

THE HEALTH BILL, 2014

ARRANGEMENT OF CLAUSES

Clause

PART 1—PRELIMINARY PROVISIONS

- 1—Short title and commencement.
- 2—Interpretation.
- 3—Objects of Act.
- 4—Responsibility for health.
- 5—Standard of health.

PART II—RIGHTS AND DUTIES

- 6—Reproductive health.
- 7—Emergency treatment.
- 8—Health information.
- 9—Consent.
- 10—Information dissemination.
- 11—Confidentiality.
- 12—Health care providers.
- 13—Duty of users.
- 14—Complaints.
- 15—Duties of national government.
- 16—Office of the Director- General.
- 17—Functions of the Director -General.
- 18—Directorates.
- 19—County health system.
- 20—Duties of county executive department of health.
- 21—Coordination.

PART III—PUBLIC HEALTH FACILITIES

- 22—Public health facilities.
- 23—Public-private partnerships.
- 24—Devolution.
- 25—Retention of service provision.
- 26—Classification of levels of healthcare delivery.

**PART IV— ESTABLISHMENT OF THE KENYA HEALTH
PROFESSIONS OVERSIGHT AUTHORITY**

- 27— Establishment of the Authority.
- 28—Composition of the Authority.
- 29— Funds of the Authority.
- 30—Functions of the Authority.
- 31—Relationship with other regulatory bodies.

**PART V—REGULATION OF HEALTH PRODUCTS AND HEALTH
TECHNOLOGIES**

- 32—Establishment of a single health products and technologies body.
- 33— Functions of the single regulatory body.
- 34—Conditions.
- 35—Licences.
- 36—Standards.
- 37—Procurement of health products and technologies.

**PART VI—PROMOTION AND ADVANCEMENT OF PUBLIC
AND ENVIRONMENTAL HEALTH**

- 38—Public and environmental health.
- 39—Policies.

40—Amendment of Cap.242.

PART VII—MENTAL HEALTH

41—Mental health.

**PART VIII—TRADITIONAL AND COMPLEMENTARY
MEDICINES**

42—Promotion of practice.

43—Regulation of practice.

44—Documentation and mapping.

45—Standardization.

46—Charges.

47—Referral.

**PART IX - HUMAN ORGANS, HUMAN BLOOD, BLOOD PRODUCTS,
OTHER TISSUES AND GAMETES**

48—Human organs transplantation.

49— Making of wills.

50— Donation purposes.

51— Revocation of a donation by a donor.

52— Postmortem.

53—Kenya National Blood Transfusion Service.

PART X- HEALTH FINANCING

54—Health finance.

55—Bank account.

PART XI—ROLE PRIVATE SECTOR PARTICIPATION

- 56—Private health services.
- 57—Licensing of private entities to operate hospitals, clinics, etc.
- 58—Private health workers.
- 59—Duty of licensees.
- 60—Partnership agreements.

PART XII—PROMOTION AND CONDUCT OF HEALTH RESEARCH

- 61—National Research for Health Committee.
- 62—Membership.
- 63—Term of office.
- 64—Functions of the Committee.
- 65—Institute.
- 66—Procedures.
- 67—Research approvals.
- 68—Minors.
- 69—Research budget.
- 70—Donor Support and collaborative arrangements.

PART XIII— E- HEALTH

- 71—E-health delivery.
- 72—E-legislation.
- 73—Health information system.

PART XIV—INTER- DEPARTMENTAL COLLABORATION

- 74—Collaboration.
- 75—Training.

76—Fields of Collaboration.

PART XV—TRANSITIONAL AND MISCELLANEOUS PROVISIONS

77—Existing laws.

78—Public service.

79—Regulations.

**FIRST SCHEDULE – TECHNICAL CLASSIFICATION OF THE
LEVELS OF HEALTHCARE DELIVERY**

**SECOND SCHEDULE – PROVISIONS AS TO THE CONDUCT OF
BUSINESS AND AFFAIRS OF THE
AUTHORITY**

**THIRD SCHEDULE – PROVISIONS AS TO THE CONDUCT OF
BUSINESS AND AFFAIRS OF THE
COMMITTEE**

THE HEALTH BILL, 2014

A Bill for

AN ACT of Parliament to establish a unified health system, to coordinate the inter-relationship between the national government and county government health systems, to provide for regulation of health care service and health care service providers, health products and health technologies and for connected purposes.

ENACTED by the Parliament of Kenya as follows—

PART 1— PRELIMINARY

Short title and commencement.

1. This Act may be cited as the Health Act, 2014 and shall come into operation on such date as the Cabinet Secretary may, by notice in the Gazette, appoint.

Interpretation

2. In this Act unless the context otherwise requires—

“abortion” means termination of a pregnancy before the offspring is viable as an independent life outside the womb;

“alternative medicine” means complementary medicine and includes a broad set of health care practices that are not part of that Country’s own tradition and are not integrated into the dominant health care system;

“Authority” means the Kenya Health Professions Oversight Authority established under section 27;

“Board” refers to the Governing Board of the Kenya Health Professions Oversight Authority;

“Cabinet Secretary” means the Cabinet Secretary for Ministry responsible for matters relating to health;

“Committee” means the National Research for Health Committee established under section 61;

“ Director-General” means the Director-General for health appointed under section 16;

“disaster” means but is not limited to an adverse situation or event, which overwhelms local capacity for response and recovery, necessitating external assistance;

“disease” refers to any physical or mental condition that causes pain, dysfunction, distress, social problems or death to the person afflicted or similar problems for those in contact with the person;

“e-Health” means the combined use of electronic communication and information technology in the health sector;

“emergency treatment” refers to necessary immediate health care that must be administered to prevent death or worsening of a medical situation;

“health” refers to a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity;

“health care professional” includes any person who has obtained health professional qualifications and licensed by the relevant regulatory body;

“health care services” means the prevention, promotion, management or alleviation of disease, illness, injury, and other physical and mental impairments in individuals, delivered by health care professionals through the health care system’s routine health services, or its emergency health services;

“health facility” means the whole or part of a public or private institution, building or place, whether for profit or not, that is operated or designed to provide in-patient or out-patient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health service;

“health technology” refers to the application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life;

“human blood products” means any product derived or produced from blood, including plasma, sera, circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;

“informed consent” refers to a process of getting permission before conducting a health care prevention on a person;

“medical emergency” means an acute situation of injury or illness that poses an immediate risk to life or health of a person or has potential for deterioration in the health of a person or if not managed timely would lead to adverse consequences in the well-being;

“private health services” means provision of health

services by a health facility that is not owned by the national or county governments and includes health care services provided by individuals, faith-based organizations and private health institutions;

“public health services” means health services owned and offered by the national and county governments;

“referral” means the process by which a given health facility transfers a client service, specimen and client parameters to another facility to assume responsibility for consultation, review or further management;

“reproductive cloning of a human being” means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose;

“research for health” includes but is not limited to research which seeks to contribute to the extension of knowledge in any health related field, such as that concerned with the biological, clinical, psychological or social processes in human beings improved methods for the provision of health services; or human pathology; or the causes of disease; or the effects of the environment on the human body; or the development or new application of pharmaceuticals, medicines and other preventative, therapeutic or curative agents; or the development of new applications of health technology;

“risk” means probability or threat of damage, injury, liability, loss or any other negative occurrence caused by external or internal vulnerabilities that may be avoided through pre-emptive action;

“telemedicine” refers to the provision of health care services and sharing of medical knowledge over distance using telecommunications and it includes consultative, diagnostic, and treatment services;

“therapeutic manipulation or cloning” means handling of genetic material of zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues;

“tissues” shall include but not limited to the placenta, embryonic or foetal tissue, stem cells and umbilical cord; and

“traditional medicine” includes the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness..

Objects of the Act.

3. The object of this Act is to-

- (a) establish a national health system which encompasses public and private institutions and providers of health services at the national and county levels and facilitate in a progressive and equitable manner, the highest attainable standard of health services;

- (b) protect, respect, promote and fulfill the health rights of all persons in Kenya to the progressive realization of their right to the highest attainable standard of health, including reproductive health care and the right to emergency medical treatment;

- (c) protect, respect, promote and fulfill the rights of children to basic nutrition and health care services contemplated in Articles 43(1) (c) and 53(1) (c) of the Constitution;
- (d) protect, respect, promote and fulfill the rights of vulnerable groups as defined in Article 21 of the Constitution in all matters regarding health; and
- (e) recognize the role of health regulatory bodies established under any written law and to distinguish their regulatory role from the policy making function of the national government.

Responsibility for health.

4. It is a fundamental duty of the State to observe, respect, protect, promote and fulfill the right to the highest attainable standard of health including reproductive health care and emergency medical treatment by *inter alia* -

- (a) developing policies, laws and other measures necessary to protect, promote, improve and maintain the health and well-being of every person;
- (b) ensuring the prioritization and adequate investment in research for health to promote technology and innovation in health care delivery;
- (c) ensuring the realization of the health related rights and interests of vulnerable groups within society, including women, older members of society, persons with disabilities, children, youth, members of minority

or marginalized communities and members of particular ethnic, religious or cultural communities;

- (d) ensuring the provision of a health service package at all levels of the health care system, which shall include services addressing promotion, prevention, curative and rehabilitation, as well as physical and financial access to health care;
- (e) ensuring adequate investment in research for health to promote technology and innovation in health care delivery.

Standard of health.

5. (1) Every person has the right to the highest attainable standard of health which shall include progressive access for provision of promotive, preventive, curative and rehabilitative services.

(2) Every person shall have the right to be treated with dignity, respect and have their privacy respected in accordance with the Constitution and this Act.

PART II - RIGHTS AND DUTIES

Reproductive health.

6. (1) Every person has a right to reproductive health care which includes—

- (a) the right of men and women of reproductive age to be informed about, and to have access to reproductive health services including to safe, effective, affordable

and acceptable family planning services, except elective abortions;

- (b) the right of access to appropriate health-care services that will enable parents to go safely through pregnancy, childbirth, and the post-partum period, and provide parents with the best chance of having a healthy infant;
- (c) access to treatment by a trained health professional for conditions occurring during pregnancy including abnormal pregnancy conditions, such as ectopic, abdominal and molar pregnancy, or any medical condition exacerbated by the pregnancy to such an extent that the life or health of the mother is threatened. All such cases shall be regarded as comprising notifiable conditions.

(2) For the purposes of subsection (1) (c), the term “a trained health professional” shall refer to a health professional with formal medical training at the proficiency level of a medical officer, a nurse, midwife, or a clinical officer who has been educated and trained to proficiency in the skills needed to manage uncomplicated abortion and post-abortion care and in the identification, management and referral of abortion-related complications in women, and who has a valid license from the recognized regulatory authorities to carry out that procedure.

(3) Any procedure carried out under subsection (1) (a) or (1) (c) shall be performed in a legally recognized health facility with an enabling environment consisting of the minimum human resources,

infrastructure, commodities and supplies for the facility as defined in the norms and standards developed under this Act.

Emergency treatment.

7. (1) Every person has the right to emergency medical treatment.

(2) No person shall be denied emergency treatment by the health service provider of first contact provided the provisions of section 54(1)(e) have been implemented.

(3) For the purposes of this section, emergency medical treatment shall include-

- (a) pre-hospital care;
- (b) stabilizing the health status of the individual; or
- (c) arranging for referral in cases where the health provider of first call does not have facilities or capability to stabilize the health status of the victim.

(4) Any health care provider who fails to provide emergency medical treatment while having ability to do so commits an offence and is liable upon conviction to a fine not exceeding one million shillings or imprisonment for a period not exceeding twelve months or both.

(5) Any medical institution that fails to provide emergency medical treatment while having ability to do so commits an offence and is liable upon conviction to a fine not exceeding three million shillings.

Health information.

8. (1) Every health care provider shall inform a user or, where the user of the information is a minor or incapacitated, inform the guardian of the -

- (a) user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
- (b) range of promotive, preventive and diagnostic procedures and treatment options generally available to the user;
- (c) benefits, risks, costs and consequences generally associated with each option; and
- (d) user's right to refuse recommended medical options and explain the implications, risks, and legal consequences of such refusal.

(2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

(3) Where the user exercises the right to refuse a treatment option, the health provider may at its discretion require the user to confirm such refusal in a formal manner.

(4) In this section, the word "user" refers to any person who seeks or intends to seek medical care from a

health care provider and the expression “health care provider” includes any health facility.

Consent.

9. (1) No specified health service may be provided to a patient without the patient’s informed consent unless-

- (a) the patient is unable to give informed consent and such consent is given by a person -
 - (i) mandated by the patient in writing to grant consent on his or her behalf; or
 - (ii) authorized to give such consent in terms of any law or court order;
- (b) the patient is unable to give informed consent and no person is mandated or authorized to give such consent, but the consent is given by the next of kin;
- (c) the provision of a health service without informed consent is authorized by an applicable law or court order;
- (d) the patient is being treated in an emergency situation;
- (e) failure to treat the user, or a group of people which includes the user, will result in a serious risk to public health; or
- (f) any delay in the provision of the health

service to the patient might result in his or her death or irreversible damage to his or her health and the patient has not expressly, or by implication or by conduct refused that service.

(2) A health care provider must take all reasonable steps to obtain the user's informed consent.

(3) For the purposes of this section "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as provided for in section 8 of this Act.

Information
dissemination.

10. The national government, county governments and every organ having a role or responsibility within the National Health System, shall ensure that appropriate, adequate and comprehensive information is disseminated on the health functions for which they are responsible being cognizant of the provisions of Article 35 (1) (b) of the Constitution, which must include-

- (a) the types, availability and cost if any of health services;
- (b) the organization of health services;
- (c) operating schedules and timetables of visits;
- (d) procedures for access to the health services;
- (e) procedures for laying complaints;

- (f) the rights and duties of users and health care providers under this Act and as provided for in the applicable service charters; and
- (g) management of environmental risk factors to safeguard public health.

Confidentiality.

11. (1) Information concerning a user, including information relating to his or her health status, treatment or stay in a health facility is confidential except where such information is disclosed under order of court or informed consent for health research and policy planning purposes.

(2) Subject to the Constitution and this Act, no person may disclose any information contemplated in subsection (1) unless-

- (a) the user consents to such disclosure in writing in the prescribed form;
- (b) a court order or any applicable law requires such disclosure; or
- (c) non-disclosure of the information represents a serious threat to public health.

(3) Any proposed disclosure of information under subsection 2 (c), shall be subject to regulations published by the Cabinet Secretary of health, from time to time

Healthcare providers.

12. (1) The Rights and duties of healthcare providers shall include -

- (a) not to be unfairly discriminated against on account of their health status;

- (b) the right to a safe working environment that minimizes the risk of disease transmission and injury or damage to the health care personnel or to their clients, families or property;
- (c) the right to refuse to treat a user who is physically or verbally abusive or who sexually harasses him or her except in an emergency situation where no alternative health care personnel is available;
- (d) the right to apply for and accept a salaried post in the public service or the private sector.

(2) All healthcare providers, whether in the public or private sector, shall have the duty -

- (a) to provide health care, conscientiously and to the best of their knowledge within their scope of practice and ability, to every person entrusted to their care or seeking their support;
- (b) to provide emergency medical treatment as provided for under section 7(2);
- (c) to inform a user of the health system, in a manner commensurate with his or her understanding, of his or her health status:

Provided that where this would be contrary to the best interests of the user, then

in such cases, the requisite information should be communicated to the next of kin or guardian as case may be.

(3) Notwithstanding the provisions of section 12 (1) (a), the head of any health facility may impose conditions on the service that may be provided by a health care provider taking into account his or her health status.

Duty of users.

13. A user of the health system has the duty, in so far as it is within users -

- (a) to adhere to the rules of a health facility when receiving treatment or using the health services provided by the establishment;
- (b) to adhere to the medical advice and treatment provided by the establishment;
- (c) to supply the healthcare provider with accurate information pertaining to his or her health status;
- (d) to cooperate with the healthcare provider;
- (e) to treat healthcare providers and health workers with dignity and respect;
- (f) if so requested, to sign a discharge certificate or release of liability if he or she refuses to accept or implement recommended treatment.

Complaints.

14. (1) Any person has a right to file a complaint about the manner in which he or she was treated at a health facility and have the complaint investigated appropriately.

(2) The relevant national and county governments shall establish and publish the procedure for the laying of complaints within public and private health care facilities in those areas of the national health system for which they are responsible.

(3) The procedures for laying complaints shall-

(a) be displayed by all health facilities in a manner that is visible for any person entering the establishment and the procedure must be communicated to users on a regular basis; and

(b) be primarily handled by the head of the relevant facility or any person designated by the facility as responsible for handling user complaints.

(4) Every complainant under subsection (1) has a right to be informed, in writing and within a period of three months from the date the complaint was lodged, of the action taken or decision made regarding the complaint.

(5) Where a health facility or a regulatory body fails to resolve a complaint to the satisfaction of the complainant, the Authority shall take necessary action.

Duties of national government.

15. (1) The national government ministry responsible for health shall –

- (a) ensure the development and regular updating of a national health policy and government legal framework following the letter and spirit of the Constitution, issue guidelines for its application and promote its implementation at all levels;
- (b) develop and maintain an organizational structure of the Ministry at the national level comprising of technical directorates;
- (c) ensure the implementation of rights to health specified in the Bill of Rights, and more particularly the progressive realization of the right of all to the highest attainable standard of health including reproductive health care and the right to emergency treatment;
- (d) ensure, in consultation and collaboration with other arms of government and other stakeholders, that there is stewardship in setting policy guidelines and standards for human food consumption, dietetic services;
- (e) offer technical support at all levels with emphasis on health system strengthening;
- (f) develop and implement measures to promote equitable access to health services to the entire population, with special emphasis on eliminating the disparity in realization of the objects of this Act for marginalized areas and disadvantaged populations;

- (g) develop and promote application of norms and standards for the development of human resources for health including affirmative action measures for health workers working in marginalized areas;
- (h) provide for medical audit of deaths with a special emphasis on maternal and neonatal deaths as a tool for the further development of obstetric and neonatal care;
- (i) develop, through regulatory bodies, standards of training and institutions providing education to meet the needs of service delivery;
- (j) set guidelines for the designation of national and county referral health facilities;
- (k) through respective regulatory bodies to develop and ensure compliance on professional standards on registration and licensing of individuals in the health sector;
- (l) coordinate development of standards for quality health service delivery;
- (n) provide for accreditation of health services;
- (o) coordinate all health aspects of disaster and emergencies;
- (p) ensure through intergovernmental mechanisms that financial resources are mobilized to ensure uninterrupted access to

quality health services country wide;

- (q) promote the development of public and private health institutions to ensure their efficient and harmonious development and in the common interest work towards progressive achievement of the right to health;
- (r) provide for the development and expansion of a countrywide national health information management system;
- (s) facilitate all forms of research that can advance the interests of public health;
- (t) develop and manage the national health referral facilities;
- (u) promote the use of appropriate health technologies for improving the quality of health care;
- (v) collaborate in the common interest with the health authorities of other countries and with regional and international bodies in the field of health;
- (w) establish an emergency medical treatment fund
for emergencies to provide for unforeseen situations calling for supplementary finance;
and
- (x) provide policy guidelines in public-private partnerships for health to enhance private sector

investment.

(2) The Cabinet Secretary responsible for Health shall make regulations on any matter where it is necessary or expedient in order -

(a) to implement any provision of this Act; and

(b) to implement within Kenya measures agreed upon within the framework of any treaty, international convention or regional intergovernmental agreement to which Kenya is a party.

Office of the
Director -General.

16. (1) There shall hereby be established the office of the Director-General for health.

(2) The Director-General for health shall be recruited through a competitive process in conformity with the rules and regulations set from time to time by the Public Service Commission of Kenya.

(3) A person appointed under subsection (2) must-

(a) be a medical practitioner registered by the Medical Practitioners and Dentists Board;

(b) at least be a holder of a Masters degree in public health, medicine or any other health related field;

(c) have experience of at least ten years in management of health services, five of

which must be at a senior management position; and

(d) meet the provisions of Chapter Six of the Constitution of Kenya.

(4) The Director-General shall hold office for a period of five (5) years.

Functions of the
Director-General.

17. The Director-General shall-

- (a) be the technical advisor on all the matters relating to health within the health sector;
- (b) be the technical advisor to the Cabinet Secretary of health;
- (c) be responsible for preventing and guarding against the introduction of infectious diseases into Kenya;
- (d) promote the public health and the prevention, limitation or suppression of infectious, communicable or preventable diseases within Kenya;
- (e) advice and direct the National and County Governments on matters affecting public health;
- (f) promote and facilitate research and investigations in connection with the prevention or treatment of human diseases;
- (g) prepare and publish reports and statistical or

other information relative to the public health;

- (h) obtain and publish periodically information on infectious diseases and other health matters and such procurable information regarding epidemic diseases in territories adjacent to Kenya or in other Countries as the interests of public health may require;
- (i) register, license and gazette all health facilities;
- (j) be responsible of internship program for health workers;
- (k) supervise the directorates within the national Ministry of health; and
- (l) perform any other duties as may be assigned by the appointing authority and any other written law.

Directorates.

18. For the purposes of section 15 (1) (b) of this Act, the directorates shall be formed by the Cabinet Secretary based on policy priority areas.

County health system.

19. (1) There shall be established with respect to every county, a county executive department responsible for health, which shall be in line with the health policy guidelines for setting up county health system and shall in all matters be answerable to the Governor and the County Assembly subject to the provisions of the Constitution and of any applicable written law.

(2) There shall be established the office of the County Director of health who shall be a technical advisor on all

matters of health in the County.

(3) The County Director of health shall be recruited through a competitive process in conformity with the rules and regulations set from time to time by the County Public Service Board.

(4) A person appointed a County Director of health shall-

- (a) be a medical practitioner registered by the Medical Practitioners and Dentists Board;
- (b) be at least a holder of a Masters degree in public health, medicine or any other health related discipline; and
- (c) have at least five (5) years experience in management of health services.

(5) The County Director of health shall-

- (a) be the technical advisor on all matters relating to health within the County;
- (b) be the technical advisor to the County Executive Commissioner and the Governor;
- (c) supervise all health services within the County;
- (d) promote the public health and the prevention, limitation or suppression of infectious, communicable or preventable

diseases within the County;

- (e) prepare and publish reports and statistical or other information relative to the public health within the County;
- (f) report periodically to the Director-General for health on all public health occurrences including disease outbreaks, disasters and any other health matters; and
- (g) perform any other duties as may be assigned by the appointing authority and any other written law.

Duties of county executive department for health.

20. The county executive department responsible for health shall, in furtherance of the functions assigned to it under Fourth Schedule of the Constitution be responsible for—

- (a) implementing the national health policy and standards as laid down by national government Ministry responsible for health;
- (b) service delivery, including the maintenance, financing and further development of those health services and institutions that have been devolved to it;
- (c) coordination of health activities in order to ensure complementary inputs, avoid duplication and provide for cross-referral, where necessary to and from institutions in other counties;

- (d) facilitating registration, licensing and accreditation of providers and health facilities respectively according to standards set nationally by the national government department responsible for health and relevant regulatory bodies;
- (e) designation of county referral hospitals according to criteria agreed upon by the intergovernmental health coordinating mechanism;
- (f) developing and implementing, in consultation with the Salaries and Remuneration Commission, such policies as may be necessary to guarantee the staffing of the public health service in marginal areas including taking into account the use of equalization fund;
- (g) procuring and managing health supplies;
- (h) maintaining standards of environmental health and sanitation as laid down in applicable law;
- (i) providing access and practical support for monitoring standards compliance undertaken within the county by the national government department responsible for health, the Authority and professional regulatory bodies established under any written law;
- (j) providing access and practical support for technical assistance, monitoring and

evaluation, research for health by the national and county government department responsible for health;

- (k) developing supplementary sources of income for the provision of services, in so far as these are compatible with the applicable law;
- (l) making due provision to compensate health care facilities for debts arising through failure to secure payment for bills;
- (m) reporting, according to standards established by law, on activities, development and the state of finance within the county health services;
- (n) making known to the public at all times the health facilities through which generalized or specialized services are available to them;
- (o) developing and promoting public participation in the planning and management of local health facilities so as to promote broad ownership;
- (p) ensuring and coordinating the participation of communities in the governance of health services at the county level so as to promote a participatory approach in health care governance.

Coordination.

21. The National Health System shall work in a manner that respects the distinct levels of government,

while respecting the principles of cooperation and coordination as outlined in this Act and in legislation regulating the relationships and functions of the county and national government.

PART III- PUBLIC HEALTH FACILITIES

Public health facilities.

22. The national and county governments shall ensure the progressively equitable distribution throughout the country of such publicly owned health institutions, including hospitals, health centers, pharmacies, clinics and laboratories, as are deemed necessary for the promotive, preventive and rehabilitative health services.

Public private partnership.

23. Notwithstanding the provisions of section 35 and subject to any other law regulating public-private partnerships, nothing under this Act shall prevent the national and county governments from entering into public-private partnerships for the purpose of establishing and deepening health service provision.

Devolution.

24. Subject to section 15 of the Sixth Schedule to the Constitution, the management, operation and further development of public health facilities institutions shall be devolved progressively to the county government, and in assessing suitability of devolution to a given county the following considerations shall apply -

- (a) the eligibility and capacity of a given county to assume the responsibility involved; and
- (b) maintenance of access to any such devolved institution by authorized bodies.

Retention of service provision.

25. Without prejudice to the distribution of health functions and services between the national and county levels of government as set out in Fourth Schedule of the Constitution, the national Government shall manage and be responsible for—

- (a) any public health institution classified as a national referral facility under this Act;
- (b) any institution or health facility engaged in such specialized health activities as can only be provided effectively and efficiently at the national level;
- (c) any institution or service dependent for its function on expertise that is a shared resource as classified from time to time in regulations under this Act;
- (d) laboratories and other institutions designated as serving a national rather than a regional purpose;

- (e) regulation of health products and health technologies including assessment, licensing and control of commercial and industrial activities;
- (f) facilitation through inter-governmental institutions, procurement and supply chain management of public health goods including vaccines, pharmaceutical and non-pharmaceuticals for the purpose of ensuring control of highly infectious and communicable health conditions, putting measures for quality assurance and standards as well as measures for guarding against resistance strains in the interest of public health; and
- (g) any health care function or service that is not otherwise assigned to the county government.

classification of levels of health care.

26. The technical classification of levels of health care shall be as set out in the First Schedule.

**PART IV – ESTABLISHMENT OF THE
KENYA HEALTH PROFESSIONS OVERSIGHT
AUTHORITY**

Establishment of the Authority.

27. (1) There is hereby established the Kenya Health Professions Oversight Authority charged with the responsibility of providing an oversight role to the regulatory function of the national health system and ensuring the adequate co-ordination of joint activities of regulatory bodies within the health sector.

(2) The Authority shall be a body corporate with perpetual succession and a common seal and capacity to sue and be sued in its own name and to acquire and alienate property.

Composition of the Authority.

- 28.** (1) The Authority shall comprise -
- (a) a chairperson who shall be appointed by the Cabinet Secretary and shall be a health professional who meets the requirements of Chapter six of the Constitution of Kenya;
 - (b) the Principal Secretary of the Ministry of health or his representative;
 - (c) the Director-General for health or his representative;
 - (d) the Attorney General or his representative;
 - (e) one member nominated by each of the health regulatory bodies established under an Act of Parliament;
 - (f) three representatives nominated by the health professional associations registered by the Registrar of Societies who are not regulated or registered by any regulatory body;
 - (g) one representative from the private sector appointed by the Cabinet Secretary;
 - (h) one representative from consumer rights bodies appointed by the Cabinet Secretary; and

- (i) the Chief Executive Officer, appointed by the Authority, through a competitive process and who shall be the secretary to the Authority.

(2) The Authority shall be supported by a Secretariat which shall be headed by the Chief Executive Officer.

(3) The powers of the Authority shall be vested in the advisory Board.

(4) The business and affairs of the Authority shall be conducted in accordance with the Second Schedule.

Funds of the Authority.

29. (1) The Authority shall prepare an annual estimate of revenue and expenditures and submit the same to the Ministry for inclusion in the estimates of revenue and expenditure submitted by the Ministry.

(2) The funds of the Authority shall comprise of money appropriated by Parliament, loans or grants received for its activities and other revenues or fees collected from its activities.

Functions of the Authority.

30. The Authority shall -

- (a) maintain a master register of all health professionals working within the National Health System;
- (b) promote and regulate inter-professional liaison between statutory regulatory bodies;

- (c) coordinate joint inspections with all regulatory bodies;
- (d) receive and facilitate the resolution of complaints from patients, aggrieved parties and regulatory bodies;
- (e) ensure the execution of respective mandates and functions of regulatory bodies recognized under an Act of Parliament;
- (f) arbitrate disputes between statutory regulatory bodies, including conflict or dispute resolution amongst Boards and Councils; and
- (g) ensure the necessary standards for health professionals are not compromised by the regulatory bodies.

Relationship with other regulatory bodies.

31. (1) The obligation to inspect, monitor and evaluate the standard of performance in all the services regulated and professionals engaged in the health sector, both public and private shall be undertaken by the respective regulatory bodies provided that they are not in conflict with the functions of the Authority as stipulated in this Act or under any other written [law](#).

(2) For the avoidance of doubt the regulatory bodies referred to in subsection (1) shall include—

- Cap.260 (a) the Clinical officers Council established under the Clinical Officers Act;
- Cap.257 (b) the Nursing Council of Kenya established

- under the Nurses Act;
- No. 10 of 1999. (c) the Kenya Medical Laboratory Technicians and Technologists Board established under the Medical Laboratory Technicians and Technologists Act;
- Cap.253. (d) the Medical Practitioners and Dentists Board established under the Medical Practitioners and Dentists Act;
- Cap. 243. (e) the Radiation Protection Board established under the Radiation Protection Act;
- Cap.244. (f) the Pharmacy and Poisons Board established under the Pharmacy and Poisons Act;
- Cap. 253B. (g) the Council of the Institute of Nutritionists and Dieticians established under the Nutritionists and Dieticians Act, 2007;
- No. 12 of 2013. (h)
(i) the Public Health Officers and Technicians Council established under the Public Health Officers (Training, Registration and Licensing) Act; and
(j) any other body as may be prescribed by the Cabinet Secretary under this Act.

PART V - REGULATION OF HEALTH PRODUCTS AND HEALTH TECHNOLOGIES

Establishment of a single regulatory body for health products and technologies.

32. There shall be established by an Act of Parliament, a single regulatory body for regulation of health products and health technologies.

Functions of the regulatory body.

33. (1) The regulatory body shall –

- (a) licence health products and health technologies;
- (b) licence manufacturers and distributors of health products;
- (c)
- (d) conduct laboratory testing and inspection of manufacturing, storage and distribution facilities of health products and technologies;
- (e)
- (f) control of clinical trials;
- (g)
- (h) conduct advertising and promotion, post marketing surveillance for quality, safety and disposal of health products and health technologies ;
- (i)
- (j) regulate contractors for medical devices and physical security for products including radioactive material and biological weapons.

(2) The classes of products governed by legislation shall extend to therapeutic feeds and nutritional formulations.

Conditions.

34. Legislation under section 32 shall provide for the granting of marketing approval only by a technically competent body after appropriate assessment has

established that such a product meets generally recognized standards and approval may be made subject to conditions, notably with respect to the conduct and content of promotion and advertising.

Licences.

35. (1) No person, firm or institution may engage in one or more of the activities specified in section 33(1) whether by way of trade or otherwise, unless one has a valid licence granted by the single regulatory body established under this Part.

(2) Any person, firm or institution in the possession of such a licence shall display the same at a conspicuous place and shall produce the same for inspection when required to do so by any officer from the single regulatory body established under this Act.

Standards.

36. Any medicine, vaccine or other health product and technology intended for sale to members of the public shall be eligible for licensing only if-

- (a) after due assessment, it is found to achieve the therapeutic or the intended effect it claims to possess or which may reasonably be attributed to it;
- (b) it is sufficiently safe under the normal conditions of use;
- (c) it is made and packaged according to satisfactory standards.

Procurement of health products and technologies.

37. (1) The procurement for the public health services of health products and technologies shall be undertaken in line with the Public Procurement and Disposal Act as well as the inter-governmental

arrangements for medicine and medical products agreed upon where the Kenya Medical Supplies Authority is the primary provider

(2) The classes of products procured by Kenya Medical Supplies Authority shall extend to therapeutic feeds and nutritional formulations.

(3) The Kenya Medical Supplies Authority may be the point of first call for procurement of health products at the county national referral level and it shall endeavor to establish branches within each county at such locations as it may determine.

(4) The national government shall provide guidelines for the procurement, distribution and management of health products and technologies including essential medicines, laboratory chemicals and reagents and non-pharmaceuticals at all levels of the national health system.

PART VI - PROMOTION AND ADVANCEMENT OF PUBLIC AND ENVIRONMENTAL HEALTH

Public and environmental health.

38. (1) The National health system shall devise and implement measures to promote health and to counter influences having an adverse effect on the health of the people including—

- (a) interventions to reduce the burden imposed by communicable and non-communicable diseases and neglected diseases, especially among marginalized and indigent population;

- (b) interventions to promote healthy lifestyle including physical activity, counter the excessive use of alcoholic products and the adulteration of such products, reduce the use of tobacco and other addictive substances and to counter exposure of children and others to tobacco smoke;
 - (c) the promotion of supply of safe foodstuffs of sufficient quality in adequate quantities and the promotion of nutritional knowledge at all population levels;
 - (d) general health education of the public;
 - (e) a comprehensive programme to advance reproductive health including—
 - (i) effective family planning services;
 - (ii) implementation of means to reduce unsafe sexual practices;
 - (iii) adolescence and youth sexual and reproductive health;
 - (iv) maternal and neo- natal and child health;
 - (v) elimination of female genital mutilation; and
 - (vi) maternal nutrition and micro nutrient supplementation.
- (2) The national health system shall ensure that measures for managing environmental risk factors to

curtail occurrence and distribution of diseases are put in place and implemented. In particular such measures shall target—

- (a) the reduction of disease burden arising from poor environmental hygiene, sanitation, occupational exposure and environmental pollution;
- (b) the reduction of morbidity and mortality of waterborne, foodborne and vector transmitted diseases, and mitigate the health effects of climate change;
- (c) the reduction of morbidity, mortality, prolonged hospital stays, long-term disabilities, antibiotic resistance that emanate from health care acquired infections;
- (d) the strengthening of national and county capacity to address or forestall transmission of diseases of international concern; and
- (e) building community capacity in providing solutions to public health challenges.

Policies.

39. (1) Pursuant to meeting the objects set out in section 38, the national government department of health shall formulate national strategic and operation policies that shall provide for measures that include—

- (a) ensuring and promoting the provision of quarantine especially in ports, borders and frontiers health services;

- (b) ensuring that food and water available for human consumption are hygienic and safe;
- (c) ensuring houses, institutions, hospitals and other public places maintain environment to the highest level of sanitation attainable to prevent, reduce or eliminate environmental health risks;
- (d) developing risk-based, sustainable, integrated food safety systems, occupational health practices, water safety systems, appropriate housing, and vector and vermin control;
- (e) strengthening infection prevention and control systems including health care waste management in all health facilities;
- (f) mobilizing resources including human resources for action;
- (g) public education and participation;
- (h) promoting the public health and the prevention, limitation or suppression of preventable diseases including communicable and non-communicable, diseases neglected within Kenya;
- (i) ensuring provision of environmental health and sanitation mechanisms to prevent and guard against the introduction of infectious disease into Kenya from outside;
- (j) dissemination of public health guidelines to counties in regard to matters affecting the

public health from the environment and sanitation;

- (k) promoting disease surveillance in connection with the prevention of environmental, food, water and sanitation related diseases; and
- (l) addressing all issues pertaining to environmental hygiene and sanitation.

Amendment of
Cap. 242.

40. The Public Health Act is amended by deleting the expression “Director of Medical Services” and substituting therefor the expression “Director-General for health”, wherever it appears.

PART VII - MENTAL HEALTH

Mental health.

41. Appropriate legislation shall be developed by the National government department of health to-

- (a) protect the rights of any individual suffering from any mental disorder or condition;
- (b) ensure the custody of such persons and the management of their estates as necessary;
- (c) establish, manage and control mental hospitals having sufficient capacity to serve all parts of the country;
- (d) advance the implementation of other measures introduced by specific legislation in the field of mental health; and
- (e) ensure research is conducted to indentify

the factors associated with mental health.

**PART VIII - TRADITIONAL AND
ALTERNATIVE MEDICINE**

Promotion of practice.

42. (1) The national government department of health shall formulate policies to guide the practice of traditional and alternative medicine.

(2) The county executive department for health shall ensure implementation of any policies thereto.

Regulation of practice .

43. (1) There shall be established regulatory body by an Act of Parliament, to regulate the practice of African traditional medicine and alternative medicine.

(2)The regulatory body shall, maintain a register at both the national and county levels.

(3)The regulatory body in consultation with the National government department for health shall set the minimum standards of practice for African traditional medicine and alternative medicine.

(4)The regulatory body shall be responsible for registration, licensing and standards compliance of practice in traditional and alternative medicine.

Documentation and mapping.

44. The regulatory body shall institute measures for documentation and mapping of traditional and alternative medicine practice and the county executive departments for health shall facilitate the mapping of traditional and alternative medicine.

Standardization.

45. The national government department for

health shall, in consultation with key stakeholders develop policies for standardization of traditional and alternative medicine practice.

Charges.

46. The charges levied on the practice of traditional medicine shall be approved by the Authority in consultation with statutory bodies.

Referral.

47. The national government department of health shall develop policy guidelines for referral mechanisms and a system of referrals from practitioners of traditional and alternative medicine to conventional health facilities and may prescribe regulations for incidental and connected purposes which shall be implemented by county departments.

**PART IX - HUMAN ORGANS, HUMAN BLOOD,
BLOOD PRODUCTS, OTHER TISSUES AND
GAMETES**

Human organs
transplantation.

48. (1) No person shall remove tissue from a human being for transplantation in another human being or carry out the transplantation of such tissue except -

(a) in a duly authorized health facility for that purpose; and

(b) on the written authority of -

(i) the medical practitioner in charge of clinical services in that health facility or any other medical practitioner authorized by him or her; or

(ii) in the case where there is no medical

practitioner in charge of the clinical services at that health facility, a medical practitioner authorized by the person in charge of the hospital.

(2) The medical practitioner mentioned subsection (1) (b) shall not be the lead participant in a transplant for which he or she has granted authorization under that subsection.

(3) The Cabinet Secretary shall prescribe through regulations-

(a) the criteria for the approval of organ transplant facilities; and

(b) the procedural measures to be applied for such approval.

(4) (a) Any person who contravenes the provision of this section or fails to comply therewith or who charges a fee for a human organ commits an offence.

(b) Any person convicted of an offence under paragraph (a) is liable on conviction to a fine not exceeding one million shillings or to imprisonment for a period not exceeding five years or to both a fine and imprisonment.

Making of wills.

49. (1) (a) A person who is competent to make a will may-

(i) in the will; or

- (ii) in a document signed by him or her in the presence of at least two competent witnesses who are present when he or she signs and signed by them in his or her presence; or
- (iii) in an oral statement made in the presence of at least two competent witnesses,

donate his or her body or any specified tissue thereof to be used after his or her death, or give consent to the post mortem examination of his or her body, for any purpose provided for in this Act.

- (b) A person who makes a donation as contemplated in paragraph (a) must nominate an institution or a person contemplated under this Act.
- (a) If no donee is nominated in terms of paragraph (b), the donation shall be null and void.
- (d) Paragraph (b) does not apply in respect of an organ donated for the purposes contemplated in section 48(1) and the donee of such organ must be determined as provided in section 48(2).

(2) In the absence of a donation under subsection (1) (a) or of a contrary direction given by a person whilst alive, the spouse, partner, elder child, parent, guardian, elder brother or sister of that person, in the specific order mentioned, may, after that person's death, donate the body or any specific tissue of that person to an

institution or a person contemplated in this subsection.

(3) (a) The Cabinet Secretary may, after the death of a person and if none of the persons contemplated in subsection (2) can be located, donate the body or part or any specific tissue of that person to an institution or a person contemplated in section 49(2).

(b) The Cabinet Secretary shall only allow the donated tissue to be used if all the prescribed steps have been taken to locate the persons contemplated in subsection (2).

Donation purposes.

50. (1) A donation under section 51 may only be made for-

- (a) the purposes of the training of students in health sciences;
- (b) the purposes of health research;
- (c) the purposes of the advancement of health sciences;
- (d) therapeutic purposes, including the use of tissue in any living person; or
- (e) the production of a therapeutic, diagnostic or prophylactic substance.

(2) This Part does not apply to the-

- (a) preparation of the body of a deceased

person for the purposes of embalming;

(b) making of incisions in the body for the infusion thereof by a preservative; or

(c) restoration of any disfigurement or mutilation of the body before its burial.

Revocation.

51. A donor may, prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way in which it was made or, in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document.

Postmortem.

52. (1) Subject to subsection (2), a post mortem examination of the body of a deceased person may be conducted if -

- a) the person when alive gave consent thereto;
- (b) the spouse, partner, major child, parent, guardian, major brother or major sister of the deceased, in the specific order mentioned, gave consent thereto; or
- (c) such an examination is necessary for determining the cause of death.

(2) A post mortem examination may not take place unless-

- (a) the medical practitioner in charge of clinical services in the hospital or authorized institution or of the mortuary in question, or any other medical practitioner authorized by such practitioner; or

(b) in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorized by the person in charge of such hospital or authorized institution,
authorizes the post mortem examination in writing and in the prescribed manner.

Kenya National Blood
Transfusion
Service.

53. (1) There shall be established by an Act of Parliament, a body to be known as the Kenya National Blood Transfusion Service.

(2) The legislation contemplated under subsection (1) shall provide for among other things, the institutional organization of blood transfusion service within the Republic of Kenya.

(3) The Service shall be charged with the mandate of developing a comprehensive and coordinated national blood service based on voluntary non remunerated blood donations so as to guarantee availability of adequate and safe blood.

(4) The Service shall establish settings and mechanisms that will enable it superintend, regulate and provide blood transfusion services in the Republic of Kenya as required by this Act or any other written law.

(5) Any person who contravenes the provisions of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine not exceeding one million Shillings or to imprisonment for a term not exceeding five years or to both fine and imprisonment.

PART X - HEALTH FINANCING

Health finance.

54. (1) The Ministry of health shall ensure progressive financial access to universal health coverage by taking measures that include—

- (a) developing mechanisms for financial and risk pooling to progressively reduce the out of pocket expenditure;
- (b) developing mechanisms for an integrated national health insurance system, including making provisions for social health protection and health technology assessment;
- (c) establishing in collaboration with the department responsible for finance oversight mechanism to regulate all health insurance providers;
- (d) developing policies and strategies that ensure realization of universal health coverage;
- (e) defining, in collaboration with the department responsible for finance, public financing of health care framework, including annual allocations towards reimbursing all health care providers responding to disasters and emergencies as contemplated under this Act;
- (f) establishing in collaboration with the ministries responsible for finance, planning and any other relevant

department to secure health care for vulnerable groups and indigents;

- (g) determining, during each financial period and in consultation with individual county authorities, cost sharing mechanisms for services provided by the public health system without significantly impeding the access of particular population groups to the system in the areas concerned;
- (h) examining means of optimizing usage of private health services as a result of relieving the burden carried by the publicly financed system; and
- (i) establishing a harmonized common mechanism for coordinating planning and financing and monitoring and evaluation within the health sector.

Bank account.

55. The National Treasury shall facilitate the opening and maintenance of a bank account for purposes of operationalizing conditional grants, donations and any other monies for every health facility both at national and county levels in line with public financial management Regulations.

PART XI - THE PRIVATE SECTOR PARTICIPATION

Private health services.

56. (1) The Cabinet Secretary shall pursue strategies conducive to the development of private health

services and their attunement to the needs of the population.

(2) The public and private health services and facilities shall complement each other in the provision of comprehensive and accessible health care to the people.

Licensing of private entities to operate hospitals, clinics, etc.

57. (1) Private entities shall be permitted to operate hospitals, clinics, laboratories and other institutions in the health sector, subject to licensing by the appropriate regulatory bodies.

(2) The standards to be met in order to qualify for the issue of an operational licence under this section and the conditions that may be attached to such a licence shall be as defined in regulations issued under this Act by the Cabinet Secretary.

Private health workers.

58. Private health workers appropriately qualified to practice any health profession shall similarly be entitled to practice their profession in Kenya, subject to licensing by the appropriate regulatory bodies.

Duty of licensees.

59. Institutions licensed under section 57 and private health workers licensed under section 58 shall irrespective of any specific conditions attached to such a licence be bound -

- (a) to permit and facilitate inspection at any time by the Authority and regulatory bodies;
- (b) to provide emergency services in their field of expertise required or requested either by individuals, population groups or

institutions, without regard to the prospect or otherwise of direct financial reimbursement.

Partnership agreements.

60. (1) Where appropriate, and subject to the provisions of the Public Private Partnerships Act, the Cabinet Secretary and the County Governors shall be entitled to enter into partnership agreements with companies operating in the private sector in order to develop specific services or facilities that will serve the needs of public health.

(2) Counties or individual facilities may similarly enter into agreements of this type with the private sector subject to the provisions of the Public Private Partnerships Act.

PART XII - PROMOTION AND CONDUCT OF RESEARCH FOR HEALTH

Establishment of the National Research for Health Committee.

61. (1) There shall be established by the Cabinet Secretary, a National Research for Health Committee which shall be a technical committee.

(2) The membership of the Committee shall be as provided for under section 62 and shall consist of not more than eleven members appointed by the Cabinet Secretary.

Membership.

62. (1) The membership of the Committee established under this section shall as much as possible reflect ethnic, gender, county and regional balance and shall include membership drawn from the following -

- (a) the chairperson who shall be a distinguished health researcher and

renowned in a health discipline;

- (b) one representative from Kenya Medical Research Institute;
- (c) one representative from the National Commission for Science, Technology and Innovation;
- (d) head of the directorate of the Ministry of health responsible for research and development;
- (e) one representative from the Authority;
- (f)
- (g) two representatives from public universities;
- (h) one representative from private universities
- (i) one research expert with orientation to traditional and alternative medicine;
- (j) one research expert with orientation in clinical trials; and
- (k) one distinguished bio-medical science researcher.

Term of office.

63. (1) The term of office of the Chairperson shall be five years, renewable for one further term of five years.

(2) The chairperson may resign through a letter addressed to the Cabinet Secretary.

(3) A member of the Committee shall hold office for a term of three years, renewable for one further term of three years.

(4) A member of the Committee may resign through a letter addressed to the Cabinet Secretary.

Functions of the
Committee.

64. (1) The Committee shall make recommendations on the development on the national research for health policy and on the various priorities to be accorded in the area of research for health in the light of current knowledge and needs, recognized priorities and economic resources.

(2) In identifying research for health priorities, the Committee shall give due regard to—

- (a) the burden of disease;
- (b) the cost-effectiveness of interventions aimed at reducing the burden of disease;
- (c) the availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities;
- (d) the health needs of vulnerable groups such as women, older persons, children and people with disabilities;
- (e) the health needs of communities;
- (f) national security; and

(g) emerging issues on health.

(3) The Committee shall have the responsibility to –

- (a) determine the extent of research for health to be carried out by public and private health authorities whether national or international;
- (b) ensure that research for health agenda and research resources focus on priority health problems;
- (c) develop and advise the Cabinet Secretary on the application and implementation of an integrated national policy and strategy for health research;
- (d) ensure that the intellectual property benefits arising from any health research conducted in the country are commensurately enjoyed by all involved parties;
- (e) ensure resource mobilization or budget allocation for the National Research Fund for the established research for health priorities;
- (f) create a framework for linking research outcomes into policy and legislation; and
- (g) enhance capacity building and strengthening in the research for health activities.

(4) The Committee shall execute its functions through the head of the directorate of the Ministry of health responsible for research and development who shall be its secretary.

Institute.
Cap. 250

65. (1) The Kenya Medical Research Institute established under the Science and Technology Act shall review its programmes to optimally attune to the health interests of the population and the overall programme of health research.

(2) The Committee shall collaborate with other research organizations to make recommendations for the formulation of the national health policy.

Procedures.

66. Except as may be provided in the Third Schedule, the Committee may regulate its own procedure.

Research Approval.

67. (1) Where medical and scientific research is to be conducted on human subjects, details shall in all cases be submitted as per the regulations articulated under the Commission for Science, Technology and Innovation established under the Science and Technology Act.

(2) The Committee shall give ethical clearance on all health research approvals.

Minors.

68. (1) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted-

(a) if it is in the best interest of the minor;

(b) in such manner and on such conditions as may be prescribed; and

(c) with the informed written consent of the parent or guardian of the minor.

(2) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted –

(a) in such manner and on such conditions as may be prescribed by the Committee; and

(b) with the informed written consent of the parent or guardian of the minor.

(3) Parliament shall enact legislation to give full effect to the provisions of this Part.

Research budget.

69. Having regard to the necessity of both scientific and policy research in the field of health in Kenya, a portion of not less than 30% of the National Research Fund shall be allocated for health research.

Donor support
and collaborative
arrangements

70. Notwithstanding the responsibility of national government under section 60 of this Act, non-governmental and international organizations may cooperate with research institutions including the Kenya Medical Research Institute, universities and health institutions with approval from the Committee in providing support for promotion and conduct of health research.

PART XIII – E - HEALTH

E-health delivery.

71. E- Health shall be a recognized mode of health

service.

E-legislation.

72. The Cabinet Secretary shall, in consultation with the Director-General for health ensure the enactment of legislation that provides for among other things -

- (a) administration of health information banks including interoperability framework, data interchange and security;
- (b) collection and use of personal health information;
- (c) management of disclosure of personal health information;
- (d) protection of privacy;
- (e) business continuity, emergency and disaster preparedness;
- (f) health service delivery through M-health, E-learning and telemedicine;
- (g) E-waste disposal; and
- (h) health tourism.

Health information system.

73. (1) The Ministry of health shall facilitate the establishment and maintenance of a comprehensive health information system.

(2) The Cabinet Secretary may, for the purpose of

creating, maintaining or adapting databases within the national health information system desired in subsection (1), prescribe categories or kinds of data for submission, collection and the manner and format in which and by whom the data is to be compiled or collated and submitted to the Ministry of health.

(3) All health care providers shall-

- (a) establish and maintain a health information system as part of the health information system as specified under subsection (1); and
- (b) ensure compliance with the provision of paragraph (a) as a condition necessary for the grant or renewal of annual operating licenses.

(4) Any health care provider that neglects or fails to comply with the provision of subsection (3)(a) of this section commits an offence and on conviction shall be liable to imprisonment for a term of six months or a fine of five hundred thousand shillings or to both.

(5). Nothing in the foregoing precludes a county government from making laws with regards to health information system for that county and the city, urban and municipal areas within that county.

PART XIV - INTER-DEPARTMENTAL COLLABORATION

Collaboration.

74. While the Cabinet Secretary responsible for health shall bear primarily responsibility for the implementation of the provisions of this Act, it is

recognized that in certain matters there is a need for collaboration, consultation and agreement between two or more arms of Government in the interpretation of the law, the introduction of regulations and the further development and adaptation of legislation.

Training.

75. (1) The establishment, management and maintenance of institutions for the training of all categories of health professionals shall be the subject of national policy providing for collaboration, consultation and cooperation between the state department responsible for education, science, technology and innovation and the Commission for Higher Education.

(2) The Cabinet Secretary shall issue administrative guidelines and regulations on professional post basic training of all health workers for implementation in line with the national training policy for health professionals.

(3) All specialists shall be treated as a national asset in order to sustain internship training and specialist services to ensure standards and equity.

(4) Regulatory bodies shall ensure that the training of health professionals meet the set standards and quality.

Fields of collaboration.

76. Subject to section 74, the fields in which the need for collaboration, consultation and cooperation shall be necessary include, though not exclusively, those that deal with matters relating to—

- (a) workers' health;
- (b) health aspects of environmental protection;

- (c) issues of animal health;
- (d) professional education and training;
- (e) public education;
- (f) financing of health services; and
- (g) bio-medical sciences.
- (h)

**PART XV - TRANSITIONAL AND
MISCELLANEOUS PROVISIONS**

Existing laws.

77. (1) Except to the extent that this Act expressly provides to the contrary, all rights and obligations, however arising, of the Government and subsisting immediately before the effective date shall continue as rights and obligations of the national and county governments as assigned under this Act.

(2) All law in force immediately before the effective date continues in force and shall be construed with the alterations, adaptations, qualifications and exceptions necessary to bring it into conformity with this Act.

(3) If, with respect to any particular matter—

- (a) a law that was in effect immediately before the effective date assigns responsibility for that matter to a particular State organ or public officer; and
- (b) a provision of this Act that is in effect assigns responsibility for that matter to a

different State organ or public officer,

the provisions of this Act shall prevail to the extent of the conflict.

Public service.

78. (1) Any public officer appointed by the Public Service Commission in exercise of its constitutional powers and functions before the coming to effect of this Act and is serving under the National Government and in a county before the constitution of that county government shall be deemed to be in the service of the county on secondment from national government with their terms of service as at that date.

(2) The officer's terms of service including remuneration, allowances and pension or other benefits shall not be altered to the officer's disadvantage but to his or her advantage.

(3) The officer shall not be removed from the service except in accordance with the terms and conditions applicable to the officer as at the date immediately before the establishment of the county government or in accordance with the law applicable to the officer at the time of commencement of the proceedings for the removal.

(4) Any public officer appointed by the Public Service Commission in exercise of its constitutional powers and functions before the coming to effect of this Act and is providing health services assigned to county government under the Fourth Schedule of the Constitution and is serving in a county on the date of the constitution of that county government shall be deemed to be in the service of the county government with their terms of service as at that date and—

- (a) the officer's terms of service including remuneration, allowances and pension or other benefits shall not be altered to the officer's disadvantage but only to his or her advantage; and
- (b) the officer shall not be removed from the service except in accordance with the terms and conditions applicable to the officer as at the date immediately before the establishment of the county government or in accordance with the law applicable to the officer at the time of commencement of the proceedings for the removal.

(6) Every public officer holding or acting in a public office to which the commission had appointed the officer as at the date of the establishment of the county government shall discharge those duties in relation to the relevant functions of the county government or national government as the case may be.

(7) The Authority acting in consultation with the Public Service Commission, the County Public Service Board and the National Ministry and county executive department responsible for health shall facilitate the redeployment, transfers and secondment of staff to the national and county governments.

(8) The provision under subsection (7) shall not preclude the County Public Service Board or other lawful body from promoting or appointing the officer to another position.

(9) The period of secondment under subsection (1)

shall cease upon the transfer of a public officer from the national government to a county government or upon the release of an officer by the county government to the national government.

(10) Appointment of a public officer by the Public Service Commission includes appointment of a public officer on powers delegated by the Public Service Commission.

Regulations.

79. The Cabinet Secretary shall make regulations generally for the better carrying out of the provisions of this Act and without limiting the generality of the foregoing, the Cabinet Secretary may make regulations for—

- (a) the fees to be paid to access services in a public health facility;
- (b) the norms and standards for health service delivery;
- (c)
- (d) specified types of protective clothing and the use, cleaning and disposal of such clothing;
- (e) co-operation and interaction between private health care providers and private health establishments on the one hand and public health care providers and public health establishments on the other;
- (f) returns, registers, reports, records, documents and forms to be completed and kept by national referral institutions and county health institutions, public health

facilities and private health facilities;

- (g) communicable and non-communicable diseases;
- (h) notifiable medical conditions;
- (i) rehabilitation;
- (j) emergency medical services and emergency medical treatment;
- (k) health nuisances and medical waste;
- (l) the import and export of pathogenic micro-organisms;
- (m) health research;
- (n) health technology;
- (o) the national health information system;
- (p) the documentation of traditional medicines and a database of herbalists;
- (q) the rendering of forensic pathology, forensic medicine and related laboratory services, including the provision of medico-legal mortuaries and medico-legal services;
- (r) the procurement of health products and health technologies; and
- (s) anything which may be prescribed under this Act.

FIRST SCHEDULE

(s. 26)

**TECHNICAL CLASSIFICATION OF LEVELS OF HEALTHCARE
DELIVERY**

LEVEL 1: COMMUNITY HEALTH SERVICES

Functions-

- (a) Facilitates individuals, households and communities to carry out appropriate healthy behaviours;
- (b) Provides agreed health services;
- (c) Recognizes signs and symptoms of conditions requiring referral;
- (d) Facilitates community diagnosis, management and referral.
- (e)

Note: The In-charge is the community health extension worker.

LEVEL 2: DISPENSARY/CLINIC

Functions-

- (a) This is a health facility with no in-patient services and provides consultation, treatment for minor ailments;
- (b) Provides rehabilitative services;
- (c) Provision of preventive and promotive services.

Note: The In-charge is a nurse or clinical officer.

LEVEL 3: HEALTH CENTRE

Functions-

- (a) It provides out-patient care;

- (b) Provision of limited emergency care;
- (c) Maternity for normal deliveries;
- (d) Laboratories, oral health and referral services;
- (e) Provision of preventive and promotive services;
- (f) In-patient observations.

Note: The In-charge is the clinical officer.

LEVEL 4: PRIMARY HOSPITAL

Functions-

- (a) Clinical supportive supervision to lower level facilities;
- (b) Referral level out-patient care;
- (c) In-patient services;
- (d) Emergency obstetric care and oral health services;
- (e) Surgery on in-patient basis;
- (f) Client health education;
- (g) Provision of specialized laboratory tests;
- (h) Radiology service;
- (i) Proper case management of referral cases through the provision of four main clinical specialties (i.e internal medicine, general surgery, gynaecobstetrics and paediatrics) by general practitioners backed by

appropriate technical devices;

- (j) Proper counter referral;
- (k) Provision of logistical support to the lower facilities in the catchment area;
- (l) Coordination of information flow from facilities in the catchment area.

Note: The In-charge is a registered medical practitioner with a Masters degree in a health related field.

LEVEL 5: SECONDARY HOSPITAL

Functions-

- (a) Provision of specialized services;
- (b) Training facilities for cadres of health workers who function at the primary care level (nursing staff and clinical officers);
- (c) Serves as internship centre for all staff, up-to medical officers;
- (d) Research centre.

Note: The In-charge is a registered medical practitioner with a Masters degree in a health related field.

LEVEL 6: TERTIARY HOSPITAL

Functions-

- (a) Provides highly specialized services. These include-

(i) general specialization;

(ii) discipline specialization; and

(iii) geographical/regional specialization including highly specialized healthcare for area/regional specialization;

(b) Training and research services for issues of national importance.

Note:

1. The In-charge is a registered medical practitioner with a Masters degree in a health related field and with training and experience of over ten (10) years in senior management.

2. Level 5 and 6 shall be National Referral Hospitals.

3. Facilities from levels 2-5 can be upgraded by the Director-General based on a set criteria.

SECOND SCHEDULE (s. 28)

PROVISIONS AS TO THE CONDUCT OF AFFAIRS AND BUSINESS OF THE AUTHORITY

Disclosure of interest by members of the Board.

5. A disclosure of interest in a matter shall be recorded in the minutes of the meeting of the Board and the member shall not be present while that matter is being dealt with by the Board and shall not take part in any deliberations or vote relating to the matter.

Remuneration of members of the Board.

6. The Authority shall pay the members of the Board such allowances and expenses as are determined by the Cabinet Secretary.

THIRD SCHEDULE

(s. 66)

PROVISIONS AS THE CONDUCT OF BUSINESS AND AFFAIRS OF THE COMMITTEE

Meetings.

1. (1) The Committee shall hold at least four

Disclosure of interest by members of the Committee.

5. A disclosure of interest in a matter shall be recorded in the minutes of the meeting of the Committee and the member shall not be present while that matter is being dealt with by the Committee and shall not take part in any deliberations or vote relating to the matter.

Remuneration of Committee members.

6. The Committee shall pay the members of the Committee such allowances and expenses as shall be determined by the Cabinet Secretary.

MEMORANDUM OF OBJECTS

Whereas the change in the structure of government of the Republic of Kenya has brought forward challenges in terms of allocating functions between the national and county governments, the Constitution of Kenya, 2010 provides

for the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.

The Constitution also provides that no person shall be denied emergency medical treatment.

There is need to define how national health policy shall be formulated, implemented and coordinated between the two levels of government.

There is also need to capture the developments in technology that can positively contribute to health care services while curbing negative developments.

There is need for coordination amongst the various health professions so as to harness capacity and enhance relevance of the service to the health industry.

The Health Bill seeks to achieve the following -

- (1) Establishment of a National Health System which shall progressively realize the right to the highest attainable standard of health, which includes the right to healthcare services including reproductive health.
- (2) To define the functions of national government and devolved functions of the county government.
- (3) To establish the office of the Director General of Health as the technical advisor on all health matters.
- (4) To establish a Kenya Health Professions Oversight Authority to provide oversight role on regulatory role within the health sector as well as coordinate and supervise the activities of the regulatory bodies.
- (5) To establish a single regulatory body for regulation of health products and technologies.

- 1) (6) To establish a National Research for Health Committee as an advisory body for research for health.
- (7) To establish the Kenya National Blood Transfusion Service.
- (8) To provide for e- Health and the use of technological approaches to advance health objectives.
- (9)

The enactment of this Bill will occasion additional expenditure of public funds which shall be provided in the estimates.

Dated the, 2014.

JAMES MACHARIA,
Cabinet Secretary for Health.