SPECIAL ISSUE



Kenya Gazette Supplement No. 44 (National Assembly Bills No. 14)



REPUBLIC OF KENYA

KENYA GAZETTE SUPPLEMENT

NATIONAL ASSEMBLY BILLS, 2015

NAIROBI, 17th April, 2015

CONTENT

Bill for Introduction into the National Assembly—

PAGE

MATIONAL COUNCIL FOR LAW REPORTING RECEIVED

29 JUL 2015

R. D. Par 18448= 99199 NAIROBI, KENVA TEL: 2719231 FAX: 2712694

THE HEALTH BILL, 2015 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, 2015

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

- 1. This Act may be cited as the Health Act, 2015 and shall come into operation upon the expiry of ninety days from the date of publication.
- Short title and commencement.
- 2. In this Act unless the context otherwise requires—

Interpretation

- "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...

3. The object of this Act is to—

Objects of the

- (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.
- **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

Responsibility for health.

- 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.
- 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.

Standard of health.

(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

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

Reproductive health.

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

Emergency 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.
- 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—
- Health information.
- (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.
- 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—

Consent.

- (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.
- 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;

Information dissemination.

- (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.
- 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.

Confidentiality.

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

Healthcare providers.

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

Duty of 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.
- 14. (1) Any person has a right to file a complaint about

Complaints.

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

Duties of national government.

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

Office of the
Director -General.

- (2) The Director-General for health shall be recruited through a competitive process and appointed by the Cabinet Secretary.
 - (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 term of five (5) years renewable once.

17. The Director-General shall—

Functions of the Director-General.

- (a) be the technical advisor on all the matters relating to health within the health sector;
- (c) be the technical advisor to the Cabinet Secretary of health;
- (d) be responsible for preventing and guarding against the introduction of infectious diseases into Kenya;
- (e) promote the public health and the prevention, limitation or suppression of infectious, communicable or preventable diseases within Kenya;
- (f) advice the two levels of Government on matters of national security on public health;
- (g) promote and facilitate research and investigations in connection with the prevention or treatment of human diseases;
- (h) prepare and publish reports and statistical or other information relative to the public health;
- (i) 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;
- (j) register, license and gazette all health facilities;
- (k) be responsible of internship program for health workers;