

SPECIAL ISSUE

Kenya Gazette Supplement No. 88 (National Assembly Bills No. 18)



REPUBLIC OF KENYA

KENYA GAZETTE SUPPLEMENT

NATIONAL ASSEMBLY BILLS, 2026

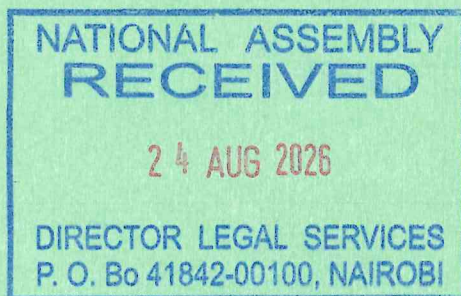
NAIROBI, 2nd April, 2026

CONTENT

Bill for Introduction into the National Assembly—

PAGE

The Kenya Blood, Cells, Tissues and Organs Bill, 2026 771



SPECIAL ISSUE

Kenya Gazette Supplement No. 1 of 2008



REPUBLIC OF KENYA

KENYA GAZETTE SUPPLEMENT

NATIONAL ASSEMBLY BILL NO. 1 OF 2008

NATURAL GAS ACT, 2008

CONTENT

Part I. Introduction and Short Title

Part II. The National Gas Board

Part III. The National Gas Board

Part IV. The National Gas Board

Part V. The National Gas Board

**THE KENYA BLOOD, CELLS, TISSUES AND
ORGANS BILL, 2025**

ARRANGEMENT OF CLAUSES

Clause

PART I—PRELIMINARY

1. Short title.
2. Interpretation.
3. Guiding principles.
4. Objects of the Act.
5. Application of the Act.

**PART II—ESTABLISHMENT, FUNCTIONS AND
POWERS OF THE KENYA BLOOD AND
TRANSPLANT AUTHORITY**

6. Establishment of the Kenya Blood and Transplant Authority.
7. Functions of the Authority.
8. Role of the Authority.
9. Powers of the Authority.
10. Board of the Authority.
11. Tenure of the Board members.
12. Remuneration of the members of the Board.
13. Conduct of the affairs of the Board.
14. Vacancy of office of the members of the Board.
15. Filling of a vacancy in the membership of the Board.
16. Powers of the Board.
17. Delegation by the Board.
18. Chief Executive Officer.
19. Removal of the Chief Executive Officer.
20. Staff of the Authority.
21. Protection from personal liability.

22. Liability for damages.

23. Common seal.

PART III –ROLE OF COUNTY GOVERNMENTS

24. Role of county governments.

PART IV –REGISTRATION, LICENSING AND CERTIFICATION

25. Transfusing facility

26. Transplant facility.

27. Retrieval facility.

28. Blood, cells, tissues and organs banks.

29. Sample referral courier providers.

30. Distributors.

31. Deregistration of a blood, cells, tissues, organs, banks.

PART V –BLOOD DONOR SERVICE MANAGEMENT

32. Blood, cells, tissues and organs centres.

33. National blood and transplant reference laboratory.

34. Blood collection centres.

35. Health information.

36. Duties of the donor.

37. Informed consent.

38. Counselling.

39. Confidentiality.

40. Adverse event management.

41. Blood donor eligibility.

42. Blood donor education, mobilization and recruitment.

43. Blood collection

44. Donor notification.

**PART VI—BLOOD TESTING, PROCESSING,
STORAGE AND UTILIZATION**

- 45. Testing.
- 46. Processing.
- 47. Labelling and storage.
- 48. Utilization of blood and blood components.
- 49. Facility transfusion committee
- 50. Disposal of blood, blood components, products and consumables.
- 51. Import and export of blood and blood components.
- 52. Monitoring and Evaluation.
- 53. Disclosure of information by blood bank and transfusion facility.

**PART VII—BLOOD SERVICE QUALITY
MANAGEMENT SYSTEM**

- 54. Blood services quality management systems.

**PART VIII—MANAGEMENT OF TRANSPLANT
SERVICE**

- 55. Blood donors.
- 56. National waiting list.
- 57. Fair and transparent system.
- 58. Cells, tissues, organs donor education, advocacy and public awareness.
- 59. Living donor management.
- 60. Notification, allocation and distribution of human cells, tissues and organs.
- 61. Sampling of cells, tissues and organs.
- 62. Evaluation and maintenance for potential donor.
- 63. Retrieval of organs, tissues or cells from deceased donors.
- 64. Testing requirements.

- 65. Disposal of by-products of cells, tissues, organs and consumables.
- 66. Monitoring and evaluation.
- 67. Transplant related data and information.
- 68. Reconstruction of deceased donor.
- 69. Restriction of purposes.
- 70. Donation and transplant of organs, tissues and cells removed from living non-related donors.
- 71. Donation from a deceased person.
- 72. Determination of brain death.
- 73. Determination of circulatory death.
- 74. Donation of unclaimed bodies.
- 75. Cells, tissues and organs bank.

PART IX—TRANSPLANT QUALITY MANAGEMENT SYSTEM

- 76. Transplant quality management systems.
- 77. Notification requirements.

PART X—CELLS TISSUES OR ORGANS DONOR CONSENT

- 78. Consent to living donation.
- 79. Donation of a human body.
- 80. Witness consent.
- 81. Protection of persons suffering from mental disorder.

PART XI—DISPUTE RESOLUTION

- 82. Complaints.
- 83. Complaints at facility level.
- 84. Complaints at Authority.
- 85. Functions of the complaints committee.
- 86. Powers of the complaints committee.
- 87. Blood and Transplant Appeals Tribunal.
- 88. Jurisdiction of the Tribunal.

PART XII—ENFORCEMENT

- 89. Appointment of authorized persons and inspectors.
- 90. Powers of entry, inspection and search.
- 91. Duty of authorized officers and inspectors to investigate.
- 92. Duty of authorized officers and inspectors to inspect.
- 93. Duty of authorized officers and inspectors to seize.
- 94. Obstruction of inspectors.

PART XIII—FINANCIAL PROVISIONS

- 95. Funds of the Authority.
- 96. Financial year.
- 97. Annual estimates.
- 98. Accounts and audit.

PART XIV—MISCELLANEOUS

- 99. Disclosure of information.
- 100. Exclusion of liability of persons acting in pursuance of consent.
- 101. Transfusion services without informed written consent.
- 102. Transplanting services without informed written consent.
- 103. Prohibition of commercial dealings in human material for transplantation.
- 104. Retrieval of human organs, cells or tissues without authorization.
- 105. Prohibited activities.
- 106. Exceptions to prohibited activities.
- 107. Retrieval of human organs, tissues or cells from living donor without consent or authorisation.
- 108. Restriction of activities in relation to donated material.
- 109. Offences by a legal entity.

110. Regulations.

PART XV— CONSEQUENTIAL AMENDMENTS

111. Amendment of section 80 of Cap. 241.

112. Repeal of section 81 of Cap. 241.

113. Repeal of section 82 of Cap. 241.

114. Repeal of section 83 of Cap. 241.

115. Repeal of section 84 of Cap. 241.

116. Repeal of section 85 of Cap. 241.

117. Repeal of Cap 252. of 2012.

PART XVI— TRANSITIONAL PROVISIONS

118. Existing private blood collection and processing centres.

119. Implementation of transitional provisions.

**THE KENYA BLOOD, CELLS, TISSUES AND
ORGANS BILL, 2025**

A Bill for

An ACT of Parliament to provide for the establishment of the Kenya Blood and Transplant Authority; to provide a framework for blood and transplant services; to regulate and coordinate blood donation, transfusion, cells, tissues and organs donation and transplantation; to promote and secure the effective supply of safe blood, cells, tissues and organs and the effective transfusion of blood and blood components and transplantation of cells, tissues and organs for therapeutic purposes; to promote the adoption of globally accepted ethical principles for the donation and management of blood, cells, tissues and organs; promote research and development in blood and transplant services and for connected purposes

ENACTED by the Parliament of Kenya, as follows—

PART I—PRELIMINARY

1. This Bill may be cited as the Kenya Blood, Cells, Tissues and Organs Bill, 2025. *Short title.*

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

“adverse event” means any undesirable or unintended occurrence associated with donation, transfusion and or transplantation and includes all adverse reactions, incidents, near misses, errors, omissions and accidents;

“advertisement” includes any form of commercial promotion;

“advertising” means to make a representation by any means for the purposes of directly or indirectly promoting the sale or use of blood, cells, tissues and organs, including—

- (a) written publication, a television or radio broadcast, film or electronic transmission, including the internet, video or telephone;
- (b) displays, signs, symbols, colours, billboards or notices; or

(c) exhibition of pictures or models;

“Authority” means the Kenya Blood and Transplant Authority established under section 6;

“authorized officer” means a person appointed under section 89;

“authorization to donate” means the right to retrieve any cells, tissues, organs or body from a deceased donor in accordance with this Act;

“blood, cells, tissues and organs bank” means an establishment where some or all of the following functions are conducted—

- (a) collection;
- (b) screening;
- (c) testing;
- (d) processing;
- (e) storage;
- (f) distribution and;
- (g) notification;

“biovigilance” means a set of organized surveillance procedures relating to adverse or unexpected events or reactions in cells, tissues or organ donors or recipients, and the epidemiological follow-up of donors and cells, tissues or organ recipients;

“blood donor” means any living voluntary non-remunerated person from whom blood or blood component is collected;

“blood establishment” means a facility that performs all or any of the following functions: mobilization and public awareness, recruiting blood donors, screening and selecting blood donors, blood collection, testing, and processing of blood units, transportation, receiving, and storage of blood units;

“blood” means the body fluid in the circulatory system that delivers oxygen and nutrients and carries away carbon dioxide and other blood products;

“blood component” means a therapeutic constituent of human blood including red cells, white cells, platelets and plasma, and includes concentrates or suspensions, granulocytes, and cryoprecipitate produced from whole blood or by apheresis;

“blood product” means a therapeutic product derived from blood or blood component;

“blood service” means donor education, mobilization, recruitment, counselling, consent, donor screening, blood collection, notification and adverse events management; screening, testing, processing, component preparation, storage, transport, distribution, hemovigilance and includes transfusion service;

“Board” means the Board of the Authority constituted under section 10;

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

“cells” means human cells or a collection of human cells not bound by any form of connective tissue, including cell lines grown outside the human body;

“child” has the meaning assigned under the Children Act; Cap. 141.

“consent” means a voluntary, wilful, expressive, unequivocal, free, specific and informed indication obtained from a donor or recipient or their immediate family member or any other legal representative;

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

“health care professional” means a person who has obtained health professional qualifications and is licensed by a relevant regulatory body;

“health care provider” means a person who provides health care services and includes a health care professional;

“human by-product” means any product derived or produced from blood, cells, tissues or an organ;

“immediate family member” means spouse, son, daughter, father, mother, brother or sister;

“independent team” means neurological specialists, anaesthesiologists, critical care physicians or paediatricians;

“legal representative” means a person authorized by law to represent the interest of a donor or recipient;

“mobilizer” includes an individual or an organisation responsible for coordinating and organizing the collection of blood, blood products, cells, tissues and organs donations for medical purposes, such as transfusions or transplantation;

“organ” means a section of a human body which consists of a structured and functional arrangement of tissues which when transplanted offers similar function to the recipient;

“plasma” means a liquid portion of blood in which red blood cells have been removed;

“recipient” means a person who receives blood, blood components, cells, tissues or organs;

“retrieval” means the medical procedure that is conducted to remove cells, organs or tissues from a donor;

“retrieval facility” means a facility designated by the Authority to participate in the procedure of retrieval of cells, tissues and or organs from a donor for the purpose of transplantation, research and training as defined under regulations;

“regional blood centre” means an establishment where donor mobilization, recruitment, counselling, consent, donor screening blood collection, screened and tested, processed and component preparation, manufacturing, storage and distribution occurs for purposes of transfusion, research or training;

“regional cell and tissue bank” means an establishment where cells and tissues are processed, tested, matched, stored and distributed for purposes of transplantation, research or training;

“satellite blood centre” means an establishment where blood, is collected, processed and component preparation, storage and distribution occur for purposes of transfusion, research and training;

“supply network” means a network that manages the sourcing, storage and banking, allocation and distribution of human blood, cells, tissues and organs for transfusion and transplantation, training and research;

“third party service provider” means a person certified to perform any function relating to blood, blood components, blood products, cells, tissues, organs and related services under this Act;

“tissue” means a functional and structural group of human cells;

“tissue bank” means an establishment where cells and tissues are stored for purposes of transplantation, research and training as the case may be;

“transfusion” means the therapeutic administration of safe blood, blood components or blood products to a recipient;

“transfusing facility” means a registered health facility where the therapeutic administration of safe blood, blood components or blood products to recipients is performed;

“transfusion services” means the services relating to therapeutic administration of safe blood, blood components or blood products;

“transplant facility” means a registered health facility that conducts any transplantation;

“transplant services” include donor education, counselling of donors and recipients, donation, testing, matching, retrieval, processing, distribution, transportation, grafting, preparation, storage and conducting vigilance of cells, tissues and organs;

“transplant team” means a team appointed under this Act for purposes of transplant;

“transplantation” means the procedure of transferring cells, tissues or organs from a donor whether living or dead to a living human recipient; and

“Tribunal” means the Blood and Transplant Appeals Tribunal established under section 87.

3. The administrator of this Act shall be guided by the following principles—

Guiding principles.

- (a) ethical collection and retrieval of blood, cells, tissues and organs;
- (b) safe and quality collection, processing, testing, storage and distribution of blood, cells, tissues and organs;
- (c) biovigilance of transfusion and transplantation of blood, cells, tissues and organs;
- (d) transparency and openness of transfusion and transplant services;
- (e) equity in allocation of blood, cells, tissues and organs; and
- (f) compliance with this Act or any other written law.

4. The objects of this Act is to —

Objects of the Act.

- (a) establish the Kenya Blood and Transplant Authority;
- (b) establish and coordinate an organized national blood and transplant service;
- (c) regulate transfusion and transplantation services;
- (d) ensure availability and accessibility of safe blood, cells, tissues and organs;
- (e) ensure ethical use of blood, blood components and products, cells, tissues and organs;
- (f) promote advocacy and awareness on donation of blood, cells, tissues and organs;
- (g) ensure the safety, and well-being of donors and recipients when accessing blood and transplant services;
- (h) establish and maintain systems that monitor the biosafety and biosecurity of blood and transplant services;

- (i) develop and enforce the implementation of standards in blood and transplant services;
- (j) promote research and innovation in blood and transplant services; and
- (k) organize, coordinate and integrate blood, cells, tissues, and organs supply networks.

5. (1) This Act shall apply to—

Application of the Act.

- (a) blood, blood components, blood products, cells, human breast milk, tissues, organs and gene therapy;
- (b) research, innovation and development in blood, cells, tissues and organs in transfusion and transplantation; and
- (c) all facilities blood banks, satellite blood centres, regional blood centres, regional cell and tissue, skin and breast milk banks, transfusing and transplant facilities, retrieval facilities, blood and transplant reference laboratories relevant research and training institutions and related regulatory bodies.

(2) This Act shall not apply to—

- (a) the retrieval of tissue from the body of a living person, in the course of a medical procedure or operation carried out in the interests of the health of the person;
- (b) the embalming of the body of a deceased person; and
- (c) the preparation, including the restoration of any disfigurement or mutilation, of the body of a deceased person for the purpose of interment or cremation.

**PART II—ESTABLISHMENT, FUNCTIONS AND
POWERS OF THE KENYA BLOOD AND
TRANSPLANT AUTHORITY**

6. (1) There is established an authority known as the Kenya Blood and Transplant Authority.

Establishment of the Kenya Blood and Transplant Authority.

(2) The Authority 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) taking, purchasing, holding, charging and disposing of movable and immovable property;
- (c) receiving, 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.

7. The Authority shall—

Functions of the Authority.

- (a) establish and maintain a system for demand planning of blood, blood components and products, cells, tissues, organs and their derivatives;
- (b) enforce adherence to standards relating to blood, blood components, blood products for transfusion services and human cells, tissue and organs for transplant services;
- (c) provide and coordinate blood donor education, mobilization, recruitment, counselling, consent, donor screening, blood collection, notification and adverse events management, screening, testing, processing, component preparation, storage, transport, distribution and hemovigilance;
- (d) provide and coordinate donor education, counselling of donors and recipients, donation, testing, matching and allocation, retrieval, processing, distribution, transportation, tissue typing, preparation, storage and conducting vigilance of cells, tissues and organs;
- (e) provide and coordinate specialized blood therapeutic services;
- (f) develop and coordinate the implementation of policies, standards, national algorithms, guidelines, procedures and manuals in conducting transfusion and transplant services;

- (g) establish an ethical, fair and transparent mechanism for matching and allocation of blood, blood components, blood products, cells, tissues and organs;
- (h) promote ethical use of blood, blood components, blood products, cells, tissues and organs;
- (i) establish registries necessary for blood and transplant services;
- (j) promote public awareness and education on the donation of blood, blood components, cells, tissues and organs;
- (k) promote access to equitable, quality and affordable transplant care;
- (l) certify transfusion and transplant facilities, distributors, cells and tissues bank, sample referral couriers, retrieval facilities and testing laboratories in blood and transplant services;
- (m) coordinate, mobilize and recruit donors, blood collection, screening, testing, processing, blood component preparation, manufacturing, storage and distribution;
- (n) coordinate retrieval, allocation, processing, storage and distribution of cells, tissues and organs;
- (o) develop and monitor systems for surveillance and reporting for blood and transplant services;
- (p) coordinate all stakeholders involved in transfusion or transplant services on the ethical, legal and clinical issues related to transfusion and transplantation;
- (q) regulate the exchange and transportation of blood, blood components and products, cells, tissues, and organs, both nationally, and internationally where appropriate;
- (r) regulate gene therapy in transplant services;
- (s) establish a system of verification, evaluation and validating commodities and equipment in blood and transplant service supply chain;

- (t) establish and maintain a national database for blood, blood components, cells, tissue and organ donors;
- (u) collaborate with other stakeholders, in conducting research and innovation in blood and transplant services;
- (v) investigate any complaint on breach of the provisions of this Act or any of the regulations made thereunder and take appropriate action;
- (w) periodically inspect blood, cells and tissue banks, transfusing, and transplant facilities, to ascertain the quality of blood and transplant service;
- (x) carry out a follow-up medical care to donors and recipients;
- (y) identify and adopt international best practices in blood and transplant services and align them to the national needs and structures as applicable to Kenya; and
- (z) perform such other functions as the Board, with the approval of the Cabinet Secretary, may determine.

8. The Authority shall —

Role of the
Authority.

- (a) advise the Cabinet Secretary on policy matters relating to blood, blood components and products cells, tissues and organs;
- (b) advise the county governments on policy matters relating to blood, blood components, cells, tissues and organs;
- (c) regulate blood and transplant services as stipulated in this Act;
- (d) provide technical assistance on matters relating to blood, cells, tissues, organs; and
- (e) ensure compliance with policies and standards for blood and transplant service practice.

9. The Authority shall have the power to—

Powers of the
Authority

- (a) receive any grants, gifts, donations or endowment and make legitimate disbursements therefrom;

- (g) establish an ethical, fair and transparent mechanism for matching and allocation of blood, blood components, blood products, cells, tissues and organs;
- (h) promote ethical use of blood, blood components, blood products, cells, tissues and organs;
- (i) establish registries necessary for blood and transplant services;
- (j) promote public awareness and education on the donation of blood, blood components, cells, tissues and organs;
- (k) promote access to equitable, quality and affordable transplant care;
- (l) certify transfusion and transplant facilities, distributors, cells and tissues bank, sample referral couriers, retrieval facilities and testing laboratories in blood and transplant services;
- (m) coordinate, mobilize and recruit donors, blood collection, screening, testing, processing, blood component preparation, manufacturing, storage and distribution;
- (n) coordinate retrieval, allocation, processing, storage and distribution of cells, tissues and organs;
- (o) develop and monitor systems for surveillance and reporting for blood and transplant services;
- (p) coordinate all stakeholders involved in transfusion or transplant services on the ethical, legal and clinical issues related to transfusion and transplantation;
- (q) regulate the exchange and transportation of blood, blood components and products, cells, tissues, and organs, both nationally, and internationally where appropriate;
- (r) regulate gene therapy in transplant services;
- (s) establish a system of verification, evaluation and validating commodities and equipment in blood and transplant service supply chain;

- (t) establish and maintain a national database for blood, blood components, cells, tissue and organ donors;
- (u) collaborate with other stakeholders, in conducting research and innovation in blood and transplant services;
- (v) investigate any complaint on breach of the provisions of this Act or any of the regulations made thereunder and take appropriate action;
- (w) periodically inspect blood, cells and tissue banks, transfusing, and transplant facilities, to ascertain the quality of blood and transplant service;
- (x) carry out a follow-up medical care to donors and recipients;
- (y) identify and adopt international best practices in blood and transplant services and align them to the national needs and structures as applicable to Kenya; and
- (z) perform such other functions as the Board, with the approval of the Cabinet Secretary, may determine.

8. The Authority shall —

Role of the
Authority.

- (a) advise the Cabinet Secretary on policy matters relating to blood, blood components and products cells, tissues and organs;
- (b) advise the county governments on policy matters relating to blood, blood components, cells, tissues and organs;
- (c) regulate blood and transplant services as stipulated in this Act;
- (d) provide technical assistance on matters relating to blood, cells, tissues, organs; and
- (e) ensure compliance with policies and standards for blood and transplant service practice.

9. The Authority shall have the power to—

Powers of the
Authority

- (a) receive any grants, gifts, donations or endowment and make legitimate disbursements therefrom;

- (b) levy fees for services rendered by the Authority as may be determined from time to time;
- (c) enter into association with other institutions as it considers necessary for the fulfilment of the objects of this Act or for the performance of its functions under this Act;
- (d) summon any person or facility who is in possession of information relating to violation of the provisions of this Act;
- (e) order the production of any document or material object;
- (f) make and enforce directives to ensure compliance with this Act and with the conditions of the licences issued under this Act;
- (g) collaborate with law enforcers in the search of any place suspected to be indulging in unauthorized retrieval, tissue typing, matching and allocation, tissue banking, procurement or transplantation of cells, tissues, and organs;
- (h) collaborate with law enforcers in the search of any place suspected to be indulging in unauthorized blood mobilization, recruitment, collection, testing, component and products preparation, distribution, transfusion of blood, blood components and products;
- (i) suspend and revoke certification for cells, tissues and organ banks, transfusing and transplant facilities and retrieval facilities, distributors, and health information systems in transfusion and transplantation, distributors, sample referral couriers and testing laboratories found in violation of the Act; and
- (j) investigate complaints over any matter under this Act.

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

Board of the
Authority.

- (a) a chairperson appointed by the President;

- (b) the Principal Secretary in the Ministry for the time being responsible for matters related to health or a representative designated in writing;
- (c) the Principal Secretary responsible for the National Treasury or a representative designated in writing;
- (d) the Director-General for Health or a representative designated in writing;
- (e) three other members, being health care professionals with requisite expertise not being public officers, appointed by the Cabinet Secretary by virtue of gender, disability, regional balance;
- (f) a health representative nominated by the Council of Governors; and
- (g) the Chief Executive Officer who shall be the secretary to the Board and an ex-officio member of the Board and with no right to vote.

(2) In making the appointment under subsection (1), the President and the Cabinet Secretary shall ensure that the appointments fulfil the requirements of the gender and ethnic balance as provided for in the Constitution.

(3) The President shall appoint the chairperson of the Board by a notice in the *Kenya Gazette*.

(4) The Cabinet Secretary shall appoint the members of the Board under subsection (1) (e) by a notice in the *Kenya Gazette*.

(5) The Cabinet Secretary shall appoint of the members of the Board under subsection (1) (e) in a staggered manner separated by five months.

11. The chairperson and members of the Board appointed under section 10 (e) and (f) 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.

12. The members of the Board shall be paid such remuneration, fees or allowances as prescribed by the Public Service Commission, in consultation with the Salaries and Remuneration Commission.

Remuneration of
the members of
the Board.

13. The conduct of the affairs of the Board shall be as provided in the Code of Governance for State Corporations, subject thereto, the Board shall regulate its own procedure and of any of its committees.

Conduct of the affairs of the Board.

14. (1) A person shall cease to be a member of the Board if such person —

Vacancy of office of the members of the Board.

(a) resigns in writing to —

(i) the President, in the case of the chairperson of the Board; or

(ii) the Cabinet Secretary, in the case of a member of the Board appointed under section 10 (1) (e);

(b) is adjudged bankrupt;

(c) is convicted of an offence and sentenced to a term of imprisonment exceeding six months without the option of a fine;

(d) has been absent from three consecutive meetings of the Board without any notice to the chairperson;

(e) is incapable by prolonged physical or mental illness from performing his or her duties as a member of the Board; or

(f) conducts himself or herself in a manner deemed by the appointing authority to be inconsistent with membership of the Board.

(2) Any removal of a member of the Board under subsection (1) above, shall be through formal revocation.

15. Whenever the office of the chairperson or a member of the Board appointed under section 10 (1) (e) falls vacant, the vacancy shall be filled in the same manner as specified for that office under section 10.

Filling of a vacancy in the membership of the Board.

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

Powers 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 Authority in such a manner as best promotes the purpose and objects of the Authority;

- (b) determine the provisions to be made for the capital, recurrent expenditures and reserves of the Authority;
- (c) open such bank accounts for the funds of the Authority as may be necessary;
- (d) appropriately invest any funds of the Authority not immediately required for its purposes as guided by treasury regulations;
- (e) receive any grants, gifts, donations or endowment and make legitimate disbursements therefrom;
- (f) levy fees for services rendered by the Authority as may be determined from time to time;
- (g) provide expert advice on the safety and sufficiency of the National blood, blood components and blood products, cells, tissue, organ supply and safe transfusion and transplant service;
- (h) provide strategic direction and oversight to the Authority;
- (i) approve contracts, undertakings, and other activities entered into by the management or otherwise undertaken in the name of the Authority; and
- (j) undertake any other activity that may be necessary for the performance of the functions of the Authority under this Act.

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

Delegation by the Board.

18. (1) There shall be a Chief Executive Officer of the Authority who shall be competitively recruited and appointed by the Board.

Chief Executive Officer.

(2) The Chief Executive Officer shall hold office on such terms as the Board may, on the advice of the Salaries and Remuneration Commission, determine.

(3) A person is qualified for appointment as the Chief Executive Officer of the Authority if such person—

- (a) is a Kenyan citizen;
- (b) possesses at least ten years' experience in leadership and management;
- (c) has at least a health-related postgraduate degree from a university recognized in Kenya;
- (d) satisfies the requirements of Chapter Six of the Constitution; and
- (e) has distinguished public, private or academia records on matters relating to health.

(4) The Chief Executive Officer shall—

- (a) subject to the direction of the Board, be responsible for the day-to-day operations of the Authority; and
- (b) perform any other function necessary for the implementation of this Act, as determined by the Board.

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

19. 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.

20. (1) The Board shall, through an open and competitive process, employ such staff as are necessary for the proper discharge of the functions of the Authority under this Act.

*Staff of the
Authority.*

(2) The staff appointed under subsection (1) shall serve on such terms and conditions as the Board may in consultation with the Salaries and Remuneration Commission determine.

21. (1) Nothing done, or omitted, by a member of the Board, member of staff or agent of the Authority shall, if the act or omission, was done in good faith for the purpose of executing the functions or powers of the Authority under this Act, render the member of the Board, or any person acting on the directions of the member of the Board, member of staff or agent, 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 Authority, unless such expenses are recoverable by him or her in such suit or prosecution.

22. Section 21 shall not relieve the Authority of the liability to pay compensation or damages to a person for an injury to that person, or the person's property or of the person's interests caused by the exercise of power or performance of a function conferred by this Act or by the failure, wholly or partially, of works thereof.

*Liability for
damages.*

23. (1) The common seal of the Authority shall be kept in the custody of the Chief Executive Officer and shall not be used except upon the order of the Board.

Common seal.

(2) The affixing of the common seal of the Authority shall be authenticated by the signature of the Chairperson of the Board 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 of the Board and the Chief Executive Officer.

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

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

PART III—ROLE OF THE COUNTY GOVERNMENTS

24. The county governments, in furtherance of the functions assigned under the Fourth Schedule to the Constitution, shall be responsible for—

Role of county governments.

- (a) implementing policies, guidelines, procedures and standards in conducting blood and transplant services;
- (b) in collaboration with the Authority to promoting public education and public awareness in the donation of blood, cells, tissues and organs;
- (c) in collaboration with the Authority mobilizing members of the public to volunteer in the donation of blood, cells, tissues and organs;
- (d) providing safe blood transfusion and collaboration with the Authority on transplantation;
- (e) in partnership with the Authority, collaboration with local and international partners and stakeholders in the provision of safe blood transfusion and transplantation as per the prescribed regulations;
- (f) providing follow-up comprehensive care to the donors and recipients; and
- (g) implementing biovigilance.

PART IV—REGISTRATION, LICENSING AND CERTIFICATION

25. (1) A designated transfusing facility shall conduct the transfusion of blood, blood components and blood products as provided under this Act.

Transfusing Facility.

(2) A health care professional or health care provider shall not conduct, cause to be conducted or aid in conducting by themselves or through any other person, any activity relating to transfusion at a place other than a transfusing facility certified under this Act.

(3) A health facility registered with the relevant authority which seeks to offer blood transfusion services shall apply for certification through the prescribed form to the Authority.

(4) The Authority shall issue a certificate to the health facility if it complies with blood transfusion guidelines issued by the Authority.

(5) The certificate issued in accordance with subsection (4) shall not be transferrable.

(6) The Authority shall maintain an updated database of transfusing facilities.

(7) A transfusing facility which contravenes subsection (2) commits an offence and shall be liable, upon conviction, to a fine not exceeding five hundred thousand shillings or imprisonment for a term not exceeding two years or to both.

26. (1) A designated transplant facility shall conduct transplant services of cells, tissues or organs as provided under this Act.

Transplant
facility.

(2) A person shall not conduct, cause to be conducted or aid in conducting by himself or herself or through any other person, any activity relating to transplantation unless the person is duly registered with the relevant regulatory bodies and authorized by the Authority.

(3) A health facility registered with the relevant authority which seeks to offer transplant services shall apply for certification through the prescribed form to the Authority.

(4) The Authority shall issue a certificate to the health facility if it complies with transplant guidelines issued by the Authority.

(5) The certificate issued in accordance with subsection (4) shall not be transferrable.

(6) The Authority shall maintain an updated database of transplant facilities.

(7) A transplant facility which contravenes subsection (2) commits an offence and shall be liable, upon conviction, to a fine not exceeding five hundred thousand

shillings or imprisonment for a term not exceeding two years or to both.

27. (1) The Authority shall designate retrieval facilities that participate in the procedure of retrieval of cells, tissues and or organs from a donor for the purpose of transplantation, research and training as defined under regulations.

Retrieval Facility.

(2) A person shall not conduct, cause to be conducted or aid in conducting by himself or herself or through any other person, any activity relating to retrieval unless the person is duly registered with the relevant regulatory bodies and authorized by the Authority.

(3) A person or facility that contravenes subsection (1) above commits an offence and shall be liable upon conviction, to a fine not exceeding five hundred thousand shillings or imprisonment for a term not exceeding two years or to both.

28. (1) Blood, cells, tissues or organs banks shall not retrieve, screen, test, process, store or distribute any blood, cells, tissue, organ or unless it is duly registered and certified by the Authority in accordance with this Act.

Blood, cells
tissues and organs
banks.

(2) An application for registration of a blood, cells, tissues and organs bank shall be made to the Authority in a prescribed form and manner and shall be accompanied by the prescribed fee.

29. The Authority shall register and certify all blood, cells, tissues and organs sample referral courier providers.

Sample referral
courier providers.

30. The Authority shall register and certify all distributors of blood and transplant services.

Distributors

31. (1) A certificate of registration for a blood bank, cell bank, tissue bank, organ bank or may be suspended or cancelled where—

Deregistration of a
blood, cells,
tissues, organs,
banks
deregistration

- (a) there is a breach of any of the provisions of this Act;
- (b) it is necessary or expedient due to public interest;
- (c) the facility is not operating in accordance with the terms and conditions of the certificate of registration;

(d) the facility is not operating in accordance with the standard of operation issued in accordance with this Act; or

(e) there is any other relevant and justifiable ground.

(2) Before suspension or cancellation of registration of a bank under this section, the bank shall be given a reasonable opportunity to be heard.

(3) A person aggrieved by the decision of the Authority relating to registration as a bank or a suspension or revocation may appeal to the Tribunal.

PART V— BLOOD DONOR SERVICE MANAGEMENT

32. (1) The Authority shall establish—

Blood Cells,
Tissue and Organ
Centres.

(a) regional cells and tissue centres that shall provide specialized testing, processing, matching and allocation of cells, tissues, organs and banking of cells and tissues.

(b) regional blood cells to carry out blood services;

(c) satellite blood centres to carry out blood services;

(d) other blood establishments as stipulated in regulations.

33. (1) The Authority shall establish a national blood and transplant reference laboratory to provide basic and specialized testing references, internal and external quality assessments, standardization, validation, verification and methodological guidance to other laboratories for—

National blood
and transplant
reference
laboratory.

(a) blood and blood disorders and other responsibilities assigned; and

(b) cells, tissue and organ and other responsibilities assigned.

(2) The Authority shall ensure that the reference laboratory referred to in subsection (1) is registered by the relevant regulatory body and meets national and international standards.

34. The Authority shall establish blood collection centres, which may be static or mobile.

Blood collection
centres.

35. (1) Each person may donate blood for transfusion, training or research purposes unless otherwise prohibited under this Act and regulations.

Health
information.

(2) A blood donation shall be voluntary and non-remunerated unless in special circumstances where innovative approaches may be employed.

(3) A health care provider shall inform a blood donor of—

- (a) information of their health conditions and risks posed to their health as a blood donor;
- (b) clear and appropriate information, including the purpose of donor selection;
- (c) the consequences of failure to provide relevant information to the blood service;
- (d) information on treatment for any adverse events;
- (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.

(4) 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 and be sensitive to cultural and religious beliefs.

36. Every blood donor shall have the responsibility to—

Duties of the
donor.

- (a) supply a health care provider 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) agree to be informed about their transfusion transmissible infection status;
- (d) withdraw from blood donation at any time during the procedure; and
- (e) inform the blood service, after donating blood, of any doubts about their suitability or health status.

37. (1) A blood donor shall give a written and informed consent prior to donating blood. Informed consent.

(2) 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.

38. Every blood collection centre shall provide counselling services to a person who wishes to donate blood, both before and after the donation. Counselling.

39. (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) for the purposes of an epidemiological study or research authorised by the relevant authorities;
- (c) to a court of law; or
- (d) 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.

40. (1) A blood donor who experiences an adverse event after a blood donation shall be immediately referred for management. Adverse event management.

(2) The Authority shall be notified of any case of adverse event under subsection (1).

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

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

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

- (c) pass additional eligibility criteria as stipulated in the regulations as prescribed by the Cabinet Secretary.

42. (1) The Authority shall promote public awareness about blood and blood donation through a comprehensive nationwide education and information campaign.

Blood donor education, mobilization and recruitment.

(2) The recruitment and mobilization of blood donors shall be conducted according to regulations under this Act as prescribed by the Cabinet Secretary.

(3) Any institution that seeks to conduct blood donor education, mobilize or recruit blood donors shall seek approval from the Authority.

43. (1) The collection of blood under this Act shall be carried out by a qualified healthcare professional.

Blood collection.

(2) Upon the collection of blood from a donor, the blood shall be a national resource.

(3) Every blood collection activity shall be organized and carried out, as prescribed in the regulations.

44. All blood donors shall be notified of their test results as prescribed in regulations.

Donor notification.

PART VI—BLOOD TESTING, PROCESSING, STORAGE AND UTILIZATION

45. (1) All blood donated under this Act shall undergo mandatory testing as prescribed in the guidelines of a blood establishment.

Testing.

(2) The Authority shall issue general testing guidelines from time to time.

(3) The guidelines shall be issued to a donor before collection and testing is done.

(4) A donor shall give consent before collection and testing is done.

46. The processing of blood and blood components for distribution to transfusing facilities shall be carried out at registered and certified blood establishments as prescribed in regulations.

Processing.

47. (1) A transfusing facility shall ensure that on each unit of blood supplied to it is labelled, or imported by it contains information as the Authority shall determine.

Labelling and storage.

(2) A transfusing facility shall keep such records of the information referred to in subsection (1) and such additional records as are necessary—

(a) for identification of each single blood donation; and

(b) to ensure full traceability to the point of delivery.

48. Blood and blood components which are utilized shall be from a registered and certified blood bank.

Utilization of blood and blood components.

49. A transfusing facility shall have a facility transfusion committee as prescribed in the regulations.

Facility Transfusion committee.

50. (1) Blood, blood components, products and consumables found to be unsuitable for use shall be disposed as prescribed in the regulations.

Disposal of blood, blood components, products and consumables.

(2) The Authority shall prescribe an inventory to be maintained in respect of blood and blood components, disposed under this section.

51. (1) The Authority shall approve all imports and exports of blood and blood components as prescribed in the regulations.

Import and export of blood and blood components.

(2) A person shall not import or export any blood or blood components without the prior written approval of the Authority.

(3) A person who contravenes the provisions of subsection (1) or (2) 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. (1) The Authority shall develop standard data collection tools and systems and shall monitor their use by blood establishments, and transfusing facilities.

Monitoring and Evaluation.

(2) The Authority shall receive reports from blood establishments and transfusing facilities regularly at a frequency as prescribed in the regulations.

(3) The Authority shall publish annual reports from blood establishments and transfusing facilities.

(4) The Authority shall establish the necessary data and information security mechanisms in accordance with existing laws.

53. (1) A blood establishment and transfusing facility shall ensure that all information collected for the purposes of this Act is held securely and shall be —

Disclosure of information by blood bank and transfusion facility.

- (a) available for the purpose of tracing donations; and
- (b) subject to safeguards against unauthorized additions, deletions or modifications.

(2) Disclosures on information collected from a donor shall be made —

- (a) with the approval of the Authority as specified in this Act and other existing laws;
- (b) with an order of a court or is otherwise required by law;
- (c) for the purposes of tracing a donation from donor to recipient or vice versa.

(3) Any person while in the course of lawful functions of their work privileged to access any information from the blood establishment shall not further disclose the information.

(4) A person responsible for blood transfusion service shall put in place procedures to ensure that discrepancies relating to data are brought to the attention of the donor and resolved without delay.

PART VII—BLOOD SERVICE QUALITY MANAGEMENT SYSTEM

54. The Authority shall establish a blood service quality management system that ensures access to safe blood and blood components and safety to donors and recipients as prescribed in regulations.

Blood service quality management systems.

(2) The system established under subsection (1) shall provide for a quality control and quality assurance system for equipment, commodities, consumables and all other devices in the blood service.

(3) The Authority shall approve all devices and equipment that apply in the blood service as prescribed in the regulations.

(4) All adverse events in transfusing facilities and blood establishments shall be reported to the Authority as per the regulations.

(5) The Cabinet Secretary in consultation with the Authority may, by regulations, prescribe additional requirements for blood services.

PART VIII—MANAGEMENT OF TRANSPLANT SERVICE

55. (1) Every person is a potential cells, tissues or organs donor for transplantation, training or research purposes unless otherwise prescribed under this Act and regulations. Blood donors.

(2) Blood donors shall consist of—

- (a) a person who has attained eighteen years; and
- (b) a related donor is either genetically related either as a—
 - (i) parent, sibling or offspring;
 - (ii) extended family;
 - (iii) spouse;
 - (iv) adopted family member; or
 - (v) friend to a recipient.

56. The Authority shall establish and maintain a national waiting list for recipients of individual cells, tissues and organs. National waiting list.

57. (1) The Authority shall ensure that cells, tissues and organs are allocated to patients on the national waiting list in a transparent and fair manner as shall be prescribed in the regulations. Fair and Transparent system.

(2) For the purposes of subsection (1), the Authority—

- (a) shall consider a recipient's citizenship or residency status in Kenya;
- (b) shall not be influenced by politics, race, ethnicity, sex, religion, or financial status.

(3) The Authority may authorize the allocation of the organs, tissues or cells to any other recognized international

transplantation programs which the Authority has an agreement, where no suitable recipient is identified within the country.

(4) The Authority shall authorize the importation or exportation of cells, tissues, and organs, from an internationally recognized transplant program.

(5) Documentation relating to the distribution of cells, tissues and organs including the date of requests for offer of, and delivery of cells, tissues and organs shall be available for examination by the Authority or an authorized officer.

(6) A person who contravenes the provisions of this section 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

58. (1) The Authority shall promote public awareness about cells, tissues and organs donation through a comprehensive nationwide education and information campaign.

Cells, tissues, organs donor education, advocacy and public awareness.

(2) The advocacy and public awareness to donate cells, tissues and organs shall be conducted according to regulations under this Act.

(3) There shall be a register of persons or institutions that conduct public awareness and education on the donation of cells, tissues and organs.

59. (1) A cells, tissues or organs donor shall be provided with sufficient information upon which they can give an informed consent.

Living donor management.

(2) All potential donors shall be enlisted in the national donor registry maintained by the Authority.

(3) The Cabinet Secretary shall prescribe regulations on cells, blood, tissues and organs' donor follow up.

(4) The retrieval of cells, tissues or organs from a potential donor shall not be performed unless the potential donor has been examined and tested for evidence of transmissible diseases, viability and in accordance with this Act.

(5) Prior to making an eligibility determination, the donor must be screened and tissues evaluated for suitability as prescribed by regulations.

60. (1) The Authority shall establish mechanisms for notification, allocation and distribution for cells, tissues and organs as prescribed in the regulations.

Notification,
allocation and
distribution of
cells, tissue and
organs

(2) In carrying out the functions under subsection (1), the Authority shall —

- (a) establish and maintain the national waiting list for recipients;
- (b) receive notification of potential donors from Retrieval facilities;
- (c) authorize retrieval of cells, tissues and organs;
- (d) coordinate allocation of human cells, tissues and organs as prescribed in the regulations; and
- (e) coordinate distribution of cells, tissues and organs and any other function as approved by the Authority.

(3) The Authority shall ensure that —

- (a) organs, tissues and cells are allocated to patients on the national waiting list in a fair and transparent manner;
- (b) a candidate's citizenship or residency status in the Country shall be considered when allocating deceased donor organs to candidates for transplantation;
- (c) allocation of deceased donor organs shall not be influenced by politics, ethnicity, sex, religion, creed, or financial status;
- (d) where no suitable recipient is identified on the national waiting list, the Authority may authorise the allocation of the organ, tissue or cells to any other recognised international transplantation programs to which the Authority has an agreement; and
- (e) any other as prescribed and approved by the Authority in collaboration with other relevant regulatory bodies.

61. (1) A registered health care professional who intends to conduct cell, tissue or organ sampling for purposes of transplantation or transfusion shall—

Sampling of cell, tissue and organ.

- (a) obtain consent from the donor;
- (b) verify the viability of the cells, tissues or organs for transplantation; and
- (c) be satisfied with the safety of the transplant for the recipient.

(2) The Authority shall make regulations for sampling of cells, tissues or organs referred to under subsection (1).

62. A retrieval facility shall take all necessary measures to evaluate and maintain the potential donor who has been declared brain-dead and whose cells, tissues, organs are suitable for retrieval in accordance with this Act.

Evaluation and maintenance for potential donor.

63. (1) A retrieval facility shall notify the Authority of a potential donor under section 59 as stipulated in the Regulations.

Retrieval of organs, tissues or cells from deceased donors.

(2) A retrieval facility shall not retrieve any cells, tissues, organs from a potential donor referred to under subsection (1) without the approval of the Authority.

64. (1) A designated transplant facility shall, before retrieval, carry out tests to determine the suitability of a donor of cells, tissues or organs in accordance with this Act.

Testing requirements.

65. (1) Cells, tissues, organs found to be unsuitable for transplantation, research or training use shall be disposed as prescribed in the regulations.

Disposal of by-products of cells, tissues, organs and consumables.

66. The Authority shall develop standard data collection tools and systems and shall monitor the use of cells, tissues, organs by transplant facilities.

Monitoring and evaluation.

67. (1) Transplant related data and information shall be securely maintained as stipulated under the Data Protection Act.

Transplant related data and information.

68. (1) The Authority shall develop regulations for the reconstruction of the body of a donor which is integral to maintaining the dignity of the donor.

Cap. 411C.
Reconstruction of deceased donor.

69. (1) A person's cells, tissue, organs or body may only be donated under this Act for—

Restriction of purposes.

- (a) transplantation purposes;
- (b) therapeutic purposes;
- (c) medical education and training; or
- (d) scientific research.

(2) A person shall not put in use, procure, transfer, trade or process any cells, tissues, organs or body donated under this Act—

- (a) except for the purpose for which it was donated; and
- (b) in accordance with this Act and the Regulations made hereunder.

(3) A person shall not offer, give or receive any reward, payment or benefit for any cells, tissues, organs or body for use in any of the purposes specified under subsection (1).

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

70. (1) The donation of cells, tissues or organs, from living donors shall not take place without the prior authorisation of the Authority.

Donation and transplant of organs, tissues and cells removed from living non-related donors.

(2) A person shall not retrieve any human cells, tissues, organs from any living person who does not have the capacity to give valid consent in accordance with this Act.

(3) The Authority shall, in the following circumstances authorise the retrieval of cells tissues or organs from a living non-related donor—

- (a) if the person concerned is willing to donate and consents to the donation; and
- (b) the procedure carries minimal risk and burden to the donor.

(4) The Authority shall where it is satisfied that the proposed donation is consensual, authorise the donation.

(5) The transplantation facility shall in addition ensure that the recipient —

- (a) understands the nature and risks of both the donor retrieval procedure and those of the transplant procedure;
- (b) understands that it is illegal to offer any inducement or use coercion to obtain a donation and that no such inducement has been offered or coercion used by the recipient; and
- (c) understands that the donor may freely withdraw his or her consent at any time before harvest.

(6) The Authority shall register all living organ donors and offer follow up, where required.

(7) A living non related donor shall inform the Authority of their intention to donate within seven days of informing the transplanting facility and the Authority shall respond within seven days of receipt of the notice by the donor.

(8) A person who transplants cells, tissues, organs from a living donor without prior authorisation of the Authority commits an offence and is liable, on conviction, to a fine of twenty million shillings not exceeding fifty million shillings or imprisonment to a term not exceeding ten years or to both.

71. (1) A donor's cells, tissues or organs may be retrieved from deceased body who is brain dead or suffering from circulatory death for the purposes specified under this Act if —

Donation from a deceased person.

- (a) the donation or transplantation is approved by the Authority in accordance with the Act;
- (b) the deceased had provided consent to the donation before certification of brain death or circulatory death;
- (c) the person has been certified as dead in accordance with the medical criteria;

- (d) a registered health care professional certifying the death of a potential donor shall not participate directly in the retrieval of any cells, tissues organs, or subsequent transplant procedures or have care of a potential transplant recipient;
- (e) retrieval of any cells, tissues, organs or body from deceased donor shall be done as stipulated in the regulations under this Act;
- (f) the donation and allocation are approved by an independent transplant committee in accordance with the Act.

72. (1) The brain death of the potential donor shall be confirmed in accordance with the Act before any procedure related to donation is commenced.

Determination of brain death.

(2) The determination of brain death under subsection (1) shall be confirmed by two independent teams as defined in this Act, eight hours apart and these teams will comprise registered healthcare professionals with appropriate qualifications and experience sanctioned by the Authority.

(3) For purposes of this Act, brain death shall be confirmed in a person with irreversible damage to the vital centres in the brain, while cardio-respiratory function is artificially maintained, by specific testing criteria approved by the Authority.

73. (1) In the case of a potential cells, tissues or organ, donation from a circulatory dead person, the circulatory death of the potential donor must be confirmed in accordance with the Act before any procedure related to donation is commenced.

Determination of circulatory death.

(2) The determination of circulatory death under subsection (1) shall be confirmed by registered medical officer.

74. (1) Where there is a dead body lying in a mortuary and not claimed by any relative of the deceased person within six months from the time of the death of the concerned person, the authorization for retrieval of any cells, tissues, or organs from the unclaimed body may be given, by the relevant authority.

Donation of unclaimed bodies.

(2) An authorization shall not be given under subsection (1) if the relevant authority has reason to believe that a relative of the deceased person is likely to claim the dead body but has not come forward to claim the body of the deceased person within the time specified in subsection (1).

(3) The Authority shall inform the public through newspapers of wide circulation of its intention to grant the authority to retrieve cells, tissues or organs from unclaimed bodies.

75. (1) Where applicable, retrieved cells, tissues and organ which are not immediately used for transplantation shall be tested, preserved, processed, stored and distributed to banks approved by the Authority.

Cells, tissues and organs Bank.

(2) Only cells, tissues, organs, supplied by approved banks shall be used for purposes of transplantation, research and training.

(3) All approved banks shall be independently inspected by the Authority to ensure that they comply with this Act.

PART IX—TRANSPLANT QUALITY MANAGEMENT SYSTEM

76. (1) The Authority shall establish transplant services quality management system which ensures access to safe cells, tissue and organs and safety to donors and recipients.

Transplant quality management systems.

(2) The system established under subsection (1) shall provide for quality control and quality assurance system for transplant infrastructure, devices and consumables as prescribed in the regulations.

(3) The Authority shall approve all devices and consumables that apply in the Transplant Service as prescribed in the standards and regulations.

(4) All adverse events in retrieval facilities and transplant facilities shall be reported to the Authority as prescribed in the standards.

77. All cells, tissues and organ living donors shall be notified of their test results as prescribed by the regulations.

Notification requirements.

PART X—CELLS TISSUES OR ORGANS DONOR CONSENT

78. (1) A consent given under this Act shall be dated and signed by a person who —

Consent to living donation.

- (a) has attained the age of eighteen years;
- (b) is of sound mind; and
- (c) is under medical advice furnished to him prepared to do so.

(2) A person, in writing or orally, at any time in the presence of two or more witnesses may consent to the retrieval from their body of cells, tissue, organs specified in the consent —

- (a) for the purpose of the transplantation of the cells, tissues or organs to the body of another living person; or
- (b) for use in medical training and research purposes.

(3) A person who has given consent referred to in subsection (1) may, at any time before the retrieval of the cells, tissues and organ to which the consent applies, revoke, either orally or in writing, their consent to the retrieval.

79. (1) A person, either in writing or orally at any time in the presence of two or more witnesses may consent to the donation of their body upon their death, specified in the consent for use in medical training and research purposes.

Donation of a human body.

(2) A person who has given consent referred to in subsection (1) may, at any time before his or her death revoke, either orally or in writing, his consent to donate.

(3) Upon the death of a person who consented to the donation of his or her body, the family shall further give authority of the deceased body.

80. The following persons shall not witness an informed written consent —

Witness consent.

- (a) a health care professional who will retrieve the cells, tissue or organ;
- (b) a health care professional who will perform the transplantation;

- (c) a recipient of the transplant;
- (d) an immediate family member of the recipient of the transplant; and
- (e) a person who is required to give a consent in respect of the same donation.

81. A person of unsound mind shall not be a donor of cells, tissues or organs.

Protection of persons mentally disabled.

PART XI—DISPUTE RESOLUTION

82. (1) A person has a right to file a complaint to the Authority on any services related to—

Complaints.

- (a) blood and transplant services;
- (b) blood donation and transfusion; or
- (c) cells, tissues and organs donation and transplantation.

83. (1) Every blood and transplant service facility shall establish a complaints committee to receive and investigate complaints and where necessary resolve the complaint.

Complaints at facility level.

(2) The committee under subsection (1) shall consist of—

- (a) one member who is conversant with administration and shall be the chair;
- (b) three members appointed by the head of the facility, two of whom shall be independent and have knowledge in blood transfusion or transplant medicine; and
- (c) the committee may co-opt any other member on need basis;

(3) Any person dissatisfied with the findings of the committee shall appeal to the Authority.

84. (1) The Authority shall establish a complaints committee to receive, investigate, and resolve complaints reported to the Authority.

Complaints at the Authority.

(2) The committee under subsection (1) shall be a subcommittee of the Board and its composition shall be determined by the Board.

(3) Any person dissatisfied with the findings of the complaints committee shall appeal to the Tribunal.

(4) The quorum at meetings of the committee shall be three members where one of them shall be a co-opted member.

85. (1) The functions of the complaints committee shall be to—

Functions of the
complaints
committee.

- (a) conduct inquiries into and hearings over complaints at a transfusing and transplant facilities;
- (b) receive and process appeals by individual health care professionals, health facilities or a member of the public to the Authority when not satisfied by a decision of the committee;
- (c) ensure that the necessary administrative and evidential arrangements have been met;
- (d) promote mediation between the parties and refer such matters to a mediator where a transfusing or transplant facility fails to resolve a complaint to the satisfaction of the complainant;
- (e) take necessary action as the parties may agree in writing;
- (f) at its own liberty, adopt mediation agreements or compromise between the parties, on such agreed terms; and
- (g) carry out any other complaint or appeals handling function that the Authority may from time-to-time delegate.

(2) Any person aggrieved by the decision of the committee may appeal to the tribunal within thirty days.

86. The complaints committee shall have the power to, summon persons to attend and give evidence and order for the production of relevant documents.

Powers of the
complaints
committee

87. (1) There is established a Tribunal to be known as the Blood and Transplant Appeals Tribunal.

Blood and
Transplant
Appeals Tribunal.

(2) The Tribunal shall consist of—

- (c) a recipient of the transplant;
- (d) an immediate family member of the recipient of the transplant; and
- (e) a person who is required to give a consent in respect of the same donation.

81. A person of unsound mind shall not be a donor of cells, tissues or organs.

Protection of persons mentally disabled.

PART XI—DISPUTE RESOLUTION

82. (1) A person has a right to file a complaint to the Authority on any services related to—

Complaints.

- (a) blood and transplant services;
- (b) blood donation and transfusion; or
- (c) cells, tissues and organs donation and transplantation.

83. (1) Every blood and transplant service facility shall establish a complaints committee to receive and investigate complaints and where necessary resolve the complaint.

Complaints at facility level.

(2) The committee under subsection (1) shall consist of—

- (a) one member who is conversant with administration and shall be the chair;
- (b) three members appointed by the head of the facility, two of whom shall be independent and have knowledge in blood transfusion or transplant medicine; and
- (c) the committee may co-opt any other member on need basis;

(3) Any person dissatisfied with the findings of the committee shall appeal to the Authority.

84. (1) The Authority shall establish a complaints committee to receive, investigate, and resolve complaints reported to the Authority.

Complaints at the Authority.

(2) The committee under subsection (1) shall be a subcommittee of the Board and its composition shall be determined by the Board.

(3) Any person dissatisfied with the findings of the complaints committee shall appeal to the Tribunal.

(4) The quorum at meetings of the committee shall be three members where one of them shall be a co-opted member.

85. (1) The functions of the complaints committee shall be to—

Functions of the
complaints
committee.

- (a) conduct inquiries into and hearings over complaints at a transfusing and transplant facilities;
- (b) receive and process appeals by individual health care professionals, health facilities or a member of the public to the Authority when not satisfied by a decision of the committee;
- (c) ensure that the necessary administrative and evidential arrangements have been met;
- (d) promote mediation between the parties and refer such matters to a mediator where a transfusing or transplant facility fails to resolve a complaint to the satisfaction of the complainant;
- (e) take necessary action as the parties may agree in writing;
- (f) at its own liberty, adopt mediation agreements or compromise between the parties, on such agreed terms; and
- (g) carry out any other complaint or appeals handling function that the Authority may from time-to-time delegate.

(2) Any person aggrieved by the decision of the committee may appeal to the tribunal within thirty days.

86. The complaints committee shall have the power to, summon persons to attend and give evidence and order for the production of relevant documents.

Powers of the
complaints
committee

87. (1) There is established a Tribunal to be known as the Blood and Transplant Appeals Tribunal.

Blood and
Transplant
Appeals Tribunal.

(2) The Tribunal shall consist of—

- (a) a chairperson who shall be appointed by the President from among persons qualified to be judges of the High Court; and
- (b) six other members who shall be appointed by the Judicial Service Commission, two of whom shall be advocates of the High Court with seven years standing and two professionals in the medical field and two persons representing the interests of donors or recipients.

(3) The Chairperson and the members shall hold office for a term of three years and may be reappointed for one further term of three years.

(4) A person shall not be qualified to be appointed as a member of the Tribunal if that person is an official of a political party.

(5) A person qualifies to be appointed under this section if the person meets the requirements of Chapter Six of the Constitution.

(6) The quorum of the Tribunal shall be three members one of whom shall be a health care professional.

(7) The members of the Tribunal shall be entitled to receive such allowances as the Cabinet Secretary, in consultation with the Salaries and Remuneration Commission, may determine.

(8) The Cabinet Secretary shall appoint a public officer to be the secretary to the Tribunal who shall be paid such allowances as the Cabinet Secretary shall determine.

88. (1) The Tribunal shall determine appeals against decisions of the Authority on registration and licensing under this Act.

Jurisdiction of the Tribunal.

(2) Any person who is aggrieved with a decision of the Authority on registration and licensing, may appeal in writing to the Tribunal against such decision.

(3) Notwithstanding subsection (1), the Tribunal shall hear appeals against decisions of the Authority where the Authority has failed to resolve a complaint as the Tribunal shall determine.

(4) 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 Authority; and
- (b) set out the grounds of appeal.

(5) After considering the grounds of appeal and the reasons for the decision, the Tribunal shall, as soon as is practicable—

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

(6) Any person aggrieved by the decision of the Tribunal may, within thirty days of such decision, appeal to the High Court.

PART XII—ENFORCEMENT

89. (1) The Board shall, for purposes of enforcing the provisions of this Act appoint such number of authorized officers and inspectors with adequate training on matters related to this Act as the Cabinet Secretary may consider appropriate.

Appointment of authorized persons and inspectors.

(2) The appointment of authorized officers and inspectors under subsection (1) shall be by notice in the gazette for a renewable period of three years.

(3) The Board shall issue a certificate of appointment to every person appointed as an authorized officer or inspector under this section.

90. (1) An authorized officer or inspector may, at any time and with or without a warrant, enter, inspect and search any premises or facility where the authorized officer or inspector has reasonable cause to believe—

Powers of entry, inspection and search.

- (a) trades in human organs, cells and tissues;
- (b) is carrying out trafficking in human cells, tissues and organs;
- (c) obtains financial gain or comparable advantage from the medical and scientific use of the human body and its parts;

- (d) transplantation is being conducted in an unregistered facility;
- (e) transplantation is being conducted by unregistered healthcare professionals;
- (f) unauthorized retrieval of cells, tissues and organs is taking place;
- (g) is carrying out unauthorized blood or component collection;
- (h) is carrying out unauthorized storage, transportation or distribution; or
- (i) is performing any other activity contrary to this Act.

91. (1) An authorized officer or inspector shall perform the following duties—

Duty of authorized officers and inspectors to investigate.

- (a) investigate whether any provision of this Act has been or is being contravened;
- (b) investigate any complaint or matter in respect of which the Authority may take action under this Act;
- (c) assess whether the practices and procedures of a research institution, a researcher or an institutional review board in relation to any human biomedical research are in compliance with this Act and the regulations made under this Act; and
- (d) assess whether the practices and procedures of a tissue bank and transplant facilities in relation to any tissue banking activity or transplant activities are in compliance with this Act and the regulations made under this Act.

(2) An authorized officer or inspector shall report to the Board on their findings.

92. An authorised officer may —

Duty of authorized officers and inspectors to inspect.

- (a) inspect and make copies of and take extracts from, or require the occupier or any person having the

management or control of, the premises to provide copies of or extracts from, any book, document, record or electronic material;

- (b) inspect and make copies of and take extracts from, or require the occupier or any person having the management or control of, the premises to provide copies of or extracts from, any medical record of any person who has been or who is being treated or examined at the premises, even though the prior consent of such person has not been obtained;
- (c) inspect any apparatus, appliance, equipment or instrument used or found in the premises;
- (d) inspect any test or procedure relating to any human biomedical research that has been or is being conducted on the premises;
- (e) inspect, test, examine, remove and detain any biological material or organism or any product of human biomedical research found on the premises; and
- (f) inspect, test, examine and remove any container, article and other thing that the authorised officer reasonably believes to contain or to have contained any biological material or organism or any product of human biomedical research that has been or is being conducted in the premises.

(2) An authorized officer or inspector shall report to the Board on their findings.

93. (1) An authorised officer may seize from any premises or place—

Duty of authorized officers and inspectors to seize.

- (a) any biological material or organism or any product of human biomedical research; or
- (b) any book, document, record, apparatus, appliance, equipment or instrument,

which the authorised officer reasonably believes to be the subject matter of, or to be connected with the commission of, an offence under this Act.

(2) An authorized officer or inspector shall report to the Board on their findings.

94. (1) A person commits an offence if without reasonable cause—

Obstruction of inspectors.

- (a) obstructs or hinders an authorized officer or an inspector in the exercise of the officer's or inspector's powers under this Part, or
- (b) knowingly or recklessly makes a statement or produces a document that is false or misleading in a material particular to the inspector or authorised officer engaged in carrying out his duties and functions under this Act.

(2) A person who contravene this section shall be liable upon conviction to a fine not exceeding ten million shillings or imprisonment for a term not exceeding three years, or both.

PART XIII—FINANCIAL PROVISIONS

95. The funds of the Authority shall consist of—

Funds of the Authority.

- (a) such monies as may be appropriated by the National Assembly;
- (b) fees, monies or assets as may accrue to or vest in the Authority 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 Authority;
- (d) such monies as may be payable to the Authority pursuant to this Act or any other written law; and
- (e) all monies from any other lawful source provided, donated or lent to the Authority.

96. The financial year of the Authority shall be a period of twelve months ending on the thirtieth June of each year.

Financial year.

97. (1) The annual budget estimates shall be prepared in accordance with the Public Finance Management Act and any other guidelines provided in law.

Annual estimates.

Cap. 412A.

- (2) The annual estimates shall provide for —
- (a) payment of the salaries, allowances and other charges in respect of Board members and staff of the Authority;
 - (b) payment of pensions, gratuities and other charges in respect of members of staff of the Authority;
 - (c) the proper maintenance of the infrastructure and grounds of the Authority;
 - (d) maintenance, repair and replacement of the plant, equipment and other property of the Authority;
 - (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; and
 - (f) the carrying out of core activities of the Authority.

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

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 Authority together with—

- (a) a statement of the income and expenditure of the Authority during that financial year; and
- (b) a statement of the assets and liabilities of the Authority on the last day of that year.

PART XIV—MISCELLANEOUS

99. (1) A person shall not disclose or give to any other person any information or document indicating the identity of a person or a donor or a recipient or with respect to whom whose body a consent or authorization has been given under this Act.

Disclosure of
information.

(2) Subsection (1) shall not apply to any information disclosed—

- (a) in accordance with an order of a Court or required by law;

- (b) for the purposes of hospital administration or bona fide medical research;
- (c) with the consent of the person to whom the information relates; or
- (d) in circumstances in which the disclosure is or would be privileged.

100. (1) Subject to this Act, a person shall not be liable in any proceedings for any act done as a result of a consent or authorization given under this Act, where the act is done without negligence and in good faith.

Exclusion of liability of persons acting in pursuance of consent.

(2) Without prejudice to the generality of subsection (1), a person shall be regarded as having done an act in good faith if the person establishes that the person had—

- (a) an honest and reasonable belief that the requisite consent or authorization required by this Act had been given; or
- (b) no reason to doubt that the consent or authorization had been given in accordance with this Act.

101. Any person who conducts any transfusion service on another person without the consent of that person or, in the case of a deceased person, minor or an incapacitated person, without the consent of their parents or legal guardian, commits an offence and shall be liable, upon conviction, to a fine not less than five hundred thousand and not exceeding one million shillings or imprisonment for a term of two years not exceeding three years, or both.

Transfusion services without informed written consent.

102. (1) Any person who conducts any transplant service on another person without the consent of that person or, in the case of a deceased person, minor or an incapacitated person, without the consent of their legal representative, commits an offence and shall be liable, upon conviction, to a fine of five million and not exceeding ten million shillings or imprisonment for a term of five years and not exceeding ten years, or to both.

Transplanting services without informed written consent.

(2) A person who removes any cells, tissues or organs from a living or deceased person without consent obtained in accordance with this Act commits an offence and shall be liable, upon conviction, to a fine of twenty million and

not exceeding fifty million shillings or imprisonment for a term of five years and not exceeding ten years, or to both.

103. (1) A person who receives any monetary or other forms of compensation for cells, tissues, organs other than reimbursement of donation-related expenses, commits an offence, and is liable, upon conviction, to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.

Prohibition of commercial dealings in Substances of Human Origin for transplantation.

(2) A person who sells one or a pair of organs by a living donor for financial or any other form of compensation, commits an offence, and is liable, upon conviction, to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.

(3) Any person who—

- (a) gives or receives a reward for the supply of, or for an offer to supply a human organ, cell or tissue;
- (b) seeks to find a person willing to supply for payment, any human organ, cell or tissue;
- (c) offers to supply any human organ, cell or tissue for reward;
- (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any human organ, cell or tissue;
- (e) takes part in the management or control of a body of persons corporate or unincorporated whose activities consist of or include the initiation or negotiation of arrangements to seek or offer human organs, tissues or cells for reward;
- (f) takes part in the management or control of a body of persons, whether a society, firm or body corporate, whose activities consist of or include the initiation or negotiation of any arrangement referred to in paragraph (d); or
- (g) publishes or distributes or causes to be published or distributed any advertisement —
 - (i) inviting persons to supply for payment any human organ, cell or tissue;

- (ii) offering to supply any human organ, cell or tissue for payment; or
- (iii) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in paragraph (d);

commits an offence, and is liable, upon conviction, to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.

(4) A reference in this section to “reward”, in relation to the supply of any human organ, tissue or cell does not include payment in money or money’s worth for defraying or reimbursing—

- (a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing any human organ, cell or tissue;
- (b) any liability incurred in respect of expenses incurred by a third party in, or in connection with, any of the activities mentioned in paragraph (a); or
- (c) any expenses or loss of earnings incurred by the person from whose body the organ, tissue or cell is removed so far as reasonably and directly attributable to his or her organ, tissue or cell, for a period of six months from the date of donation.

104. (1) A person who renders his or her services to or at any hospital and who, for purposes of transplantation, conducts, associates with, or helps in any manner, in the retrieval of any human organ, cell or tissue without authorization and contrary to this Act commits an offence and is liable, on conviction, to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.

Retrieval of human organ, cell or tissue without authorization.

(2) A person who renders his or her services outside a hospital environment for purposes of transplantation, conducts, associates with, or helps in any manner, in the retrieval of any human organ, cell or tissue without authorization and contrary to this Act commits an offence and is liable, on conviction to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.

-
- 105.** (1) A person shall not — Prohibited activities.
- (a) trade in human organs, cells and tissues;
 - (b) trafficking in human organs, cells and tissues;
 - (c) obtaining financial gain or comparable advantage from the medical and scientific use of human body and its parts.
- 106.** A recipient of a donation may compensate a living donor for— Exceptions to prohibited activities.
- (a) loss of earnings and any other justifiable expenses caused by the retrieval or by related medical examinations;
 - (b) payment of a justifiable fee for legitimate medical or other related technical services rendered in connection with the transplantation; and
 - (c) undue damage resulting from the retrieval of an organ, tissue or cell from a living person.
- (2) A recipient shall report to the Authority any compensation made to a living donor.
- (3) The transplantation of cells, tissues and organs from a living or brain-dead donor shall be carried out solely for the therapeutic benefit of the recipient where there is no alternative therapeutic method of comparable effectiveness.
- (4) All publicity relating to transplantation activities shall be authorised by the Authority.
- (5) A person who uses force or any form of coercion to obtain a donation of organs, tissues or cells commits an offence.
- (6) A person who contravenes this section commits an offence and is liable, on conviction, to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.
- 107.** (1) A person who, without authorisation and appropriate consent in accordance with this Act, removes cells, tissues or organs from the body of any person intending that it be used for transplantation, commits an offence. Retrieval of human organ, tissue or cell from living donor without consent or authorisation.

(2) A person who commits an offence under subsection (1) is liable on conviction, to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.

108. (1) A person who—

Restriction of activities in relation to donated material.

(a) uses any donated cells, tissues or organ for a purpose which is not a qualifying purpose; or

(b) stores donated material for use for a purpose which is not a qualifying purpose; commits an offence.

(2) A person who commits an offence under subsection (1) is liable, on conviction, to a fine not exceeding fifty million shillings or imprisonment not exceeding twenty-five years or both.

109. (1) A director, secretary or manager of a body corporate shall be liable for any offence committed by the body corporate under this Act or regulations made hereunder.

Offences by a legal entity.

It shall be a defence on a charge under this section if the offence was committed without consent or connivance of the director, secretary or manager and that he or she exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard the nature of his functions and circumstances of the case.

(2) If an offence under this Act or any regulations made hereunder is committed by a partner in a firm, every person who, at the time of the commission of the offence, was a partner in that firm, or was purporting to act in that office shall be deemed to have committed the offence, unless there is proof that the offence was committed without the consent or connivance of the partner and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions and the circumstances of the case.

110. (1) The Cabinet Secretary shall on the recommendation of the Authority, make regulations generally for the better implementation of this Act.

Regulations.

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

- (a) the medical eligibility criteria for donors and recipients and procedures for donation of cells, tissues, organs;
- (b) the conduct of any transfusion service or transplanting service;
- (c) the procedure for obtaining and categories of informed written consent;
- (d) the fees chargeable for the services offered by the Authority;
- (e) the production and use of blood products;
- (f) the banking, storage and registry of cells, tissues or organs;
- (g) the importation or exportation of blood, blood components, blood products, cells, tissues or organs; and
- (h) any other matter which may be prescribed under this Act.

PART XV— CONSEQUENTIAL AMENDMENTS

- | | | |
|-----|---|-----------------------------------|
| 80. | 111. The Health Act is amended by repealing section | Repeal of section 80 of Cap. 241. |
| 81 | 112. The Health Act is amended by repealing section | Repeal of section 81 of Cap. 241. |
| 82 | 113. The Health Act is amended by repealing section | Repeal of section 82 of Cap. 241. |
| 83. | 114. The Health Act is amended by repealing section | Repeal of section 83 of Cap. 241. |
| 84. | 115. The Health Act is amended by repealing section | Repeal of section 84 of Cap. 241. |
| 85. | 116. The Health Act is amended by repealing section | Repeal of section 85 of Cap. 241. |
| | 117. The Human Tissue Act is repealed. | Repeal of Cap 252. |

PART XVI—TRANSITIONAL PROVISIONS

- | | |
|---|---|
| 118. The existing private blood collection and processing centres operating prior to the enactment of this Act shall apply to be registered and licensed by the | Existing private blood collection and processing centres. |
|---|---|

Authority in accordance with this Act within six months from the date of commencement of this Act.

119. The Authority in consultation with 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) The Kenya Blood and Transplant Authority shall be the successor to the Department of the National Blood Transfusion, Tissue and Human Organ Transplant Services existing at the Ministry of Health at the commencement of this Act.

MEMORANDUM OF OBJECTS AND REASONS

Statement of Objects and Reasons

The principal object of the Kenya Blood Cells Tissue and Organs Bill, 2025 is to provide for the establishment of the Kenya Blood and Transplant Authority which shall be responsible for the regulation of blood and transplant services, blood donation and transfusion, cells, human breast milk, tissues and organs donation and transplantation. This Bill regulates and coordinates blood donation, transfusion and cells, tissue and organ donation and transplantation.

The Bill also regulates the secure and effective supply of safe blood, cells, tissues and organs and the effective transfusion of blood and blood components and transplantation of cells, tissues and organs for therapeutic purposes. The Bill seeks to promote the adoption of globally accepted ethical principles for the donation and management of blood, cells, tissues and organs.

Part I of the Bill deals with interpretation and definitions, principles of the Bill and application of the Bill. The object of the Bill is to establish the Kenya Blood and Transplant Authority, to establish and coordinate an organized national blood service and to establish and coordinate an organized national transplant service.

Part II of the Bill deals with the establishment, functions and powers of the Kenya Blood and Transplant Authority. The role of the Authority is to advise the Cabinet secretary and county governments on policy matters relating to blood, blood components and products cells, tissues and organs; and to regulate blood and transplant services as stipulated in this Act provide technical assistance on matters relating to blood, cells, tissues, organs; and also ensure compliance with policies and standards for blood and transplant service practice.

Part III of the Bill provides for the role of the county governments which includes implementing policies, guidelines, procedures and standards in conducting blood and transplant services in collaboration with the Authority; to promote public education and public awareness in the donation of blood, cells, tissues and organs in partnership with the Authority; and to collaborate with local and international partners and stakeholders in the provision of safe blood transfusion and transplantation as per the prescribed regulations.

Part IV of the Bill provides for registration and certification of Transfusing facilities, Transplant facilities, Retrieval Facilities, Blood,

Cells, Tissues, Organ Banks, Sample Referral Courier Providers and Distributors by the Authority.

Part V of the Bill deals with the establishment of blood, cells, tissue and organ centers, for the carrying out of Blood services. The part also provides for the National blood and transplant reference laboratory to provide basic and specialized testing references, internal and external quality assessments, standardization, validation, verification and methodological guidance

Part VI of the Bill deals with blood testing, processing, storage and utilization including blood labelling and storage, establishment of Facility Transfusion Committees, disposal of blood and import and export of blood.

Part VII of the Bill deals with the establishment of a blood service quality management system that ensures access to safe blood and blood components and safety to donors and recipients as prescribed in regulations.

Part VIII of the Bill deals with the management of transplant services, including the definition of donors, establishment and maintenance of a national waiting list for recipients of individual cells, tissues and organs; establishment of a National Centre for Notification, Allocation and Distribution for cells, tissues and organs and establishment of a National Transplant Committee. The Bill also provides for the regulation of transplantation of brain-dead patients as well as unclaimed bodies in the mortuary.

Part IX of the Bill provides for the establishment of a transplant services quality management system which ensures access to safe cells, tissue and organs and safety to donors and recipients.

Part X of the Bill deals with consent to the retrieval of cells, tissue and organs from a living donor as well as minors; it also provides for revocation of consent. This part also provides for the prohibition of mentally disabled persons.

Part XI of the Bill deals with dispute resolution which includes the establishment of a complaints committee and the Blood and Transplant Appeal Tribunal which reviews the decision of the board on registration and licensing.

Part XII of the Bill deals with the appointment of authorized persons and investigators who have duties and powers to investigate, search and seize matters related to unlawful and unregulated transfusion and

transplanting; as well as creates an offence of obscuration of investigations.

Part XIII of the Bill outlines the financial provisions which include reporting and accounting obligations of the Authority.

Part XIV of the Bill deals with offences such as disclosure of information of a donor, transfusion services without informed written consent, transplanting services without informed written consent, commercial dealings in Substances of Human Origin for transplantation, retrieval of human organs, cells or tissue without authorization, trade in human organs, cells and tissues; trafficking in human organs, cells and tissues; obtaining financial gain or comparable advantage from the medical and scientific use of human body and its parts; and retrieval of human organ, tissue or cell from living donor without consent or authorisation.

Part XV of the Bill provides for consequential amendments which repeal provisions of the Health Act and the Human Tissue Act.

Part XVI of the Bill deals with transitional provisions on the registration of blood collection and processing centres and the implementation of the Act.

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

The Bill delegates legislative powers to the Cabinet Secretary for the better implementation of this Act, however, it does not limit rights and fundamental freedoms in the Bill of Rights.

Statement that the Bill concerns county governments

The Bill affects the functions of the county governments pursuant to the Fourth Schedule to the constitution which provides that health is a shared function between the National and County Governments.

Statement that the Bill is a money Bill within the meaning of Article 114 of the Constitution

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

Dated the, 2025.

JAMES WAMBURA NYIKAL,
*Chairperson of
the Departmental Committee on Health.*