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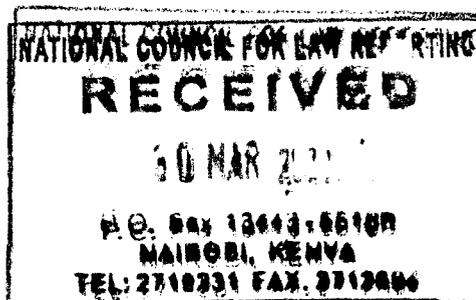
NAIROBI, 23rd March, 2020

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**THE KENYA NATIONAL BLOOD TRANSFUSION
SERVICE BILL, 2020**

A Bill for

AN ACT of Parliament to establish the Kenya National Blood Transfusion Service; to provide for the regulation of the activities relating to blood donation, testing, processing, safeguarding, transfusion, quality control; and for connected purposes

ENACTED by the Parliament of Kenya, as follows—

PART I—PRELIMINARY

1. This Act may be cited as the Kenya National Blood Transfusion Service Act, 2020.

Short title.

2. In this Act, unless the context otherwise requires—

Interpretation.

“adverse reaction” means any adverse event in resulting from the process of blood donation or blood transfusion;

“apheresis” means the procedure by which blood is withdrawn from a donor or patient and a portion of it being plasma, leukocytes or platelets is separated and retained, and the remainder is reintroduced into the donor or patient;

“assignable services” means blood transfusion services which the Kenya National Blood Transfusion Service delegates to a registered private, public institutions, facilities or organisation at the national or county level;

“blood” means a circulating tissue composed of plasma, red blood cells, white blood cells, platelets, and other constituents;

“blood component” includes red blood cell concentrates or suspensions, granulocytes, platelets, plasma and cryoprecipitate produced from whole blood or by apheresis;

“blood collection” includes the collection of blood by way of whole blood or by apheresis;

“blood donation” means a process of giving blood for purposes of transfusing it into another person;

“blood donor services” means the mobilization, education, recruitment and collection of blood from blood donors;

“blood transfusion services” means the various services offered by the Service;

“Board” means the Board of the Service constituted under section 6;

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

“haemovigilance” means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors and blood recipients;

“health professional” includes any person who is qualified and licensed by the relevant regulatory body and includes medical doctor, clinical officer, medical laboratory technologist, counsellor and nurses;

“human blood products” means a therapeutic part of blood intended for transfusion, including red cells, granulocytes, platelets, plasma, plasma derivatives, circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells that are prepared through whole blood methods or by aphaeresis;

“health facility” has the meaning assigned to it in the Health Act;

No. 21 of 2017.

“informed consent” means the process of getting permission before collecting blood;

“plasma derivatives” means plasma proteins prepared under pharmaceutical manufacturing conditions, including albumin, coagulation factor concentrates and immunoglobulins;

“Service” means the Kenya National Blood Transfusion Service established under section 4;

“transfusion” means the process of infusing blood or blood products to a recipient;

“transfusing facilities” means public, private, or faith-based health facilities that conduct transfusion of blood and blood products;

“Transfusion Transmissible Infection” or “TTIs” means a potential infectious pathogen that can be

transmitted through transfusion of blood or blood products;
and

“voluntary non-remunerated blood donor” means a person who voluntarily gives his or her blood or component for transfusion without any remuneration;

3. The objects of this Act is to—

Objects of the Act.

- (a) enable the systematic supervision of recruitment of voluntary non-remunerated blood donors and collecting, testing, processing, storing, issuing, distributing, and transfusing of blood and blood products as well as disposal of waste blood;
- (b) enable implementation of a national voluntary non-remunerated blood donor system; and
- (c) enhance contribution towards universal access to an adequate and safe national blood supply.

PART II—ESTABLISHMENT, FUNCTIONS AND POWERS OF THE KENYA NATIONAL BLOOD TRANSFUSION SERVICE

4. (1) There is established a Service to be known as the Kenya National Blood Transfusion Service.

Establishment of the Kenya National Blood Transfusion Service.

(2) The Service shall be a body corporate with perpetual succession and a common seal and shall in its corporate name, be capable of—

- (a) suing and being sued;
- (b) purchasing, holding, charging and disposing of movable and immovable property;
- (c) borrowing and granting money or making investments;
- (d) entering into contracts; and
- (e) doing or performing all such other acts necessary for the proper performance of its functions under this Act.

(3) The Service shall be the successor to the department of the National Blood Transfusion Service.

5. The functions of the Service shall be to—

Functions of the Service.

- (a) co-ordinate and supervise blood transfusion related activities in the Republic of Kenya;

- (b) develop and coordinate the implementation of policies, guidelines, procedures and standards relevant to ensuring blood safety;
- (c) set standards in respect of blood donor recruitment, collecting, testing, processing, storing, importing exporting, issuing, distributing of blood and blood products as well as disposal of waste blood;
- (d) project the country's blood needs based on national and international guidelines;
- (e) ensure adequate, equitable and safe supply of blood and blood products in Kenya;
- (f) ensure blood transfusion quality at all levels by employing appropriate pathogen reduction technologies in support of the national policies and guidelines on prevention and containment of antimicrobial resistance;
- (g) mobilize, educate and sensitize potential blood donors to foster a culture of voluntary blood donation, and build and maintain a safe and sustainable national voluntary non-remunerated blood donor base;
- (h) monitor and provide oversight on utilization of blood and blood products in Kenya;
- (i) develop and roll out a functional quality management system;
- (j) oversee notification of all blood donors of their tests results through counselling and referrals where appropriate while upholding privacy and confidentiality;
- (k) oversee processing of the blood collected into blood products;
- (l) oversee maintenance of recommended storage and transportation conditions of blood and blood products;
- (m) manage data on blood donors, donations, and blood transfusion including surveillance and reporting systems;

- (n) manage blood services collaborations, networks and partnerships;
- (o) provide technical support to the private sector, county governments and national referral hospitals on best blood transfusion practices;
- (p) oversee conduct of research, development and innovation in products and clinical transfusion in collaboration with researchers, training institutions, transfusing facilities and relevant government agencies;
- (q) establish and maintain linkages with the relevant regulatory bodies on assignable blood service; and
- (r) maintain a purview of international trends in blood transfusion service practices and transfusion transmissible infections and consider applicability to Kenya.

6. (1) The management of the Service shall vest in a Board which shall consist of—

Board of the Service.

- (a) a non-executive chairperson appointed in accordance with subsection (2);
- (b) the Principal Secretary in the Ministry for the time being responsible for matters related to health or a representative designated in writing by the Principal Secretary;
- (c) a representative of the private sector nominated by the Kenya Private Sector Alliance;
- (d) a representative of the private based transfusing facilities;
- (e) a representative of the faith-based transfusing facilities;
- (f) a representative of the Council of Governors;
- (g) a representative of the medical training institutions with knowledge and experience in haematology;
- (h) a representative of universities with knowledge and experience in haematology; and
- (i) a representative of the civil society or non-governmental organisations working in the area of blood.

(2) The chairperson shall be competitively recruited and appointed by the Cabinet Secretary from among persons who have—

- (a) at least a postgraduate university degree recognized in Kenya;
- (b) at least fifteen years' experience in matters relating to leadership and management in private or public sector; or
- (c) a distinguished public, private or teaching sector record on matters relating to health.

(3) Appointments under section 6(d), (f), and (g) shall be made from nominees submitted by their duly recognised national body and appointed by the Cabinet Secretary.

(4) In making the appointment under subsection (3), the Cabinet Secretary shall ensure that the appointments fulfill the requirements of the gender balance enshrined in the Constitution.

(5) The remuneration, fees or allowances payable to members of the Board shall be determined by the Salaries and Remuneration Commission.

(6) The procedure for the conduct of business and the affairs of the Board shall be as set out in the First Schedule.

7. (1) The chairperson and members of the Board appointed under section 6(1) shall serve for a term of three years and shall be eligible for re-appointment for one further term of three years.

Tenure of the Board members.

(2) The Cabinet Secretary shall appoint one third of the members of the Board under section 6(c), (d) (e), (f), and (g) in a staggered manner separated by two months so that the respective expiry dates of their terms shall fall at different times.

8. A person shall cease to be a member of the Board if such person—

Vacation of office.

- (a) resigns in writing to the Cabinet Secretary;
- (b) is convicted of a criminal offence and sentenced to a term of imprisonment exceeding six months without the option of a fine;

- (c) is adjudged bankrupt;
- (d) is unable to perform the functions of his or her office by reason of mental or physical incapacity; or
- (e) dies.

9. Whenever the office of the chairperson or a member of the Board appointed under section 6(c), (d) (e), (f), and (g) falls vacant, the vacancy shall be filled in the same manner as specified for that office under section 6.

Filling of vacancy.

10. (1) The Board shall have all powers necessary for the proper performance of its functions under this Act.

Powers and responsibilities of the Board.

(2) Without prejudice to the generality of the foregoing, the Board shall have power to—

- (a) control, supervise and administer the assets of the Service in such a manner as best promotes the purpose and objects of the Service;
- (b) determine the provisions to be made for the capital, recurrent expenditures and reserves of the Service;
- (c) receive any grants, gifts, donations or endowment and make legitimate disbursements therefrom;
- (d) levy fees for services rendered by the Service as may be determined from time to time;
- (e) open such bank accounts for the funds of the Service as may be necessary;
- (f) invest any funds of the Service not immediately required for its purposes in the manner provided in section 24;
- (g) provide expert advice on the safety and sufficiency of the national blood and blood products supply and safe clinical transfusion practices;
- (h) provide strategic direction and oversight to the Service;
- (i) approve contracts, undertakings, and other activities entered into by the management or otherwise undertaken in the name of the Service;
- (j) appoint, assign and license any institution or organization as the Board may require to perform any of its functions under this Act;

- (k) enter into association with other bodies or organizations within or outside Kenya as it may consider desirable or appropriate in the furtherance of or for the performance of its functions under this Act;
 - (l) mobilise resources including levying fees for services rendered by the Service as may be determined from time to time by the Board;
 - (m) appoint and supervise the Chief Executive Officer and other staff of the Service;
 - (n) perform or undertake any other activity that may be necessary for the fulfillment of any of the functions of the Service under this Act.
- (3) The Board shall be responsible for—
- (a) enforcement of good corporate governance practices within the Board and senior management;
 - (b) formulation of strategies and policies of the service in accordance with this Act and best practices;
 - (c) protection of the funds, property and assets of the service;
 - (d) effective administration and implementation of this Act; and
 - (e) doing all other things necessary to give effect to the provisions of this Act.

11. (1) There shall be a Chief Executive Officer of the Service who shall be appointed by the Board through an open, transparent and competitive recruitment process.

The Chief
Executive Officer.

(2) The terms, conditions and remuneration of the Chief Executive Officer shall be determined by the Board upon the advice of the Salaries and Remuneration Commission in the instrument of appointment or otherwise in writing from time to time.

(3) A person shall be qualified for appointment as the Chief Executive Officer of the Service if such person—

- (a) is a citizen of Kenya;

- (b) possesses at least ten years' experience in a leadership or senior management position;
- (c) holds a minimum of a first degree in laboratory medicine from a recognized university;
- (d) holds a master's degree in health systems management from a recognized university; and
- (e) satisfies the requirements of Chapter Six of the Constitution.

(4) The Chief Executive Officer shall—

- (a) be an *ex-officio* member of the Board with no right to vote;
- (b) be the secretary to the Board; and
- (c) subject to the direction of the Board be responsible for—
 - (i) the day to day running and operation of the Service;
 - (ii) administration, organization and oversight of the staff of the Service;
 - (iii) management of the funds, property and affairs of the Service;
 - (iv) implementation of the policies and programmes of the Service and reporting thereon to the Board;
 - (v) development of operational plans for achieving the objectives of the Service;
 - (vi) supervision of the assets of the Service in such manner and for such purposes as to best promote the purpose for which the Service is established;
 - (vii) performance of any other function necessary for the implementation of this Act, as may be determined by the Board.

(5) The Chief Executive Officer shall hold office for a term of four years and shall be eligible for reappointment for one further term of four years.

12. The Chief Executive Officer may be removed from office by the Board through a fair administrative action for—

Removal of the Chief Executive Officer.

- (a) inability to perform the functions of the office arising out of physical or mental incapacity;
- (b) gross misconduct;
- (c) being an adjudged bankrupt;
- (d) gross incompetence or neglect of duty; or
- (e) violation of the Constitution or any other written law.

13. (1) There shall be a Medical Director for the Service who shall be appointed by the Board through an open, transparent and competitive recruitment process and whose terms and conditions of employment shall be determined by the Board.

Medical Director.

(2) The Medical Director for the Service shall be paid such remuneration and allowances as the Board may, in consultation with the Salaries and Remuneration Commission, determine.

(3) A person shall be eligible for appointment as a Medical Director under subsection (1) if the person—

- (a) is a citizen of Kenya;
- (b) is a medical practitioner registered by the Medical Practitioners and Dentists Board;
- (c) holds a postgraduate degree in medicine, pathology or a related field;
- (d) has additional training in any of the following—
 - (i) transfusion medicine;
 - (ii) haematology;
 - (iii) management of blood transfusion services;
- (e) has at least seven years proven knowledge and experience in clinical practice; and
- (f) satisfies the requirements of Chapter Six of the Constitution.

(4) The Medical Director shall hold office for a term of five years and shall be eligible for reappointment for one further term of five years.

14. The functions of the Medical Director shall be to—

Functions of the Medical Director.

- (a) provide technical support to hospital transfusion committees;
- (b) be responsible for the all medical matters that relate to the care and safety of donors;
- (c) provide consultative services to transfusing services on clinical transfusion issues;
- (d) supervise all therapeutic phlebotomy conducted at the Service; and
- (e) supervise all apheresis procedures conducted at the Service.

15. The Board shall appoint such officers and staff as are necessary for the proper discharge of its functions under this Act, upon such terms and conditions of service as it may determine, upon the advise of the Salaries and Remuneration Commission.

Staff of the Service.

16. The Board may, by resolution either generally or in any particular case, delegate to any committee or to any member, officer, employee or agent of the Service, the exercise of any of the powers or the performance of any of the functions or duties of the Service under this Act or under any other written law.

Delegation by the Board.

17. (1) No matter or thing done by a member of the Board or by any officer, staff or agent of the Service shall, if the act or omission was done in good faith for the purpose of executing the functions, powers or duties of the Service under this Act, render the officer, staff, agent or any person acting on their directions personally liable to any action, claim or demand whatsoever.

Protection from personal liability.

(2) Any expenses incurred by any officer, staff, agent or any person in any suit or prosecution brought against him or her in any court, in respect of any act which is done or purported to be done by him or her under the direction of the Board shall, if the court holds that such act was done in good faith, be paid by the Service, unless such expenses are recoverable by him or her in such suit or prosecution.

18. The provisions of section 17 shall not relieve the Service of the liability to pay compensation or damages to any person for any injury to him or her, his or her property or any of his or her interests caused by the exercise of any power conferred by this Act or any other written law or by the failure, wholly or partially, of any works.

Liability for damages.

19. (1) The common seal of the Service shall be kept in such custody as the Board may direct, and shall not be used except upon the order of the Board. Common seal.

(2) The affixing of the common seal of the Service shall be authenticated by the signature of the Chairperson and the Chief Executive Officer and any document not required by law to be made under seal and all decisions of the Board may be authenticated by the signatures of both the Chairperson and the Chief Executive Officer.

(3) Notwithstanding the provisions of subsection (2), the Board shall, in the absence of either the Chairperson or the Chief Executive Officer in a particular matter, nominate one member to authenticate the seal on behalf of either the Chairperson or the Chief Executive Officer.

(4) The common seal of the Service when affixed to a document and duly authenticated shall be judicially noticed and unless the contrary is proved, any necessary order or authorization by the Board under this section shall be presumed to have been duly given.

PART III—FINANCIAL PROVISIONS

20. The funds of the Service shall consist of— Funds of the Service.

- (a) such monies as may be appropriated by the National Assembly;
- (b) fees, monies or assets as may accrue to or vest in the Service in the course of the exercise of its powers or the performance of its functions under this Act or under any written law;
- (c) gifts, grants and donations as may accrue to the Service;
- (d) such monies as may be payable to the Service pursuant to this Act or any other written law; and
- (e) all monies from any other lawful source provided, donated or lent to the Service.

21. The financial year of the Service shall be the period of twelve months ending on the thirtieth June of each year. Financial year.

22. (1) At least three months before the end of each financial year, the Board shall cause to be prepared the Annual estimates.

estimates of the revenue and expenditure of the Service for the next financial year.

(2) The annual estimates shall be for the entire financial year and shall provide for—

- (a) payment of the salaries, allowances and other charges in respect of Board members and staff of the Service;
- (b) payment of pensions, gratuities and other charges in respect of members of staff of the Service;
- (c) the proper maintenance of the buildings and grounds of the Service;
- (d) maintenance, repair and replacement of the equipment and other property of the Service;
- (e) creation of such reserve funds to meet future or contingent liabilities in respect of disaster response, insurance or replacement of buildings or equipment, or in respect of such other matter as the Board may deem appropriate;
- (f) the carrying out of core activities of the Service including blood donor education, blood collection drives, blood donor notification and retention, testing, products preparation; banking and haemovigilance; and
- (g) procurement of commodities, supplies and consumables including testing kits, blood bags and containers.

(3) The annual estimates shall be approved by the Board before the commencement of the financial year to which they relate and, once approved, the sum provided in the estimates shall be submitted to the Cabinet Secretary for approval.

23. (1) The Board shall ensure the Service maintains proper books and records of accounts of the income, expenditure and assets of the Service.

Accounts and
audit.

(2) Within a period of three months after the end of each financial year, the Board shall submit to the Auditor General the accounts of the Service together with—

- (a) a statement of the income and expenditure of the Service during that financial year; and

(b) a statement of the assets and liabilities of the Service on the last day of that year.

No. 34 of 2015.

(3) The accounts of the Service shall be audited and reported upon in accordance with the provisions of the Public Audit Act.

24. The Board may invest any of the funds of the Board in securities in which for the time being trustees may by law invest funds or in any other securities which the Treasury may from time to time approve for that purpose.

Investment of funds.

PART IV – ROLE OF THE COUNTY GOVERNMENTS

25. Every county government shall carry out such assignable duties as licensed by the Board and shall—

Role of county governments.

- (a) ensure an enabling environment for collaboration with the Service;
- (b) in collaboration with the Service, carry out inspection on health facilities on blood transfusion and safety; and
- (c) comply with the provisions of the act on blood transfusion.

26. The Service shall—

Role of the Service.

- (a) advise the county governments on blood safety issues;
- (b) assign and where necessary provide licences for assignable duties;
- (c) provide training to the county government staff in blood transfusion safety;
- (d) provide equipment for blood collection, testing and storage; and
- (e) monitor compliance with policies and standards for transfusion practice.

PART V – MANAGEMENT OF BLOOD SERVICES

27. (1) The Board shall establish such blood service centres for the better implementation of the functions of the Service.

Blood service centres.

(2) The service centres shall be managed by accredited and licenced institutions on behalf of the Service as shall be assigned by the Board.

(3) The levels and services to be offered by the blood service centres shall be as set out in the Second Schedule.

(4) Despite the provisions of this section, there shall be established blood service centres in all Level 5 and Level 6 hospitals as defined in the Health Act.

No. 21 of 2017.

28. The assignable services by the Board shall include—

Assignable services.

- (a) blood donor mobilization;
- (b) education;
- (c) recruitment;
- (d) blood collection
- (e) processing;
- (f) blood storage and distribution; and
- (g) haemovigilance.

29.(1) The Service shall operate a National Blood Transfusion Reference Laboratory which shall—

National Blood Transfusion Reference Laboratory.

- (a) co-ordinate with other blood centres and testing laboratories;
- (b) provide scientific and technical assistance as may be required by the Service;
- (c) establish quality standards for testing, blood grouping and processing of blood in accordance with the regulations made under this Act;
- (d) manufacture and process specialized blood products; and
- (e) conduct such other quality, reference and specialized testing.

30.(1) An institution or organisation intending to carry out any of the services of the Service shall apply in writing for a licence in terms of the regulations.

Application and issuance of licence.

(2) The Service may after scrutiny of the application issue or refuse to issue a licence.

(3) The Service may, after scrutiny of the application for renewal of licence, renew or refuse to issue a new licence in accordance with the regulations.

(4) The Service shall determine the tenure of the licence and the fees to be paid for such an application for licence.

31. Where a licence holder violates any of the conditions contained in the licence or fails to abide by any notification, order or directive issued under the licence or this law, the Service may—

Administrative action.

- (a) issue a warning;
- (b) suspend the licence subject to a time limit; or
- (c) cancel the licence.

32. (1) Any institution or organisation dissatisfied with an administrative action taken in accordance with section 31 may appeal in writing to the Board against such decision.

Appeals.

(2) An appeal under subsection (1) shall—

- (a) be lodged within sixty days from the date on which the written reasons for the decision were given by the Service; and
- (b) set out the grounds of appeal.

(3) After considering the grounds of appeal and the reasons for the decision, the Board must as soon as is practicable—

- (a) confirm, set aside or vary the decision; or
- (b) substitute any other decision for the decision of the Service

(4) Any person aggrieved by the decision of the Board may appeal to the High Court.

PART VI—RIGHTS AND RESPONSIBILITIES OF BLOOD DONORS

33. (1) A health care provider shall inform a blood donor, or where the donor is a minor or the person is by any reasons incapacitated, inform the parent or guardian of the donor of—

Health information.

- (a) information of their health conditions and risks posed to their health;
- (b) clear and appropriate information, including the purpose of donor selection;

- (c) the consequences of failure to provide relevant information on the blood transmission service;
- (d) information on treatment for any adverse reaction;
- (e) information with regard to their blood test results;
- (f) notification of positive test results and the availability of appropriate counselling and referral; and
- (g) the need to ensure the confidentiality of all personal information provided by the donor.

(2) A health care provider shall where possible inform the donor in a language that the donor understands and in a manner that takes into account the donor's literacy levels.

34. Every blood donor shall have the responsibility to—

Duties of the donor.

- (a) supply the health care providers with accurate information pertaining to the donor's health status;
- (b) refrain from blood donation if they have reasons to believe that they are unsuitable to donate;
- (c) decide whether to be informed about their transmission time interval status;
- (d) withdraw from blood donation at any time during the procedure for any reasons; and
- (e) inform the blood transfusion service, after donating blood, of any doubts about their suitability or health status within twenty eight days after blood donation.

35.(1) A blood donor shall give a written and informed consent prior to donating blood on receiving information in accordance with section 33.

Informed consent.

(2) A blood donor who is below the age of eighteen years shall require the consent of parent or legal guardian before making the blood donation.

(3) A blood donor shall be provided with information in an understandable language regarding the completion of the donor questionnaire, blood collection procedure, tests to be conducted and results.

36. Every collection centre shall provide counseling services to a person who wishes to donate blood, both before and after donating blood.

Counselling.

37. (1) A person shall not disclose any information and test results of a blood donor to any other person except—

Confidentiality.

- (a) with the written consent of the donor;
- (b) if that person is a child, with the written consent of a parent or legal guardian of that child;
- (c) for the purposes of an epidemiological study or research authorised by the Cabinet Secretary;
- (d) to a court of law under a court order; or
- (e) if authorized or required to do so under this Act or under any other written law.

(2) Subsection (1) shall not apply to a disclosure of statistical or other information that cannot reasonably be expected to lead to the identification of the person to whom the information relates.

38. (1) A blood donor who experiences an adverse reaction after blood donation shall be entitled to medical treatment to be undertaken at a public hospital or institution or any other institution approved or gazetted by the Cabinet Secretary.

Medical treatment.

(2) The expenses incurred for the treatment of any person under subsection (1) shall be borne by the State.

(3) The Service shall be notified of any case of adverse reaction under subsection (1).

PART VII—BLOOD DONOR MANAGEMENT

39. (1) A blood donor shall engage in blood donation on a voluntary and non-remuneration basis.

Blood donor.

(2) The qualifications for eligibility as a blood donor shall be as prescribed by the Cabinet Secretary.

(3) In addition to the qualifications prescribed under subsection (2), a blood donor shall—

- (a) complete a donor questionnaire declaring their identity, health status and lifestyle prior to donation; and
- (b) pass a medical examination, including personal medical history and physical examination.

40. (1) The Service shall promote public awareness about blood and blood donation through a comprehensive nationwide educational and information campaign.

Blood donor education, mobilization and recruitment.

(2) In conducting the education and information campaign referred to in subsection (1), the Service shall collaborate with relevant stakeholders to ensure the involvement and participation of the public.

(3) The recruitment and mobilization of blood donors shall be conducted according to regulations and in consultation with other stakeholders.

41.(1) The collection of blood and blood products under this Act shall be carried out by a qualified health professional under the instructions of a medical practitioner.

Blood collection.

(2) Upon the collection of blood from a donor, the blood shall be deemed to be the property of the Service.

(3) Every blood collection service shall be organized and carried out at established blood centres and licensed facilities.

42.(1) All blood donated under this Act shall undergo mandatory testing and processing as prescribed in regulations.

Testing, processing and storage.

(2) The testing, processing and banking of blood and blood products for distribution to transfusing facilities shall be done at licensed blood centres as prescribed in regulations.

43.(1) The Service shall supply blood and blood products to all licensed transfusing facilities in the country.

Utilization of blood and blood products.

(2) The blood and blood products collected under this Act shall be used for the treatment of patients, in accordance with good clinical practice as provided in the regulations.

44.(1) Any blood, blood products or consumables that is found to be unsuitable for use shall be disposed of as prescribed in regulations.

Disposal of blood, blood products and consumables.

(2) The Service shall prescribe an inventory to be maintained in respect of all blood, blood products and consumables disposed under this section.

45.(1) Any blood or blood product shall not be imported into Kenya if—

Import and export of blood and blood products.

(a) its origin cannot be verified;

- (b) there is no proof of the blood or blood product having been tested at the country of origin;
- (c) the blood or blood product cannot be re-tested;
- (d) the blood cold chain was not maintained;
- (e) quality standards were compromised; or
- (f) any other reasons exist as may be stated by the Service.

(2) Any blood or blood products shall be exported from Kenya in accordance with regulations.

(3) A person shall not import or export any blood or blood products without the prior written approval of the Cabinet Secretary acting on the recommendations of the Service.

(4) A person who contravenes the provisions of subsection (3) commits an offence and shall be liable, upon conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding three years, or to both.

46. The national and county governments shall ensure that all transfusing health facilities adhere to the standards and regulations set by this Act in relation to blood transfusion management and as directed by the Service.

Transfusing health facilities.

47.(1) The Service shall develop standard data collection tools and systems and shall monitor their use by blood centres, establishments and transfusing facilities.

Documentation.

(2) The Service shall collect, collate and disseminate all data related to blood transfusion to the relevant offices.

(3) The Service shall establish the necessary data and information security mechanisms.

PART VIII—OFFENCES AND PENALTIES

48. Any person who collects, stores, issues, distributes or otherwise trades in blood or blood products in contravention of the provisions of this Act commits an offence and shall be liable, upon conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding three years, or to both.

Illegal dealing in blood and blood products.

49. Any person who engages in blood transfusion services without a valid license commits an offence and

Operating without a license.

shall be liable, upon conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding three years, or to both.

50. Any person who collects blood without the consent of the donor or, in the case of a minor, without the consent of their legal guardian, commits an offence and shall be liable, upon conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding three years, or to both.

Blood collection without consent.

51. Any person who—

- (a) transfuses into any person, blood or blood components or products not obtained from the established and licenced blood transfusion centres, blood collection centres or a duly licensed hospital blood bank;
- (b) transfuses into any person, blood or blood products imported contrary to the provisions of this Act;
- (c) transfuses into any person, blood or blood products without grouping, cross matching and conducting the transmission time interval testing as stipulated in regulations;
- (d) extracts from or transfuses into any person, blood or blood products by using a blood transfusion instrument which has expired, or which is not free from micro-organisms or which has previously been used on another person;
- (e) transfuses into any person, blood or blood products which have expired; or
- (f) transfuses into any person, blood or blood products which have not been tested,

Offences related to blood transfusion.

commits an offence and shall be liable, upon conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding three years, or to both.

52. Any person who violates any prohibition or fails to comply with any duty contained in any notification or directive issued under this Act in order to prevent the transmission of infections through blood and blood

Failure to comply with notifications or directives.

products, commits an offence and shall be liable, upon conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding five years, or to both.

53. No suit or prosecution shall lie against any medical practitioner or any person who performs any duty under the instruction of a medical practitioner in relation to transfusion of blood or blood products if—

Protection from prosecution.

- (a) the person acted in good faith;
- (b) the origin of the blood was verified; and
- (c) the blood was processed as prescribed by regulations.

PART IX—PROVISIONS ON DELEGATED POWERS

54. (1) The Cabinet Secretary shall, within one year of the date of commencement of this Act, and on the recommendation of the Service, make regulations generally for the proper carrying into effect the provisions of this Act.

Regulations.

(2) Without prejudice to the generality of subsection (1), the regulations may provide for—

- (a) blood donor qualifications;
- (b) blood donor education, mobilization, recruitment, care, retention, recall and notification, counselling, blood collection, testing and processing;
- (c) blood banking, distribution; transportation, clinical use and haemovigilance;
- (d) licensing of assignable Services;
- (e) disposal of blood and blood products and consumables;
- (f) import and export of blood and blood products; and
- (g) any other matter which may be prescribed under this Act.

PART X—TRANSITIONAL PROVISIONS

55. The Kenya National Blood Centre, National Quality and Reference Testing Laboratory, Regional Blood

Existing blood centres.

Transfusion Centres, the blood service centres existing in the counties and the Satellites established by the Ministry prior to the enactment of this law shall be deemed to be part of the Kenya National Blood Transfusion Service and shall carry on the blood transfusion service as stipulated.

56. The notifications orders, regulations and directives issued by the Ministry through the Kenya National Blood Transfusion Services in respect of blood donations, recruitment, collecting, safety, testing, storing, issuing, transportation, distributing and disposal of waste blood and blood products prior to the enactment of this Act shall continue to be applicable in so far as they are not inconsistent with this Act.

Existing notifications, orders, regulations and directives.

57. The existing private blood collection and processing centres operating prior to the enactment of this Act shall continue to operate until licensed by the Service in accordance with this Act within a period of ninety days from the date of commencement of this Act.

Existing private blood collection and processing centres.

58. Any person who, immediately before the commencement of this Act was a member of staff of the former Service shall be deemed to be a member of staff of the new Service for the unexpired period of his or her term.

Existing staff.

59.(1) The Cabinet Secretary shall ensure the implementation of the provisions of this Part within one year of the date of commencement of this Act.

Implementation of Transitional Provisions.

(2) In complying with sub-section (1) the Cabinet Secretary shall, at the end of each financial year, submit to the National Assembly a report on the status of implementation of the provisions of this Act.

FIRST SCHEDULE**(s. 6)****PROVISIONS AS TO THE CONDUCT OF THE BUSINESS AND AFFAIRS OF THE BOARD**

1. A member other than *ex-officio* member may— Vacation of office.
- (a) at any time resign from office by notice in writing to the Cabinet Secretary;
 - (b) be removed from office by the Cabinet Secretary on recommendation of the Board if the member—
 - (i) has been absent from three consecutive meetings of the Board without the permission of the chairperson;
 - (ii) is convicted of a criminal offence which is punishable by imprisonment for a term exceeding six months without the option of a fine;
 - (iii) is incapacitated by prolonged physical or mental illness for a period exceeding six months;
 - (iv) contravenes the provisions of Chapter Six of the Constitution; or
 - (v) is otherwise unable or unfit to discharge his or her functions.

2. (1) The Board shall meet not less than four times in every financial year and not more than four months shall lapse between the date of one meeting and the date of the next meeting. Meetings.

(2) Notwithstanding subparagraph (1), the Chairperson may, and upon requisition in writing by at least five members shall, convene a special meeting of the Board at any time for the transaction of the business of the Board.

(3) Unless three quarters of the total members of the Board otherwise agree, at least fourteen days' written notice of every meeting of the Board shall be given to every member of the Board.

(4) The quorum for the conduct of the business of the Board shall be half of the total number of members including the Chairperson or the person presiding.

(5) The Chairperson shall preside at every meeting of the Board but the members present shall elect one of their number to preside whenever the Chairperson is absent, and the person so elected shall have all the powers of the Chairperson with respect to that meeting and the business transacted thereat.

(6) Unless a unanimous decision is reached, a decision on any matter before the Board shall be by a majority of the votes of the members present and voting, and in case of an equality of votes, the Chairperson or the person presiding shall have a casting vote.

(7) Subject to subparagraph (4), no proceedings of the Board shall be invalid by reason only of a vacancy among the members thereof.

(8) Subject to the provisions of this Schedule, the Board may determine its own procedure and the procedure for any committee of the Board and for the attendance of other persons at its meetings and may make standing orders in respect thereof.

3. (1) The Board may establish such committees as it may deem appropriate to perform such functions and responsibilities as it may determine.

Committees of the Board.

(2) The Board shall appoint the chairperson of the committee established under subparagraph (1) from amongst its members.

(3) The Board may, where it deems appropriate, co-opt any person to attend the deliberations of any of its committees.

(4) All decisions by the committees appointed under subparagraph (1) shall be ratified by the Board.

4. (1) A member who is interested in any contract, or other matter present at a meeting shall at the meeting and as soon as reasonably practicable after the commencement of the meeting, disclose the fact thereof and shall not take part in the consideration of discussion of, or vote on, any questions with respect to the contract or other matter, or be counted in the quorum of the meeting during consideration of the matter.

Conflict of interest.

(2) A disclosure of interest made under subparagraph (1) shall be recorded in the minutes of the meeting at which it is made.

(3) A member of the Board who contravenes subparagraph (1) commits an offence and is liable, upon conviction, to a fine not exceeding two hundred thousand shillings.

5. The Service shall cause the minutes of all proceedings of its meetings to be recorded and kept, and shall be signed by the chairperson or the person presiding at the meeting. Minutes.

SECOND SCHEDULE**(s. 27)****LEVELS OF BLOOD SERVICE CENTRES**

1. (1) A Level III centre shall be located within a specific county and may serve one or more counties and shall conduct the following services—

Blood Service
Centre Level III.

- (a) blood donor services, including to mobilise, educate and recruit donors;
- (b) collection of blood from blood donors;
- (c) storage and observance of cold chain processes;
- (d) donor care services, including counselling, notification and referral;
- (e) to generate and manage all relevant data;
- (f) transport and distribution;
- (g) to process blood and blood products;
- (h) to perform and document all haemovigilance activities;
- (i) supervisory and oversight of all blood transfusion services and Level II blood service centres in their jurisdiction;
- (j) testing of transmission time intervals, blood grouping and blood products;
- (k) to serve as a training centre for establishments under them; and
- (l) compatibility testing and investigation of transfusion reactions.

2. A Level II centre will be located within a specific county and can serve one or more counties and shall conduct the following services—

Blood Service
Centre Level II.

- (a) perform blood donor services, including to mobilise, educate and recruit donors;
- (b) to collect blood or apheresis from blood donors;
- (c) to store and observe cold chain processes;
- (d) donor care services, including counselling, notification and referral;

- (e) to generate and manage all relevant data;
- (f) transport and distribution;
- (g) to process blood and blood products;
- (h) to send samples to level III for transmission time intervals, testing and blood grouping;
- (i) to perform and document all haemovigilance activities;
- (j) supervision and oversight of all Level I centres in their jurisdiction;
- (k) to serve as a training centre for establishments under them; and
- (l) compatibility testing and investigation of transfusion reactions.

3. A Level I centre will be a static or mobile blood centre located within a specific county and may serve one or more counties and shall conduct the following services—

Blood Service
Centre Level I.

- (a) blood donor services, including to mobilise, educate and recruit donors;
- (b) collection of blood or apheresis;
- (c) to store and observe cold chain processes;
- (d) to send samples to Level III centres for transmission time interval testing and blood grouping;
- (e) donor care services, including counselling, notification and referral;
- (f) to generate and manage all relevant data;
- (g) transport and distribution;
- (h) to perform and document all haemovigilance activities; and
- (i) supervision and oversight of all blood transmission units in their jurisdiction.

MEMORANDUM OF OBJECTS AND REASONS

Statement of the Objects and Reasons for the Bill

The principal object of this Bill is to provide for the regulation of the activities relating to blood donation, testing, processing, safeguarding, transfusion and quality control.

Part I of the Bill provides for the preliminary provisions, including the short title, the definition of terms as used in the Bill as well as the objects of the Bill, which is to establish the Kenya National Blood Transfusion Service.

Part II of the Bill provides for the establishment, functions and powers of the Kenya National Blood Transfusion Service. This Part established the Service as a body corporate and also provides for the composition of the Board of the Service.

Part III of the Bill provides for the financial provisions. It provides for the sources of funds of the Service, as well as the annual estimates, audit and investment of funds.

Part IV of the Bill provides for the role of county governments in Blood transfusion. In terms of this Part, county governments will be required to liaise and collaborate with the Service in activities related to blood transfusion.

Part V of the Bill provides for the management of blood services. This Part provides for the establishment of the various levels of blood service centres, as well as the procedure for the application of licenses. It also provides for administrative procedures to be taken by persons aggrieved by the decisions of the Board.

Part VI of the Bill provides for the rights and responsibilities of blood donors. It provides for the right to information and consent, the duties of the donor as well as the confidentiality requirement.

Part VII of the Bill provides for blood donor management. This Part provides for the eligibility of a blood donor as well as the need for education, mobilization and recruitment of blood donors. This Part also provides for the collection, testing, utilization and disposal of blood and blood products.

Part VIII of the Bill provides for the offences related to blood and blood products as well as offences related to blood transfusion. The Part also provides for the penalties for the various offences.

Part IX of the Bill provides for the provisions on delegated powers, and gives the Cabinet Secretary, on the recommendation of the Service,

the power to make regulations for the better carrying into effect of the provisions of the Act.

Part X of the Bill provides for the transitional provisions from the old Service to the new Service.

The First Schedule to the Bill provides the provisions as to the conduct of the business and affairs of the Board.

The Second Schedule to the Bill provides for the levels of the blood service centres.

Statement on the delegation of legislative powers and limitation of fundamental rights and freedoms

This Bill delegates legislative powers to the Cabinet Secretary to make regulations, but it does not limit fundamental rights and freedoms.

Statement of how the Bill concerns county governments

The Bill concerns county governments in terms of Article 109(5) of the Constitution as it contains provisions that affect the functions and powers of the county governments as set out in the Fourth Schedule to the Constitution.

County health services is a function of the county governments as provided in Part 2 of the Fourth Schedule to the Constitution, and these services include ambulance services, primary health care and pharmacies, all of which may involve blood transfusion services.

Statement as to whether the Bill is a money Bill within the meaning of Article 114 of the Constitution

The enactment of this Bill may occasion additional expenditure of public funds.

Dated the 12th March, 2020.

SABINA CHEGE,
Member of Parliament.