent member of the profession.

### **2.1.1 How Legal Frameworks Ought to Regulate the Health Professions:-**

The legal frameworks or legislation must make provision for:-

- i. The general area of operation of the profession,
- ii. The suitability to practice requirements for the profession; for each regulated health profession requirements to be satisfied must be stated for a person to be unconditionally registered to practice in the health profession,
- iii. In regulating a health profession, professional boards/ Councils ( statutory bodies that regulate health professionals) are responsible for among others:
  - a. Registering health professionals in the profession
  - b. Setting the required standards of practice for the profession (with other required standard of practice prescribed in additional subsidiary regulations)
  - c. Helping health professionals to continue to meet the required standard of practice
  - d. Taking action in relation to reports and complaint about health professionals'

- iv. The legal framework is not expected to establish more than one health profession board for a health profession; however it may establish a single health profession board for 2 or more health professions

The regulating bodies exercise the following:

- i. Administering a scheme for registration for, and of continuous review of the standard of practice of health professionals in the profession
- ii. Setting fees for administration of the board
- iii. Giving the Cabinet Secretary, the profession and public about matters relevant to the profession
- iv. Setting standards of practice for the profession
- v. Approving educational and training courses related to professional qualifications
- vi. Promoting and monitoring continuing competence of registered professionals
- vii. Disciplining registered professionals who contravene the required standards of practice
- viii. Providing information concerning registered professionals

#### **2.1.2 Regulating Health Professionals: Underpinning Policy Frameworks**

- a. *Draft Kenya Health Policy, 2014-2030*: The broad health policy framework in its policy orientation 5 outlines the need for adequate health information for evidence-based decision making. Among the key strategies the Government intends to achieve the foregoing is the development and implementation of the Health Information Systems (HIS) policy and the continued strengthening of accuracy, timeliness, completeness of health information from population and health facilities.
- b. The Health Bill 2015 in Part II in clauses 8, 9, 10, 11, 12 and 13 provide for Health Information, information dissemination, consent, confidentiality of the information and duty of the users of information.

### **3.0 COMPARATIVE ANALYSIS: REGULATION OF HEALTH CARE PROFESSIONALS**

#### **3.1 United Kingdom**

Registered health care professionals in the UK including social workers in England are regulated by nine statutory bodies (referred to as regulatory bodies). They include: the General Medical Council (regulates doctors), the Nursing and Midwifery Council ( nurses and midwives), the General Dental Council (Dentists), the General Optical Council ( Optometrists, dispensing opticians), The healthcare professions Council which regulates certain other health care workers in the UK, etc. As such the nine are collectively responsible for the standards of practice of over 1.47 million professionals.

Each of the regulatory bodies is governed by a separate piece of legislation. It is estimated that there are approximately 200 pieces of secondary legislation which specifically address the regulatory bodies or professional regulation in general.

On a review by the UK relating to the regulation of health care professionals and social workers, the tripartite project between the Law Commission, the Scottish Law Commission and the Northern Ireland Law Commission in its report dubbed 'Regulation of Health care Professionals in 2015': the Government's response to Law Commission Report 345, Scottish Law Commission report 237 and Northern Ireland Law Commission Report 18 (2014) recommended that there should be a single statute which provides the framework for all the regulatory bodies and the Professional Standards Authority.

### **3.2 South Africa**

In the case of South Africa, the council regulates the health professions in the Country in aspects pertaining to registration, education and training, professional conduct and ethical behaviour while ensuring continuing professional development and fostering compliance with health care standards.

### **3.3 British Columbia**

In British Columbia, there are 26 regulated health professions of which 25 are self-regulating professions governed by 22 regulatory colleges under the Health Professions Act. The Health Profession Act is a primary legislative authority under which a statute regulatory organization established by the provisional Government carries out its mandate to govern the professions in the interest of protecting public safety.

### **3.4 The Government of Dubai**

The Health Regulation Department (HRD) is the responsible entity to regulate and provide licenses to healthcare professionals in the Emirates of Dubai and as such these are issued based on the following categories: Physicians (GP, Specialists, and Consultants); Dentist (General, Specialists and Consultant); Nurses and Midwife ; Allied Health ( e.g. ART specialists, Medical imaging, Pharmacy, occupational therapy etc); Complementary medicine ( Ayurveda, Chiropractic, Homeopathy, Therapeutic, Traditional Chinese Medicine, Unani etc)

### **3.5 Australia**

The Victoria Health Records Act 2001 (the Act) created a framework to protect the privacy of individuals' health information. It regulates the collection and handling of health information. The Act

- gives individuals a legally enforceable right of access to health information about them that is contained in records held in Victoria by the private sector; and
- establishes Health Privacy Principles (HPPs) that will apply to health information collected and handled in Victoria by the Victorian public sector and the private sector.

The access regime and the HPPs are designed to protect privacy and promote patient autonomy, whilst also ensuring safe and effective service delivery, and the continued improvement of health services. The HPPs generally apply to:

- all personal information collected in providing a health, mental health, disability, aged care or palliative care service; and
- all health information held by other organisations.

#### **4.0 CONSIDERATION OF THE HEALTH RECORD AND INFORMATION MANAGERS BILL, 2015**

The Committee considered the bill clause by clause and observed the following, that:-

- i. Clause 7 of the Bill proposes for composition of the Board, however, it is to be noted that the services offered in this cadre are clerical in nature and do not merit the formation of a Board for self-regulation.
- ii. The composition of the board is not in line with the provisions of the State Corporations Act to the extent that the Board exceeds the recommended number by the Act. Further, it does not contain the mandatory representatives from the National Treasury.
- iii. In Clause 9, the Bill proposes that the Chairperson will be elected by the members of the Association of Medical Records contrary to the provisions of the State Corporations Act which require that the Chairperson to be appointed by the President or the Cabinet Secretary in the line Ministry.
- iv. The Bill does not contain a framework defining the qualification of the health record and information management officer. In clause 15, there are no clear parameters that entitle a person to be registered as a health record and information management officer.
- v. Although the Bill proposes private practice in clause 22, the Health Record services in Kenya are offered as support services to the medical sector and are confidential in nature due to the sensitivity of the information.
- vi. Under the offences in clauses 23, 24 and 25, the bill has proposed very punitive fines which are not commensurate with the officers in this cadre who are mostly clerical workers.
- vii. In clause 26 under the disciplinary Committee, the bill proposes its composition to be comprised of among others 2 representatives of the Attorney General one of whom shall be elected the secretary of the Committee. On the contrary, the registrar who is also a member of the Committee should be the secretary. In addition, the chairperson of the committee should be the chairperson of the Association as opposed to the chairperson of the Board.
- viii. Still in composition of the Disciplinary Committee under 26(1)(e), the Committee notes that there should only be one manager as it does not contemplate private practice in health record management.
- ix. Clause 33 on Professional misconduct, may not be applicable to this cadre whose work is mainly of a clerical nature.

## **5.0 PUBLIC PARTICIPATION**

The Committee received comments from two stakeholders; the Ministry of Health and Mr. Robert Wamalwa, a Lecturer at the Kenya Medical Training College, Department of Health Records and Information.

### **5.1 The Ministry of Health Submissions on the Bill**

The Ministry of Health in its submission indicated the following :-

- i. In clause 5(1)(d) the Board has been given powers to enter into agreement with organizations within or outside Kenya in furtherance of the purpose for which the Board is formed. However, the Ministry noted that entering into such agreements outside the country, the Board needs to be in consultation with the Cabinet Secretary.
- ii. Further in Clause 5(3), any fees, allowances and remuneration to be paid to the Board would be determined from time to time with the approval of the Cabinet Secretary and in consultation with the Salary and Remuneration Commission as per the Constitution.
- iii. In Clause 6(1)(b), the Board should have the approval of the Cabinet Secretary in establishing and improving the standards of professional health records and information management in Kenya.
- iv. The Ministry proposes Clause 7 be deleted such that other members can be co-opted in sub-committees thereby leaving the Board with a membership of 9 as per the MWONGOZO (Code of Governance for State Corporations) recommendations.
- v. The Ministry proposes the deletion of the words 'rolls' and 'enrolled' in clauses 13(3), 23(1), 24(1) and 24(1) since this professional discipline does not have 'enrolled' records manager.
- vi. In clause 26(1)(c), the Ministry proposes that there be only one representative of the Attorney General instead of two as indicated in the Bill. This is because the Registrar is also a member of the committee and should therefore be the secretary of the Committee.

### **5.2 Submission by Mr. Robert Wamalwa**

Mr. Wamalwa made his submission as follows:-

- i. The passing of this Bill will go a long way in hastening legal strength to the creation establishment, maintenance and provision of this much needed tool for health management it will also increase accuracy in Health Information Management. Since all agencies providing health care to the Kenyan community will be compelled to create accurate Health information as opposed to the current situation in which only government health Providers are compelled to maintain accurate Health Information hence strengthen private partnership.
- ii. In passing this Bill , there is a likelihood to embrace and improve the best practice towards health service seeking clients in Kenya since in history not much is heard of for a patients being turned away due to a missing medical record a common practice

that is reported in many quarters of other service provision like courts where clients are turned away due to a missing record.

- iii. Passing this Bill is one of the sure ways of establishing the actual cause of dilemma such as the recent one in Busia County Akichelesit Dispensary, Moding HC St Mary Chelelei Dispensary where close to twenty children were paralyzed after an Injection- Also in Kisii County where a neonate was almost buried alive. Such malpractice will only be determined by the presence of reliable records that are enhanced by this Bill.
- iv. Health is an essential service and particularly those of emergency nature and the only firm documentation that can be maintained is the creation of a medical record if made mandatory by the Bill. Such records will also be used to assess health institutions that are responsive to free emergency health care as provided for in the new Constitution. Efficient health provision instructions will be assessed from the health record maintained and this Bill strengthens this process.
- v. The Health Records and Information Managers Bill, 2015 is important in as far as current and future treatment of patients, training of health workers, evaluation and monitoring of health care, health research and preventive health care enhancement, efficient management of over 2000 professionals (Health Records and Information Practitioners) and a world best practice step in Health like The Health Records Act 2001 (the Act) created a framework to protect the privacy of individuals' health information.

## **6.0 COMMITTEE RECOMMENDATIONS**

The Committee having considered the Bill and the submissions from the stakeholders will be presenting some amendments to the bill in the following clauses; 2, 6, 7, 9, 12, 13, 15, 18, 19, 20, 21, 22, 23, 24, 25, 26, 29, 33, and 36.

## 7.0 CLAUSES OF THE HEALTH RECORD AND INFORMATION MANAGERS BILL, 2015.

The following section provides clause by clause analysis and observations

CLAUSE	GENERAL PROVISIONS
1: Object & purpose	Gives the following as the object and purpose of the act: For training, registration and licensing of health records and information managers; to regulate their practice; to provide for establishment, powers and functions of the Health Records and Information Managers Board.
Clause 2: Interpretation	Defines or provides for the definition of terms such as: health institution, manager, officer, private practitioner register , registrar, technician, unqualified person etc
Clause 3: Establishment of the Health Records and Information Managers Board	Establishes the Health Records and Information Managers Board as a corporate body with perpetual succession.
Clause 4: Headquarters of the Board.	Provides for the Board to have its headquarters in Nairobi.
Clause 5: Powers of the Board	<p>Provides for the powers of the Board as to;</p> <ul style="list-style-type: none"> <li>(a) control, supervise and administer the assets of the Board in such manner and for such purpose as best promotes the purpose for which the Board is established;</li> <li>(b) determine the provisions to be made for capital and recurrent expenditure and for the reserves of the Board;</li> <li>(c) receive any grants, gifts, donations or endowments and make legitimate disbursements there from;</li> <li>(d) enter into Agreement with other bodies or organisations within or outside Kenya as the Board may consider desirable or appropriate and in furtherance of the purpose for which</li> </ul>

CLAUSE	GENERAL PROVISIONS
	<p>the Board is established;</p> <p>(e) open a bank account or bank accounts for the funds of the Board; and</p> <p>(f) invest any funds of the Board not immediately required for its purposes;</p>
<p>Clause 6: Functions of the Board.</p>	<p>The Board has the following functions, to —</p> <p>(a) establish and improve standards of all branches of the health records and information managers profession in all their aspects and to safeguard the interests of all managers;</p> <p>(b) establish and improve the standards of professional health records and information management in Kenya;</p> <p>(c) with the approval of the Cabinet Secretary, make provision for the training and instruction for persons seeking registration or enrolment under this Act;</p> <p>(d) with the approval of the Cabinet Secretary, prescribe and regulate syllabuses of instruction and courses of training for persons seeking registration or enrolment under this Act;</p> <p>(e) recommend to the Cabinet Secretary institutions to be approved institutions for training of persons seeking</p>

CLAUSE	GENERAL PROVISIONS
	<p>registration or enrolment under this Act;</p> <p>(f) with the approval of the Cabinet Secretary, prescribe and conduct examinations for persons seeking registration or enrolment under this Act;</p> <p>(g) have regard to the conduct of persons registered, enrolled or licensed under this Act, and take such disciplinary measures as may be necessary to maintain a proper standard of conduct among such persons;</p> <p>(h) direct and supervise the compilation and maintenance of registers, rolls and records required to be kept under section 20;</p> <p>(i) advise the Cabinet Secretary on matters concerning all aspects of health records and information management.</p>
<p>Clause 7: Composition of the Board</p>	<p>The Board shall comprise of —</p> <p>(a) one appointee from the Director of Medical services.</p> <p>(b) the Deputy Director Health Records and Information Management, Ministry of Health;</p> <p>(c) the Registrar, who shall also be the secretary to the Board and shall be a registered Manager;</p>

CLAUSE	GENERAL PROVISIONS
	<p>(d) the Director of technical training in the Ministry of Education for the time being responsible for Higher Education;</p> <p>(e) one registered Manager, who shall be in private practice, to be nominated by the Board;</p> <p>(f) the Chairperson of the Association;</p> <p>(g) the Secretary General of the Association;</p> <p>(h) two Managers in Public practice appointed by the Cabinet Secretary; and</p> <p>(i) two other members co-opted by the Board from time to time whose knowledge and experience is deemed necessary for the better performance of its functions.</p>
<p>Clause 8: Disqualification from office and filling of vacancies.</p>	<p>Provides that a person shall be disqualified for appointment or election as a member of Board if the person—</p> <ol style="list-style-type: none"> <li>1) is an undischarged bankrupt; or</li> <li>2) has his or her name removed from the appropriate register or his or her registration, enrolment or licence is suspended under section 17.</li> <li>3) has been absent from more than two consecutive ordinary meetings of the Board without its leave; or</li> <li>4) gives notice in writing to the Board of</li> </ol>

CLAUSE	GENERAL PROVISIONS
	<p>his desire to resign from office and his resignation is accepted.</p> <p>5) Upon death.</p>
Clause 9: Chairperson of the Board.	Provides that the chairperson shall be appointed from an election conducted by the Association of Medical Records Officers of Kenya
Clause 9: Terms of office of the Board.	Members of the Board shall hold office for a period of 3 years.
Clause 11: Conduct of business and affairs of the Board.	Provides that the board may regulate its affairs according to the schedule or adopt its own procedures
Clause 12: Delegation by the Board	The Board may, by resolution either generally or in any particular case, delegate to any committee or to any member, officer, employee or agent of the Board, the exercise of any of the powers or the performance of any of the functions or duties of the Board under this Act or under any other written law.
Clause 13: Registrar.	Provides for powers of appointment of the registrar by the board with approval of the cabinet secretary.
Clause 14: Qualifications of Registrar.	The registrar must be a registered manager and with a minimum number of years of experience to be prescribed by the regulations.
Clause 15: Application for registration.	Provides for conditions and qualifications that an individual may be registered, which include, that a person must be a Kenyan citizen with the appropriate professional qualifications.
Clause 16: Maintenance of register.	Prescribes that the Board shall maintain a register of health records and information managers and the form and manner in which such a register is to be maintained.

CLAUSE	GENERAL PROVISIONS
Clause 17: Removal of names.	<p><b>1.</b> The Registrar shall remove from the register—</p> <ul style="list-style-type: none"> <li>(a) the names of all deceased persons;</li> <li>(b) the names of all persons struck off from the register any entries fraudulently or erroneously made.</li> </ul>
Clause 18: Approved training institutions	<p>Prohibits an unapproved training institution from</p> <ul style="list-style-type: none"> <li>(a) admitting persons for training with a view to qualifying for registration under the Act; or</li> <li>(b) conducting a course of training or administer the examinations prescribed for the purposes of registration under the Act; or</li> <li>(c) issuing any document or statement implying that the holder thereof has undergone a course of training or passed the examinations prescribed by the Board for purposes of registration:</li> </ul>
Clause 19: Conditions of practice and penalty.	<p>A person who practices without a license is liable to a fine not exceeding four million or five years imprisonment.</p>
Clause 20: Custody of registers.	<p><b>2.</b> Provides that the Registrar shall maintain custody of—</p> <ul style="list-style-type: none"> <li>(a) a register of Technicians;</li> <li>(b) a register of Officers; and</li> <li>(c) such other registers as may from time to time be prescribed by the Board with the approval</li> </ul>

CLAUSE	GENERAL PROVISIONS
	of the Cabinet Secretary.
Clause 21: Qualifications for registration..	<p>Provides that for a person to be registered under clause 21 he or she must be</p> <ol style="list-style-type: none"> <li>1) of good character,</li> <li>2) paid the registration fees; and</li> <li>3) possess the prescribed academic and professional qualifications.</li> </ol>
Clause 22: Private practice.	Provides for regulation of qualifications, consideration for issuance of a certificate for a person who wishes to undertake private practice
Clause 23: Offences by persons not eligible to be registered, enrolled or licensed.	A person who holds himself out under this section commits an offence and is liable to fine not exceeding three million or imprisonment of two years.
Clause 24: Offences by persons eligible to be registered enrolled or licensed.	A person who is qualified but not a registered practitioner under this section commits an offence and is liable to fine not exceeding three million or imprisonment of two years.
Clause 25: Offences by persons conducting training courses or examinations without authority.	A person who offers training under an unregistered institution under this section commits an offence and is liable to fine not exceeding three million or imprisonment of two years.
Clause 26: Disciplinary Committee	<p>Provides for establishment of a Disciplinary Committee of the Board, which shall consist of—</p> <ol style="list-style-type: none"> <li>(a) the chairman of the Board, or a nominee thereof who shall be the chairman of the Committee;</li> <li>(b) one representative of the Cabinet Secretary</li> </ol>

CLAUSE	GENERAL PROVISIONS
	<p>who shall not be a member of the Board;</p> <p>(c) two representatives of the Attorney-General, one of whom shall be elected the secretary of the Committee;</p> <p>(d) the registrar who shall be an ex-officio member of the Committee; and</p> <p>two Managers, one each from public and private practice, of distinguished professional standing nominated by the Board, who shall not be member of the Board</p>
Clause 27: Functions of Committee	The Committee shall hear and determine matters referred to it by the Board or any other aggrieved person.
Clause 28: Proceedings of Committee	Contains provisions empowering the committee to take evidence and conduct a fair hearing.
Clause 29: Decisions of Disciplinary Committee.	<p>Provides for powers of the Committee upon hearing a matter, such as –</p> <p>(a) suspending the practising certificate of the Manager for a period not exceeding three months;</p> <p>(b) withdraw or cancel the practising certificate of the Manager;</p> <p>(c) imposing a fine as prescribed in the Act or regulations or as it deems appropriate in the circumstances; or</p> <p>(d) removing the name of the Manager from the register.</p>
Clause 30: Lifting of suspensions	Provides that where a manager successfully appeals,

CLAUSE	GENERAL PROVISIONS
	the Board may lift a suspension.
Clause 31: Restoration of registration.	Provides that a Manager whose name has been removed from the register may appeal to the Board for restoration of his name in the register after the expiry of a period of three years from the date of such removal.
Clause 32: Effect of removal, cancellation or suspension	<p>Provides</p> <ol style="list-style-type: none"> <li>1) that a person whose name has been removed, cancelled or suspended is not governed by the Bill:</li> <li>2) for the procedure of reinstatement.</li> </ol>
Clause 33: Professional misconduct.	<p>Provides for 11 grounds that constitute professional misconduct; these are where a Manager—</p> <ol style="list-style-type: none"> <li>(a) allows any person to practise in his or her name as a registered Manager, unless such person is the holder of a practising certificate and is in partnership with or employed by the Manager;</li> <li>(b) enters into partnership with a person who does not hold a practicing certificate, or secures any professional business through the services of such a person or by means not open to a Manager;</li> <li>(c) pays or allows or agrees to pay, directly or indirectly, to any person, other than a person who holds a practising certificate, is a retired partner or the legal representative of such a partner, any share, commission or brokerage</li> </ol>

CLAUSE	GENERAL PROVISIONS
	<p>out of the fees for, or profits of his or her professional services;</p> <p>(d) solicits clients or professional work or advertises professional attainments or services by use of means not prescribed by the Board;</p> <p>(e) discloses information acquired in the course of professional engagement to any person other than a client, without the consent of the client, or otherwise than required by law;</p> <p>(f) fails to observe and apply professional standards prescribed by the Board;</p> <p>(g) is grossly negligent in the conduct of his or her professional duties;</p> <p>(h) expresses an opinion on any matter with which he is concerned in a professional capacity without obtaining sufficient information on which to base the opinion;</p> <p>(i) is convicted of a crime under the Anti-Corruption and Economic Crimes Act, 2003 (No. 3 of 2003);</p> <p>(j) fails to declare a conflict of interest in relation to any particular matter or acts in a matter notwithstanding the presence of an undisclosed conflict of interest; or</p> <p>(k) fails to do any other act which prescribed by the Board.</p>

CLAUSE	GENERAL PROVISIONS
Clause 34: Funds of the Board.	<p>3. Provides that the funds of the Board shall comprise of—</p> <p>(a) such monies as may accrue to or vest in the Board in the course of the exercise of its powers or the performance of its functions under this Act; and</p> <p>(b) all monies from any other source provided for or donated or lent to the Board.</p> <p>amount.</p>
Clause 35: Financial year.	Provides that The financial year of the Board shall be the period of twelve months ending on the thirtieth of June in every year.
Clause 36: Rules.	Empowers the Board to male rule and outlines 13 areas the rules must provide for.
Clause 37: Certificate and seal.	Provides that a certificate under the seal of the Board stating that a person is or was at any date registered, enrolled or licensed under this Act shall be conclusive evidence of the fact stated in the certificate and offences related to the same.
Clause 38: Penalty.	Provides that Any person convicted of an offence under the Act for which no penalty is provided shall be liable to a fine not exceeding five hundred thousand shillings.
Clause 39: Falsification of registers, rolls or records	Creates an where a person falsifies a register, a roll or a record established and maintained under this Bill.
First Schedule	Contains detailed provisions on the conduct of the business of the board,

**MINUTES OF THE 62<sup>ND</sup> SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN ROOM 7, MAIN PARLIAMENT BUILDINGS, ON TUESDAY, 25<sup>TH</sup> AUGUST, 2015, AT 4.00 PM.**

**PRESENT**

1. The Hon. Dr. Racheal Nyamai, M.P. (Chairperson)
2. The Hon. Dr. Robert Pukose, M.P. (Vice Chairperson.)
3. The Hon. David Karithi, M.P.
4. The Hon. Leonard Sang, M.P.
5. The Hon. John Nyaga Muchiri, M.P.
6. The Hon. Dr. Naomi Shaban, M.P.
7. The Hon. James Gakuya, M.P.
8. The Hon. Raphael Milkau Otaalo, M.P
9. The Hon. Kamande Mwangi, M.P.
10. The Hon. Dr. James Murgor, M.P.
11. The Hon. Dr. Stephen Wachira, M.P.
12. The Hon. Hassan Aden Osman, M.P.
13. The Hon. Dr. James O. Gesami, M.P.
14. The Hon. Mwinga Gunga, M.P.
15. The Hon. Dr. Dahir D. Mohamed, M.P
16. The Hon. Dr. Eseli Simiyu, M.P.

**ABSENT WITH APOLOGY**

1. The Hon. Paul Koinange, M.P
2. The Hon. Dr. Enoch Kibunguchy, M.P.
3. The Hon. Stephen M. Mule, M.P.
4. The Hon. Fred Outa, M.P.
5. The Hon. Michael Onyura, M.P.
6. The Hon. Dr. James Nyikal, M.P.
7. The Hon. Dr. Susan Musyoka, M.P.
8. The Hon. Joseph O. Magwanga, M.P.
9. The Hon. Christopher Nakuleu, M.P.
10. The Hon. Alfred Agoi, M.P
11. The Hon. Dr. Patrick Musimba, M.P.
12. The Hon. Mwahima Masoud, M.P.
13. The Hon. Zipporah Jesang, M.P.

## **IN ATTENDANCE**

### **National Assembly Secretariat**

1. Ms. Esther Nginyo - Clerk Assistant III
2. Mr. Dennis Mogare - Clerk Assistant III
3. Mr. Sydney Lugaga - Legal Counsel

### **MIN.NO. DCH 262/2015: PRELIMINARIES.**

The Chairperson called the meeting to order at 4.35 pm. Thereafter, a prayer was said by Hon. (Dr.) Dahir D. Mohamed, M.P. The Chairperson then welcomed all Members present to the meeting and introduced the agenda of the meeting as the Consideration of the Health Records and Information Managers Bill, 2015 and adoption of the report on the Bill.

### **MIN.NO. DCH 263/2015: BRIEF FROM THE LEGAL COUNSEL ON THE HEALTH RECORDS AND INFORMATION MANAGERS BILL, 2015**

The Chairperson welcomed the Legal Counsel to brief members on the contents of the Bill. In his brief, the Legal Counsel informed members that:

1. The object & purpose of the Bill is to provide for training, registration and licensing of health records and information managers; to regulate their practice; to provide for establishment, powers and functions of the Health Records and Information Managers Board.
2. The Bill establishes the Health Records and Information Managers Board as a corporate body with perpetual succession.
3. The Bill further contains provisions on:
  - a) Powers and functions and composition of the Board.
  - b) for disqualification from office and filling of vacancies, election of Chairperson of the Board, terms of office of the Board, Conduct of business and affairs of the Board and delegation by the Board
  - c) appointment of the registrar to the Board
  - d) Offences by persons not eligible to be registered enrolled or licensed.
  - e) Offences by persons eligible to be registered enrolled or licensed.
  - f) Offences by persons conducting training courses or examinations without authority.
  - g) A disciplinary Committee

The Committee considered the Bill clause by clause and observed that:

1. Clause 7 of the Bill proposes for composition of the Board, however, it is to be noted that the services offered in this cadre are clerical in nature and do not merit the formation of a Board for self-regulation.
2. The composition of the board is not in line with the provisions of the State Corporations Act to the extent that the Board exceeds the recommended number by the Act. Further, it does not contain the mandatory representatives from the National Treasury.
3. In Clause 9, the Bill proposes that the Chairperson will be elected by the members of the Association of Medical Records contrary to the provisions of the State Corporations Act which require that the chairperson to be appointed by the President or the Cabinet Secretary in the line Ministry.
4. The Bill does not contain a framework defining the qualification of the health record and information management officer. In clause 15, there are no clear parameters that entitle a person to be registered as a health record and information management officer.
5. Although the Bill proposes private practice in clause 22, the Health Record services in Kenya are offered as support services to the medical sector and are confidential in nature due to the sensitivity of the information.
6. Under the offences in clauses 23, 24 and 25, the bill has proposed very punitive fines which are not commensurate with the officers in this cadre who are mostly clerical workers.
7. In clause 26 under the disciplinary Committee, the bill proposes its composition to be comprised of among others 2 representatives of the Attorney General one of whom shall be elected the secretary of the Committee. On the contrary, the registrar who is also a member of the Committee should be the secretary. In addition, the chairperson of the committee should be the chairperson of the Association as opposed to the chairperson of the Board.

8. Still in composition of the Disciplinary Committee under 26(1) (e), the Committee notes that there should only be one manager as it does not contemplate private practice in health record management.
9. Clause 33 on Professional misconduct may not be applicable to this cadre whose work is mainly of a clerical nature.

**MIN.NO. DCH 265/2015:                    CONSIDERATION AND ADOPTION OF A  
REPORT ON THE CONSIDERATION OF THE  
HEALTH RECORDS AND INFORMATION  
MANAGERS BILL, 2015**

The Committee considered and adopted its report on the Consideration of the Health Records and Information Managers Bill, 2015 after being proposed and seconded by Hon. Dr. Naomi Shaban, M.P. and Hon. James Gakuya, M.P. respectively.

**MIN.NO. DCH 265/2015                    ADJOURNMENT**

There being no other business, the meeting was adjourned at 5.42 pm.

SIGNED.....

HON (DR.) RACHAEL NYAMAI, M.P  
CHAIRPERSON

DATE:.....

*Tuesday  
Sunday*

MINUTES OF THE 25<sup>TH</sup> SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH  
HELD IN 2<sup>ND</sup> FLOOR PROTECTION HOUSE, ON THURSDAY DAY 16<sup>TH</sup> MARCH, 2015,  
AT 10.00 AM.

**PRESENT**

1. The Hon. Dr. Racheal Nyamai, M.P. (Chairperson)
2. The Hon. Dr. Robert Pukose, M.P. (Vice Chairperson)
3. The Hon. Dr. James Murgor, M.P.
4. The Hon. Dr. Dahir D. Mohamed, M.P.
5. The Hon. Mwinga Gunga, M.P.
6. The Hon. Dr. Stephen Wachira, M.P.
7. The Hon. Raphael Milkau Otaalo, M.P.
8. The Hon. Kamande Mwangi, M.P.
9. The Hon. Michael Onyura, M.P.
10. The Hon. Zipporah Jesang, M.P.
11. The Hon. David Karithi, M.P.
12. The Hon. Leonard Sang, M.P.
13. The Hon. Dr. James O. Gesami, M.P.
14. The Hon. Dr. Susan Musyoka, M.P.
15. The Hon. Alfred Outa, M.P.
16. The Hon. John Nyaga Muchiri, M.P.
17. The Hon. Christopher Nakuleu, M.P.
18. The Hon. Stephen M. Mule, M.P.
19. The Hon. Dr. Naomi Shaban, M.P.
20. The Hon. Dr James O. Gesami, M.P.
21. The Hon. Dr. Enoch Kibunguchy, M.P.
22. The Hon. Alfred Agoi, M.P.
23. The Hon. Hassan Aden Osman, M.P.
24. The Hon. James Gakuya, M.P.
25. The Hon. Joseph O. Magwanga, M.P.

**ABSENT WITH APOLOGY**

1. The Hon. Dr. Patrick Musimba, M.P.
2. The Hon. Dr. Eseli Simiyu, M.P.
3. The Hon. Mwahima Masoud, M.P.
4. The Hon. Dr. James Nyikal, M.P.

**IN ATTENDANCE.**

National Assembly Secretariat

- |                    |   |                        |
|--------------------|---|------------------------|
| 1. Esther Nginyo   | - | Third Clerk Assistant. |
| 2. Hassan A. Arale | - | Third Clerk Assistant. |
| 3. Sidney Bwire    | - | Legal Counsel.         |
| 4. Marale Sande    | - | senior Reseacher.      |
| 5. Reyhand Mohamed | - | Research Officer.      |
| 6. Aden Ahmed Abdi | - | Fiscal Analysist.      |
| 7. Robert Ngetich  | - | Fiscal Analyst.        |
| 8. Moses Kariuki   | - | Serjeant at Arms.      |

**MIN.NO. DCH 109/2015: PRELIMINARIES.**

The Chairperson called the meeting to order at 10.30 am and prayer was said by Hon. Mwinga Gunga, M.P. The Chairperson then welcomed the Members to the meeting. The agenda for the day was adopted as proposed and seconded by Hon. Leonard Sang, MP and Hon. Hassan Osman, MP.

**MIN.NO.DCH 110/2015. PRE-SCRUTINY ANALYSIS OF THE BIOMEDICAL ENGINEERS BILL, 2015**

**1. Bill Analysis**

The Committee was brief on the Biomedical Engineers Bill, 2015 by the Parliamentary Research Office as follows;

**Preamble**

The main objective of this Bill is to provide a legislative framework for the training, registration and licensing of biomedical engineering professionals. The bill further seeks to regulate the practice of biomedical engineering and provide for the establishment, powers and functions of a Biomedical Engineering Board which shall regulate the profession.

**Situational Review**

Biomedical engineering (BME) is a discipline that advances knowledge in engineering, biology and medicine and improves human health through cross-disciplinary activities that integrate the engineering sciences with the biomedical science and clinical practice. The profession has only recently been emerging as its own discipline rather than a cross-disciplinary hybrid specialization of other disciplines.

In Kenya, Biomedical Engineering practitioners are involved with the design, manufacture, installation and maintenance of medical equipment.

The Association of Medical Engineers in Kenya (AMEK) is the professional society for Medical Engineers established under section 10 of the Societies Act. It was registered in

1998 and seeks to enhance and promote the knowledge and practice of medical engineering in the country

The Draft Health Bill in part IV creates the Kenya Health Professions Oversight Authority that is charged with the oversight role to the regulatory functions of national health system and ensuring coordination of joint activities of regulatory bodies within the health sector. The proposed membership of the authority is quite representative as it includes representation for health professional associations registered by the Registrar of Societies who are not regulated or registered by any regulatory body as well as members from existing health regulatory bodies. This gives a chance to the professionals who do not fall under any board to have their voices heard.

The Kenya Medical Training College (KMTTC) offers medical engineering training at higher diploma, diploma and certificate levels in five campuses namely; Nairobi, Eldoret, Meru, Loitokitok and Kilifi. Additionally, the Mombasa Polytechnic (now Technical University of Mombasa) introduced a diploma course in Medical Engineering in 1986.

Degree course in Biomedical Engineering is offered in few universities locally. Kenyatta University started offering a Bsc. Degree Program in Biomedical Engineering in 2013. Egerton University also offers a Bachelor in Technology program in Industrial Technology (Biomedical Engineering Option). However, these two courses did not appear in the list of accredited engineering courses published by the Engineers Board of Kenya (EBK) in September 2014.

Initially, all graduates of Medical Engineering were regularly deployed to work in Hospital Maintenance Units (HMU's) in public hospitals all over the country until 1995 due to change in government policy. The number of Medical Engineering personnel being absorbed into public service has drastically reduced, with graduates seeking employment in private hospitals, medical equipment supplies companies etc.

### **The Biomedical Engineers Bill, 2015**

The Bill seeks to regulate the profession by putting provisions similar to those in the Engineers Act, the Medical Practitioners and Dentists act and the Draft Pharmacy Practitioners Bill.

It generally seeks to provide for the regulation of the Biomedical Engineering profession. It provides for the following:

- Establishment of the Biomedical Engineers Board of Kenya
- Financial provisions of the Biomedical Engineers Board of Kenya
- Provisions for the training and registration of biomedical engineers
- Provisions for the discipline of biomedical engineers
- Provisions for regulation of biomedical engineers in private practice

- Provisions on delegated powers

The Bill establishes the Biomedical Engineers Board that will manage public funds thus making it a money bill. The board is further mandated with the inspection of health facilities offering biomedical services and will therefore be closely working with the County Governments in discharging these duties. It is therefore imperative that the County Governments are consulted during the development of this bill.

From the foregoing it is important to interrogate the following:

The Engineers Act 2012 created the Engineers Board of Kenya (EBK) that regulates engineering professionals in several specialties such as electrical, mechanical, civil and other engineering courses recognized by the Board. As such if enacted, this bill will only cater for a specific specialization i.e. Biomedical Engineering.

The proposed Biomedical Engineers Board seeks to carry out accreditation and approval of biomedical engineering courses offered in approved institutions. This will create an overlap as this function is currently being carried out by the EBK.

### **Comparative Analysis**

Biomedical engineering effectively evolved as a distinct profession in the late 1950s, when biomedical engineering professional societies came together to address issues affecting them as professionals. This culminated in the formation of the International Federation for Medical and Biological Engineering (IFMBE) in 1959 in France.

Worldwide, there is no consistency in how this profession is classified with different countries using different titles such as medical engineering, clinical engineering and biomedical engineering.

It is also important to note that the World Health Organization (WHO) is currently in the process of applying for recognition of Biomedical Engineering as a discipline in the International Standard Classifications of Occupations by the International Labour Organization to be published in 2018.

In **Nigeria**, unlike many countries in Africa, Biomedical Engineering is very visible and recognized amongst professionals. However, it is yet to get the full backing of government to certify it as a distinct profession. Practicing biomedical engineers in Nigeria are however certified by the Council of Regulation of Engineering in Nigeria (COREN) to practice as general engineers. There are few training institutions and most of the technical personnel are foreign-trained. The National Association of Biomedical Engineers and Technologists (NABET) is a membership group that serves as the mouth piece for Biomedical Engineering professionals in Nigeria.

In **South Africa**, Biomedical Engineering is regulated by The Engineering Council of South Africa (ECSA) which is a statutory body that regulates all engineering professions. However, Biomedical Engineers who want to practice in a clinical setting must register

with the Health Professionals Council of South Africa (HPCSA) which is the body that regulates all health professions in the country in aspects pertaining to registration, education and training, professional conduct and ethical behavior.

Engineering licensure in the **US** including Biomedical Engineering is largely optional, and is not specified by discipline. Each state has certain (fairly similar) requirements for becoming licensed as a registered Professional Engineer, but in practice such a license is not required to practice in the majority of situations.

In **Australia**, Biomedical Engineering just like other Engineering professions is regulated but registration is typically only recommended and not a requirement. Registration is optional and is done by the National Engineering Registration Board (NERB).

### **Conclusion**

With the improvement of health care in the country coupled with scientific and technological advances, demand for the services of medical engineers can only increase. Additionally, the Medical Equipment Supplies (MES) project that seeks to provide high-tech medical equipment in all counties will also lead to increased demand for the services of these professionals in public hospitals.

The bill is in line with Article 46 of the constitution as it seeks to regulate the profession hence ensuring the protection of the health of the consumers. However there is need to avoid duplication and overlap of functions carried out by existing regulatory authorities.

Comparative analysis with other countries has shown that Biomedical engineering is regulated together with other engineering professions but professional societies have been formed to champion for the profession's interests.

## **2. Determination of financial Implication of the legislative proposal by the Parliamentary Budget office.**

### **Basis for Costing/ Assumptions**

1. The costing and assessment of the financial implication of the proposed Bill is performed based on the following assumptions: that
  - The Board secretariat will comprise of 25 staffs.
  - The approximate cost of maintaining a board member and a committee member per month is Kshs 24,000 and Kshs 8,000 respectively; this covers allowances and transport expenses.

- The average cost of a secretariat is Kshs 80,000 per month. This is the average pay for the CEO and other staff. Annual increment is averaged at 6% which is the current inflation rate.
- The number of qualified biomedical engineers is 6,239 in 2015/16, and is expected to increase by 350 yearly. Source: **AMEK**.
- Initial registration fee per biomedical engineer is Kshs 3,000.
- Annual renewal/ membership fee is Kshs 2,000.

#### A. Financial Implication

##### 2. Expected Revenues and Expenditures

**Table 1: showing Estimated Revenues and Cost of running the Board**

Date	2015/16	2016/17	2017/18	2018/19
<b>Estimated Revenues from the Board</b>				
Initial Registration	18,717,000	1,050,000	1,050,000	1,050,000
Annual Registration	0	12,478,000	13,178,000	13,878,000
<b>Total Expected Revenue (A-I-A)</b>	<b>18,717,000</b>	<b>13,528,000</b>	<b>14,228,000</b>	<b>14,928,000</b>
<b>Estimated Cost of running the Board</b>				
Staff Salaries	24,000,000	25,440,000	26,966,400	28,584,384
Board Allowances	3,564,000	3,777,840	4,004,510	4,244,781
Committee Allowances	480,000	508,800	539,328	571,688
other Admin Expenses	24,000,000	25,440,000	26,966,400	28,584,384
<b>Total Cost</b>	<b>52,044,000</b>	<b>55,166,640</b>	<b>58,476,638</b>	<b>61,985,237</b>
<b>Estimated Deficit</b>	<b>33,327,000</b>	<b>41,638,640</b>	<b>44,248,638</b>	<b>47,057,237</b>

#### B. Observations

3. From the cost estimates, it is expected that it will cost Ksh 33 million in 2015/16, Ksh 41 million in 2016/17, Ksh 44 million in 2017/18, and Ksh 47 million in 2018/19.
4. It is observed that the creation of the Board is against the spirit of reducing the public wage bill. To be in line with the spirit, there may be need to have a one comprehensive umbrella legislation to govern/regulate all issues in the health sector.

### **3. Stakeholders' Views on the Bill**

#### **i. Commission for the implementation of constitution Views.**

The Commission while acknowledging the effort by the member towards the enactment of a legislation that regulates biomedical which is essential in order to ensure protection of consumers of the service offered by the professionals as required by the Article 46 of the constitution noted that;

- a) There is a need to have a single regulatory organ in the health sector owing to the fact that Kenya is a signatory to the EAC Protocol on Health which requires the amalgamation of the health sector regulatory bodies.
- b) The establishment of the Biomedical Engineers Board of Kenya in Clause 3 whose composition is provided for in clause 4 requiring some board members to be appointed in consultation with the Association of Medical Engineers of Kenya which is established under the Societies Act. The Commission recommends that the Association should be statutorily constituted as a professional body like the LSK to ensure professional competence of the members.
- c) In clause 4, the Board should work in consultation with the county governments to facilitate inspection of the health facilities.
- d) In clause 3(1), there is need for clarity that the Board is created to undertake the mandate of the National government.
- e) In clause 3(p), there is need for the establishment of as an intergovernmental body since the Board will be advising both the National and the County Governments.

- f) In clause 4, there is need to reduce the board members from 11 to 5 in line with the provision of Article 201 of the Constitution and Article 10 (d) on the sustainable development.
- g) The bill should set the standards that will be used in regulations by the implementers to ensure that the consumers of the biomedical engineers are protected in line with Article 46 of the Constitution.
- h) The bill is money.

In developing the Bill and other Bills which seeks to give effect to the realization of the Right to Health as provided under Article 43 of the constitution it is essential that the Bills comply with the Health policy 2013-2030. CIC recommends that parliament ensures the finalization of the Health policy and Health Bill to ensure a comprehensive policy framework is established to guide in the enactment of other laws within the health sector.

#### **ii. Kenya Law Reform Commission Views.**

- a) The creation of the Board under clauses 3 and 4 are in order, however the composition and membership of the board is wanting. The constitution threshold is to reduce the number of board members to a reasonable number, preferably not exceeding nine members.
- b) The Bill should reestablish the Association of Medical Engineers of Kenya as statutory body and apportion it functions and provide a clear legal and administrative framework to it as it makes reference to it.
- c) This bill is well drafted and recognizes the interrelations of the proposed framework to existing laws in the statute book. For example the Engineers Act, No. 43 of 2011, the universities Act, no. 42 Of 2012, Technical and vocational Education and Training Act no. 29 of 2013.

### **MIN.NO.DCH 111/2015: PRE-SCRUTINY OF THE HEALTH RECORDS AND INFORMATION MANAGERS LEGISLATIVE PROPOSAL, 2014**

#### **I. Preamble**

- 1. The objective and purpose of the Bill is to provide for the training, registration and licensing of health records and information managers. The bill further seeks to regulate the practice of health records and information managers and to provide for the establishment powers and functions of the health records and information managers board.

#### **II. Situational Review**

#### **Some Legal Frameworks for Regulating Health Professions**

To decide whether regulation of a Health Profession is necessary or desirable, the following should be considered:

- i. The likelihood of harm, and the likely extent of harm, to the health and safety of the public if a health service ordinarily provided by the profession is not provided properly;
- ii. Whether there is likelihood to be an increase in the quality of the services provided, to the benefit of the public, if the profession is regulated;
- iii. Whether the profession would operate appropriately if it were not regulated;
- iv. Whether the profession can be regulated. As such a profession can be regulated if:
  - a. The profession has a distinct area of practice
  - b. There exists an objective basis for assessing the competence of members of the profession
  - c. Significant training and education is needed to become a competent member of the profession

#### **How Legal Frameworks Ought to Regulate Health Professions:**

The legal frameworks or legislation must make provision for:

- i. The General area of operation of the profession
- ii. The suitability to practice requirements for the profession; for each regulated health profession requirements to be satisfied must be stated for a person to be unconditionally registered to practice in the health profession including the following:
- iii. In regulating a health profession, professional boards/ Councils ( statutory bodies that regulate health professionals) are responsible for among others:
  - a. Registering health professionals in the profession
  - b. Setting the required standards of practice for the profession (with other required standard of practice prescribed in additional subsidiary regulations)
  - c. Helping health professionals to continue to meet the required standard of practice
  - d. Taking action in relation to reports and complaint about health professionals'
- iv. The legal framework is not expected to establish more than one health profession board for a health profession; however it may establish a single health profession board for 2 or more health professions

What do these statutory regulating bodies do?

They exercise the following:

- i. Administering a scheme for registration for, and of continuous review of the standard of practice of health professionals in the profession
- ii. Setting fees for administration of the board
- iii. Giving the CS, the profession and public about matters relevant to the profession
- iv. Setting standards of practice for the profession
- v. Approving educational and training courses related to professional qualifications
- vi. Promoting and monitoring continuing competence of registered professionals
- vii. Disciplining registered professionals whose contravene the required standards of practice

viii. Providing information concerning registered professionals

### **Regulating Health Professionals: Underpinning Policy Frameworks**

1. *Draft Kenya Health Policy, 2014-2030*: The broad health policy framework in its policy orientation 5 outlines the need for adequate health information for evidence-based decision making. Among the key strategies the government intends to achieve the foregoing is the development and implementation of the Health Information Systems (HIS) policy and the continued strengthening of accuracy, timeliness, completeness of health information from population and health facilities.

The foregoing indicates the need for an overarching policy on health information Systems going forward even as the Health Records and Information Managers profession regulatory framework is being proposed.

2. The Draft Health Bill 2014 in Part VI - (Establishment of the Kenya Health Professions Oversight Authority) establishes an authority charged with the responsibility of providing an oversight role to the regulatory function of the national health system, and ensuring the adequate coordination of joint activities of regulatory bodies within the health sector.
3. Section 41 of the Draft Health Bill 2014 outlines the functions of the Authority which include but not limited to: ensuring the execution of respective mandates and functions of the regulatory bodies recognized under an Act of Parliament.

With the foregoing therefore the Bill as proposed envisions the likelihood of several regulatory bodies for various professions.

The functions of the board as proposed in the Bill should not be in conflict with the functions of the Authority as stipulated in the proposed Health Bill 2014  
Functions of the Board as proposed in the Bill should not be in conflict with functions of other existing regulatory bodies

### **III. Comparative Analysis : Regulation of Health Care Professionals UK experience**

Registered health care professionals in the UK including social workers in England are regulated by nine statutory bodies (referred to as regulatory bodies). They include: The General Medical Council (regulates doctors), the Nursing and Midwifery Council ( nurses and midwives), The General Dental Council (Dentists), The General Optical Council ( Optometrists, dispensing opticians), The healthcare professions Council which regulates certain other health care workers in the UK etc. As such the nine are collectively responsible for the standards of practice of over 1.47 million professionals.

Each of the regulatory bodies is governed by a separate piece of legislation. It is estimated that there are approximately 200 pieces of secondary legislation which specifically address the regulatory bodies or professional regulation in general.

The report indicates that this has led to the current legal framework becoming highly complex, inflexible, inconsistent and expensive to maintain. On a review by the UK relating to the regulation of health care professionals and social workers, the tripartite project between the Law Commission, the Scottish Law Commission and the Northern Ireland Law Commission in its report dubbed 'Regulation of Health care Professionals in 2015': the Government's response to Law Commission Report 345, Scottish Law Commission report 237 and Northern Ireland Law Commission Report 18 (2014) recommended that there should be a single statute which provides the framework for all the regulatory bodies and the Professional Standards Authority.

### **South Africa**

In the case of South Africa, the council regulates the health professions in the Country in aspects pertaining to registration, education and training, professional conduct and ethical behavior while ensuring continuing professional development and fostering compliance with health care standards.

### **British Columbia**

In BC, there are 26 regulated health professions of which 25 are self-regulating professions governed by 22 regulatory colleges under the Health Professions Act. The Health Profession Act is a primary legislative authority under which a statute regulatory organization established by the provisional Government carries out its mandate to govern the professions in the interest of protecting public safety.

### **The Government of Dubai**

The Health Regulation Department (HRD) is the responsible entity to regulate and provide licenses to healthcare professionals in the Emirates of Dubai and as such these are issued based on the following categories: Physicians (GP, Specialists, and Consultants); Dentist (General, Specialists and Consultant); Nurses and Midwife ; Allied Health ( e.g. ART specialists, Medical imaging, Pharmacy, occupational therapy etc.); Complementary medicine ( Ayurveda, Chiropractic, Homeopathy, Therapeutic, Traditional Chinese Medicine, Unani etc.)

## **IV. The Health Records and Information Managers, 2014**

The Bill generally seeks to provide for the regulation of the Health Records and Information Managers, their registration and licensing. The Bill contains provisions for

the establishment of the Health Records and information Managers Board in addition to provisions for the discipline of the health records and information managers.

It will therefore be important to interrogate the following issues:

- i. The Functions of the Board: With the existence of an Authority to oversight over the Regulatory bodies, in this case the Board as provided in Article 3, there ought to be no conflict in their respective roles.
- ii. Address the inconsistencies in Article 6 (c) (d) (f) of the proposed Health Records and Information Managers legislative proposal, on the providing for training, regulating syllabus and approving training institutions. These roles are currently be undertaken by certain institutions depending upon whether the courses is being undertaken at the Kenya Medical college level or University.
- iii. The Draft Health Bill 2014 in Part VI - recognizes Kenya Health Professions Oversight Authority). The proposed Health Records and information Managers Bill 2014 may have to consider making reference to the Authority as is proposed in the Draft Health Bill 2014.
- iv. The current trend shows that individual health professions are proposing regulatory frameworks including the provisions of regulatory bodies e.g. a Council or a Board. Health professions are numerous, as such different each profession with its own regulating body some of which are close professions may result in a national health system that is confusing, and expensive to maintain. For example the proposed Community Oral Health - creating a statutory body to regulate community Oral Health professional with an existing Medical Practitioners and Dentist Act, CAP 253 may require a lot of justifying.

Overall, there is a need to stimulate debate and develop consensus on the principles of Health professional regulation and settle on a Kenyan regulatory mod

#### **MIN.NO.DCH 112/2015: PRE-SCRUTINY OF COMMUNITY ORAL HEALTH OFFICERS LEGISLATIVE PROPOSAL, 2014**

##### **V. Preamble**

4. The Community Oral Health Officers Legislative Proposal seeks to establish a legal framework to make provision for the training, registration and licensing of community oral health officers and to regulate their practice. The Legislative proposal further establishes the Community oral health council whose functions are among others to regulate the professional conduct of registered community oral health officers.

##### **VI. Situational Review**

##### **Regulating Health Professionals: Underpinning Policy Frameworks**

1. The Draft Health Bill 2014 in Part VI - (Establishment of the Kenya Health Professions Oversight Authority) establishes an authority charged with the responsibility of providing an oversight role to the regulatory function of the national health system, and ensuring the adequate coordination of joint activities of regulatory bodies within the health sector.
2. Section 41 of the Draft Health Bill 2014 outlines the functions of the Authority which include but not limited to: ensuring the execution of respective mandates and functions of the regulatory bodies recognized under an Act of Parliament.

However, the functions of the board as proposed in the Bill should not be in conflict with the functions of the Authority as stipulated in the proposed Health Bill 2014  
**Functions of the Board as proposed in the Bill should not be in conflict with functions of other existing regulatory bodies like the Commission for University Education**

## VII. The Community Oral Health Officers, 2014

The following are some of the issues to be interrogated further:

- v. The Functions of the Board: With the existence of an Authority to oversight over the Regulatory bodies, in this case the Board as provided in Article 7, there ought to be no conflict in their respective roles.
- vi. Address the inconsistencies in the following Articles.  
 Articles 2 (Interpretation), Definition of Community Oral Health, whether it includes curative? That is already provided for in Cap 253  
 Article 17 (1) (a); The Specialists listed in (a) are already regulated in Cap 253  
 Articles 18(1) (No.42 of 2012), 19 of the proposed Bill. These roles are currently be undertaken by certain institutions depending upon whether the courses is being undertaken at a middle level College or University.
- vii. The Draft Health Bill 2014 in Part VI - recognizes Kenya Health Professions Oversight Authority). The proposed Bill will ultimately have to make reference to the Authority.
- viii. The trend currently is that individual health professions are proposing regulatory frameworks including the provisions of regulatory bodies e.g. a Council or a Board. Health professions are numerous, as such different each profession with its own regulating body some of which are close professions may result in a national health system that is confusing, and expensive to maintain. For example the proposed Community Oral Health - creating a statutory body to regulate community Oral Health professional with an existing Medical Practitioners and Dentist Act, CAP 253 with an existing Board to regulate oral health is a bit confusing

Overall, there is a need to stimulate debate and develop consensus on the principles of Health professional regulation and settle on a Kenyan regulatory model.

#### WAY FORWARD.

The committee agreed that, there is need to have further consultation and come up with a model of Health professional regulation.

The Committee resolved that the 3 legislative Proposals; namely; the Biomedical Engineers Bill, 2015, the Health Records and Information Managers Bill, 2014 and the Community Oral Health Officers Bill, 2014 to proceed for publication.

#### MIN.NO.DCH 113/2015      ANY OTHER BUSINESS

The follow matters were raised under this agenda item;

- a) The Committee resolved to go for a retreat in Mombasa during the first week of May 2015 to meet with stakeholders such as the Ministry of Health and the pharmacy and Poisons Board to conclude on the amendments for the Pharmacy Practitioners Bill, 2014. The Committee proposed the following three hotels namely Serena Beach Hotel, Flamingo Beach Hotel and Continental Beach Hotel as the venue for the retreat in order of preference.
- b) The Chair brought to the Committee's attention a proposed motion filed in Parliament by Hon. Abdul Rahim Dawood, MP seeking the government to set up intensive Care Units (ICU) and Blood Transfusion Centres in every Constituency.

#### MIN.NO. DCH 114/2015      ADJOURNMENT

There being no other business the meeting was adjourned at 12.10pm.

SIGNED.....

HON (DR.) RACHAEL NYAMAI, M.P

CHAIRPERSON

DATE:.....