A
BILL

to provide for regulation, removal, storage and transplantation of human organs, tissues and cells for therapeutic purposes in the Province of the Khyber Pakhtunkhwa and to establish the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority

WHEREAS it is expedient to provide for regulation, removal, storage and transplantation of human organs, tissues and cells for therapeutic purposes in the Province of the Khyber Pakhtunkhwa and to establish the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority and for matters connected there with and ancillary thereto;

It is hereby enacted as follows:

1. Short title, extent and commencement.---(1) This Act may be called the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority Act, 2014.

(2) It shall extend to the whole of the Province of the Khyber Pakhtunkhwa.

(3) It shall come into force at once.

2. Definitions.---In this Act, unless there is anything repugnant in the subject or context,-

(a) "Administrator" means the Administrator of the Regulatory Authority;

(b) "brain dead" means irreversible loss of brain and brain stem functions simultaneously;

(c) "death" means the irreversible cessation of the entire function of brain stem;

(d) "donor" means a person who donates any part of his body, organ, tissue or cell;

(e) "Fund" means the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority Fund, established under this Act;

(f) "Government" means the Government of the Khyber Pakhtunkhwa;

(g) "human organ" means any part of a human body, organ or tissue or cell;

(h) "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing,-

(i) the cost of removing, transporting or preserving the human organ to be supplied; or

(ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any organ from his body;

(i) “prescribed” means prescribed by rules made under this Act;

(j) “recognized institution” means a medical institution or hospital recognized by the Regulatory Authority for practice of operative surgery in transplantation of human organs;

(k) “recognized transplant surgeon or physician” means Surgeons or Physicians recognized by the Regulatory Authority and possessing appropriate qualifications, experience and training in the relevant field, to investigate, examine and carry out transplantation surgery of human organs;

(l) “Regulatory Authority” means the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority established under section 5 of this Act;

(m) “Transplantation” means the grafting of any human organ of any living or deceased person to some other living person for therapeutic purposes;

(n) “Transplant Ethical Regulatory Committee” means the Transplant Ethical Regulatory Committee constituted under section 16 of this Act;

(o) “Transplant Evaluation Committee” means a Transplant Evaluation Committee constituted under section 13 of this Act;

(p) “Transplant Monitoring Committee” means a Transplant Monitoring Committee constituted under section 14 of this Act; and

(q) “Transplant Inquiry Committee” means a Transplant Inquiry Committee constituted under section 15 of this Act.

3. Donation of organ or tissue by a living person.---(1) Notwithstanding anything contained in any other law for the time being in force, a living donor who is not less than eighteen years of age, may during his life-time voluntarily donate any organs of his body to any other living person genetically and legally related, who is a close blood relative and the donation of organ or part or tissue or cell by such person for therapeutic purpose shall be regulated in the manner as may be prescribed. In the case of regenerative tissue, i.e. stem cells, there is no restriction of age between siblings.

Explanation: For the purpose of this section, the expression “close blood relative” means parent, son, daughter, sister, brother and includes spouse:

Provided that transplantation shall be voluntary, genuinely motivated and without any duress or coercion.

(2) In case of non-availability of a donor as explained under sub-section (1), the Transplant Evaluation Committee, may allow donation by a non “close blood relative”, after satisfying itself that such donation is voluntary.

4. Donation of human organs after death.---(1) Any person who is not less than eighteen years of age, may before his death, in writing duly signed and verified by the respective Transplant Evaluation Committee, donate any of his organ or tissue for transplantation and for this purpose, may authorize any medical institution or hospital duly recognized by the Regulatory Authority.

(2) The cases of unclaimed brain dead hospitalized patients shall be presented to the Transplant Evaluation Committee for transplantation, after an intense search for their relatives within a reasonable time.

(3) Human organ may be harvested for transplantation from a brain dead hospitalized patient with no prior consent or will for donation after evaluation by the Transplant Evaluation Committee and informed consent by close blood relative as provided in sub-section (1) of section 3.

(4) On the death of a donor referred to in sub-section (1), any close relative of the deceased shall inform the Transplant Evaluation Committee about the deceased and cause the removal of the human organ or tissue in accordance with the authorization.

(5) A donation under sub-section (1), may be executed in such form and manner as may be prescribed and may be revoked at any time during the lifetime of the donor in the presence of two witnesses.

5. Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority.---(1) As soon as may be, after the commencement of this Act, Government by notification in the official Gazette, shall establish the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority.

(2) The Regulatory Authority shall have its head office at Peshawar.

(3) The Regulatory Authority shall be a body corporate, having perpetual succession and a common seal, with power to enter into contract, acquire or dispose of property, and may, by its name, sue or be sued.

(4) The Regulatory Authority shall consist of the following, namely:

(a)	Minister Health, Government of the Khyber Pakhtunkhwa;	Chairperson
(b)	Secretary to Government, Health Department;	Member
(c)	a recognized Surgical Transplant Specialist;	Member
(d)	a recognized Medical Transplant Specialist;	Member
(e)	a recognized Gastroenterologist;	Member
(f)	a recognized Hepatalogist;	Member
(g)	a recognized Ophthalmologist;	Member
(h)	representative from private transplant setup in the Province of the Khyber Pakhtunkhwa;	Member
(i)	a recognized Anesthetist; and	Member
(j)	Administrator.	Member-

cum-Secretary

(5) The non-official member at clause (h) shall be appointed by Government for a period of three years and may be removed earlier in the prescribed manner. The non-official member may, under his hand by writing resign his office.

(6) The members at clauses (c), (d), (e), (f), (g) and (i) shall be appointed by Government for a renewable period of three years.

(7) The Regulatory Authority shall regulate, monitor and control all the transplantation of human organs and various committees constituted under this Act.

(8) The Regulatory Authority shall, cause to establish a Provincial Registry and Provincial and regional networks for evaluating quality and outcome of transplant centers and cause enhancement and promotion of transplantation;

(9) It shall establish pool of voluntary donors and registry of potential recipients and regulate it in a manner as prescribed.

(10) The Regulatory Authority, by notification in the official Gazette, recognize medical institutions and hospitals for practice of operative surgery in transplantation of human organs.

(11) No hospital or medical institution shall carry out transplantation of human organs unless it is recognized as provided in sub-section (10).

06. Conduct of business.---(1) The Regulatory Authority shall meet at least after every three months and the meetings of the Regulatory Authority shall be held in such a manner as may be prescribed by rules and until rules are made in such a manner, as may be determined by the Regulatory Authority.

(2) The Administrator shall, on the direction of the Chairperson, call a meeting of the Regulatory Authority; provided that the Chairperson may also convene the meeting of the Regulatory Authority on the request of three members in writing, citing a reason.

(3) Chairperson shall preside over the meeting of the Regulatory Authority and in his absence any person nominated by him shall preside over the meeting of the Regulatory Authority.

(4) The quorum for a meeting shall be one half of the total membership.

(5) A decision shall be made by simple majority present and voting. The Chairperson or the member presiding over the meeting shall have a casting vote in case of tie.

(6) No act or proceedings of the Regulatory Authority shall be questioned or invalidated merely on the ground of existence of any vacancy or defect in the constitution of the Regulatory Authority.

07. Appointment of an Administrator.---(1) There shall be an Administrator of the Regulatory Authority, who shall be appointed by Government on deputation basis from amongst Government Officers preferably from the medical profession in Basic Pay Scale 20.

(2) Unless earlier removed, an Administrator shall hold office for a period of three years.

(3) An Administrator, subject to the control of the Regulatory Authority, shall be responsible for execution of the decisions and policy set out by the Regulatory Authority from time to time and implementation of the rules made under the this Act.

(4) An Administrator shall exercise such powers as are mentioned in this Act or as may be prescribed or delegated to him.

08. Appointment of officers and employees.---In the discharge of its function, the Regulatory Authority may, from time to time, appoint such officers, officials, consultants and advisors, as it may consider necessary for its efficient performance, on such terms and conditions, as it may deem fit.

09. Fund.---(1) There shall be established a fund to be known as the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority Fund, to be administered and controlled by the Regulatory Authority.

(2) The Fund shall consist of,-

(a) grants made by Government or Federal Government from time to time;

(b) donations by philanthropists;

(c) income from any other source; and

(d) grants from other sources.

(3) The Fund shall be utilized for the purposes of this Act, including expenses to run the affairs of Regulatory Authority.

(4) The Fund shall be kept and maintained through such Bank and invested upon in such manner as may be determined by the Regulatory Authority.

10. Budget.---The Administrator shall, in respect of each financial year, submit for the approval of the Regulatory Authority, by such date and in such manner as may be prescribed, a statement showing the estimated receipts, the current and development expenditures and the sum required as grant-in-aid from Government.

11. Maintenance of accounts.---(1) The Regulatory Authority shall maintain proper accounts and other records relating to its financial affairs including its income and expenditures and its assets and liabilities in such form and manner as may be prescribed.

(2) After the conclusion of a financial year, the Regulatory Authority, in the prescribed manner, shall cause to prepare statements of account of the Regulatory Authority which shall include a balance-sheet and an account of income and expenditures.

(3) The Regulatory Authority shall approve its annual budget for a financial year in the prescribed manner.

(4) No expenditure for which provision has not been made in any approved budget shall be incurred without prior approval of the Regulatory Authority.

12. Audit.---The Auditor General of Pakistan shall annually audit the accounts of the Regulatory Authority.

13. Transplant Evaluation Committee.---(1) As soon as may be after the commencement of this Act, the Regulatory Authority may, by notification in the official Gazette, constitute, Transplant Evaluation Committees for recognized institutions. Each Transplant Evaluation Committee shall consist of a recognized surgical specialist, a recognized medical specialist, a recognized transplant specialist, a recognized nephrologist, a recognized neurophysician and a recognized intensivist where available and two local notables having a good record of social service.

(2) The Transplant Evaluation Committee shall be chaired by the head of the recognized medical institution.

(3) The Transplant Evaluation Committee shall-

(a) ensure that no organ or tissue is retrieved from non-related living donors without the prior approval of the Evaluation Committee;

(b) determine brain death of a person;

(c) determine propriety of removal of a human organ from any living person after formal informed consent, in cases of partial donation of an organ or donation of one of the paired organs;

(d) determine propriety of removal of a human organ from any living person using brain death protocol to be formulated;

(e) determine fitness or otherwise for transplantation of a human organ into any other body; and

(f) determine the fitness of recipient.

14. Transplant Monitoring Committee.—(1) The Regulatory Authority shall, by notification in the official Gazette, constitute a Transplant Monitoring Committee

(2) The Transplant Monitoring Committee shall consist of-

(a)	Additional Secretary to Government, Health Department;	Chairman
(b)	a recognized Surgical transplant specialist;	Member
(c)	a recognized Medical transplant specialist;	Member
(d)	a recognized Gastroenterologist;	Member
(e)	a recognized Hepatalogist;	Member
(f)	a recognized Ophthalmologist; and	Member

(g)	Director Health, Khyber Pakhtunkhwa.	Member-cum-Secretary

(3) The Transplant Monitoring Committee may, co-opt such other members as it may deem fit.

(4) The members at clauses (b), (c), (d), (e) and (f) shall be appointed by Regulatory Authority for a renewable period of three years.

(5) The Transplant Monitoring Committee shall-

(a) monitor transplantation and enforce prescribed standards for recognized medical institutions and hospitals; and

(b) inspect recognized medical institutions and hospitals for examination of quality of transplantation, follow up medical care of donor and recipient and any other matter ancillary thereto and also periodically inspect institutions wishing to be recognized.

15. Transplant Inquiry Committee.---(1) The Regulatory Authority may, by notification in the official Gazette, constitute a Transplant Inquiry Committee, consisting of the following-

(a)	Director General Health Services, Khyber Pakhtunkhwa;	Chairman-cum-Secretary
(b)	a nominee of the Monitoring Committee;	Member
(c)	a nominee of the hospital concerned; and	Member
(d)	one notable of the respective district where the concerned hospital is situated to be nominated by the Minister Health.	Member

(2) The Transplant Inquiry Committee shall investigate and hold inquiry into the allegations of breach of any provision of this Act in the prescribed manner;

16. Transplant Ethical Regulatory Committee.---(1) The Regulatory Authority may constitute, for a specific time or case, a Transplant Ethical Regulatory Committee as and when required, which shall consists of two notables, two health professionals and two religious scholars.

(2) It shall address religious, cultural and ethical issues that may arise.

(3) Administrator shall be the Chairman-cum-Secretary of the Transplant Ethical Regulatory Committee.

17. Transplantation to be carried out by the team of transplant surgeons and physicians.---(1) The transplantation of human organ or removal of any part of human organ for the purpose of transplantation shall only be carried out by the recognized professionals who shall, before the removal of any human organ from the body of the deceased, ensure that written certification has been obtained from the Transplant Evaluation Committee that death has occurred.

(2) For the purpose of sub-section (1), a person shall be deemed to be medically and legally dead at the time when in the opinion of the Transplant Evaluation Committee, based upon acceptable standard of medical practice, there is-

(a) an absence of natural respiratory and cardiac functions and attempt at resuscitation are not successful in restoring those functions; or

(b) an irreversible and permanent cessation of all brain-stem functions and future attempt of resuscitation or continued supportive maintenance would not be successful in restoring such natural functions.

18. Effects to the donor and the recipient.---(1) No transplantation of a human organ from a donor other than defined in sub-section (1) of section 3, shall be carried out without prior permission of the appropriate Transplant Evaluation Committee and only at such medical institutions and hospitals which have been notified under sub- section (10) of section 5; provided that such donation by the Khyber Pakhtunkhwa citizens shall not be permissible to citizens of other countries **but it can be allowed in special cases where on the willingness of a donor and recommendations of the Evaluation Committee, the case of the recipient is having risk of death and his life can be saved by such transplantation.**.

(2) No human organ shall be removed from the body of a living person except for the purposes of section 3 and no transplantation team of a recognized medical institution or hospital shall undertake the removal or transplantation of any human organ from a living donor unless they have explained the effects, complications and hazards connected with the removal of organ or tissue or cell for transplantation to the donor and its outcome in the recipient respectively in such manner as may be prescribed.

19. Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purpose.--- No donor and no person empowered to give authority for removal of any human organ shall authorize the removal of any human organ for any purpose other than the therapeutic purposes.

20. Punishment for removal of human organ without authority.--- (1) Whoever renders his services to or at any medical institution or hospital and who for the purposes of transplantation, conducts, associates with or helps in any manner in the removal of any human organ without authority, shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to one million rupees.

(2) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall also be reported to the Pakistan Medical and Dental Council for appropriate action that includes removal of his name from the register of the Council for a period of three years for the first offence and permanently for subsequent offence.

21. Punishment for commercial dealings in human organ.---Whoever,-

(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ; or

(b) seeks to find a person willing to supply for payment of any human organ; or

(c) offers to supply any human organ for payment; or

(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supp1y any human organ; or

(e) takes part in the management or control of a body of persons, whether a society, firm, or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

(f) publishes or distributes or causes to be published or distributed any advertisement,-

(i) inviting persons to supply for payment of any human organ; or

(ii) offering to supply any human organ for payment; or

(iii) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d),

shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to one million rupees.

22. Punishment for contravention of any other provisions of this Act.--- Whoever contravenes any provision of this Act or any rules made thereunder, or any condition of the registration granted thereunder, for which no punishment is separately provided in this Act, shall be punished with imprisonment for a term which may extend to three years or with fine which may extend to three hundred thousand rupees or with both.

23. Offences by companies.--- Where any offence, punishable under this Act, has been committed by a company, its Chief Executive or Director or any other person who, at the time, the offence was committed was incharge of, and was responsible to, the company for the conduct of business of the company, as well as the company, shall be deemed to be guilty of offence and shall be liable to be proceeded against and punished accordingly:

Provided that a company shall be liable to pay fine only:

Provided further that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

Explanation-For the purposes of this section,-

(a) "company" means anybody corporate and includes a firm or other association of individuals; and

(b) "Director", in relation to a firm, means a partner in the firm.

24. Appeal.--- Any person aggrieved by any order of the Transplant Monitoring Committee may prefer an Appeal, within thirty days from passing of the order, to the Regulatory Authority, whose decision shall be final.

25. Cognizance of offences.---(1) No Court inferior to that of the Magistrate of First Class empowered under section 30 of the Code of Criminal Procedure, 1898 (Act V of 1898) shall try an offence punishable under this Act.

(2) No court shall take cognizance of an offence under this Act except on a complaint in writing made by-

(a) the Transplant Monitoring Committee or its Secretary; or

(b) an aggrieved person, who has given notice of not less than ninety days, in such manner as may be prescribed, to the Transplant Monitoring Committee, or the alleged offence and of his intention to lodge a complaint.

26. Health Protection.---(1) **The donor shall have a social health insurance scheme for provision of free health services in case after donation the remaining organ fails to function and a social insurance in case of death and disability, in a prescribed manner.**

(2) Every hospital conducting an unrelated transplant shall be bound to provide free health care and treatment to the donor of any complication arising out of the said transplant throughout his lifetime.

(3) The recipient shall have health protection mechanism for post-transplant care in a manner as prescribed.

(4) Zakat, Baitul Mal, Non Governmental Organizations, Philanthropist may be used to fulfill the requirements of Health Protection.

27. Savings.--- Neither the grant of any facilities of any authority for removal of any human organ from the body of the donor deceased or alive in accordance with the provisions of this Act nor removal of any human organ from the body of a deceased person with due care in pursuance of such

authority shall be deemed to be an offence punishable under section 297 of the Pakistan Penal Code (Act XLV of 1860).

28. Delegation.--- The Regulatory Authority may, by general or special order, delegate to the Chairperson or a member or an expert, consultant, adviser, or other officer of the Regulatory Authority, any of its powers under this Act, subject to such conditions or restrictions as it may determine.

29. Power to issue directives.--- Government may, as and when it considers necessary, issue directives to the Regulatory Authority established under section 5 in respect of any matter relating to transplantation or regulation of its funds. If a question arises whether any matter is a matter of policy or not, the decision of Government shall be final.

30. Annual Report.---(1) The recognized institutions shall submit an annual report on its activities and accounts for each financial year to Regulatory Authority.

(2) The Regulatory Authority shall submit an annual report on its activities and accounts for each financial year to Government and shall also arrange for its publication for information of the public at large.

31. Overriding effect.--- Notwithstanding anything to the contrary contained in any other law for the time being in force, the provisions of this Act, shall have an overriding effect and the provisions of any such law to the extent of inconsistency to this Act, shall cease to have effect.

32. Protection of actions taken in good faith.---(1) No suit, prosecution or other legal proceedings shall lie against any person for anything which is done in good faith or intended to be done in pursuance of the provisions of this Act or rules made thereunder.

(2) No suit or other legal proceedings shall lie against the Government for any damage caused or likely to be caused for anything which is done with due care in good faith or intended to be done in pursuance of the provisions of this Act.

33. Power to make rules.--- Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

34. Removal of difficulties.--- If any difficulty arises in giving effect to any provision of this Act, Government may make such order as it considers necessary or expedient for the purpose of removing the difficulty.

35. Repeal.--- The Transplantation of Human Organs and Tissues Act, 2010 (Act No. V of 2010) to the extent of the Province of the Khyber Pakhtunkhwa is hereby repealed.

STATEMENT OF OBJECTS AND REASONS

To provide for regulation, removal, storage and transplantation of human organs, tissues and cells for therapeutic purposes in the Province of the Khyber Pakhtunkhwa and to establish the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority. Hence this Bill.

MINISTER - IN – CHARGE

Certified that the Khyber Pakhtunkhwa Medical Transplantation Regulatory Authority Bill, 2014 was passed by the Provincial Assembly in its meeting held on 19th March, 2014 and it is further certified that this is a money Bill.