

THE BALOCHISTAN SAFE BLOOD TRANSFUSION AUTHORITY

ACT, 2004

(Baln Act III of 2004)

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'THE BALOCHISTAN SAFE BLOOD TRANSFUSION AUTHORITY
ACT, 2004

(Bal Act III of 2004)

[8" May, 2004]

An Act to provide for the establishment Safe Blood
Transfusion Authority in the Province of Balochistan.

Preamble. WHEREAS, it is expedient to regulate Transfusion Safe and Healthy Blood and Blood Products free from infective and injurious agents and to provide for matters connected therewith or ancillary thereto, in the Province of Balochistan in the manner hereinafter appearing:

It is hereby enacted as follows:

Short title, extent 1. (1) This Act may be called the Balochistan Safe and commencement. Blood Transfusion Authority Act, 2004.

(2) It extends to the whole of the Province of Balochistan.

(3) It shall come into force at once.

Definitions. 2. In this Act, unless the context otherwise requires, the following terms shall have the meaning hereby respectively assigned them, that it say;

(a) "Authority" means the Balochistan Safe Blood Transfusion Authority, established under section 4of this Act;

(b) "Blood Bank" means any the premises or unit or other establishment, independent or in a clinic or a laboratory or hospital building or any other premises where any of the purposes of receiving, preserving, storing, analysing, screening, processing, issuing, or any other process related to or towards utilization of human blood or blood products for transfusion to human beings is practiced whether maintained

by public or private concerns.

(c) "Government" means the Government of Balochistan;

(d) "License" means a time limited but renewable

1 This Act was passed by the Balochistan Assembly on 4% May, 2014: assented to by the Governor of Balochistan on 4% May, 2014. Published in the Balochistan Gazette (Extraordinary) No. 34, dated 8" May, 2014.

General Provision.

license to operate issued to a Registered Blood Bank under this Act;

(e) "License" means an individual, hospital, clinic, laboratory, group practice, firm, etc who own/Manage/operate a Registered Blood Bank and have been issued a license to operate this Blood Bank under this Act;

(f) "Medical Practitioner" means a physician or such other person who is trained and holds qualifications and is recognized for the purposes of providing medical care to a patient and practice of medical science in Pakistan, by an

official body of national or provincial status, such as the Pakistan Medical and Dental Council;

(g) "Registered Blood Bank" means a Blood Bank duly registered with the Authority under this Act, irrespective of its license status;

(h) "Safe Blood" means human blood which is cleared healthy and free from infective and injurious agent as may be prescribed under the regulations made and promulgated under this Act;

(i) "Province" means the Province of Balochistan;

G) "Regulations" means Regulations made under this Act;

3. (1) The aim and object of the Balochistan Safe Blood Transfusion Authority is to ensure insofar as possible safety protection, and promotion of human life by providing for the establishment and maintenance of comprehensive and quality Blood Transfusion Services in the Province. And to take all steps that may be required to ensure perpetual and sustained development of such service in the province to internationally acceptable standards for such services.

(2) Every Medical Practitioner or any other person qualified to do so, when engaging in transfusion of Blood or Blood products to human beings shall before such transfusion ensure that the Blood or Blood Products, as the case may be, is healthy and free from infective and injurious agent and is

transfused in a manner as may be specified by the Authority in the rules, for the time being in force:

Provided that in case of emergency or where a special situation arises, where the question of saving injury to a human life occurs, the transfusion of Blood or Blood Products may be made in a manner other than strict compliance to the

Establishment of the Authority.

provisions made under this Act. However, this provision shall be exercised in the manner to be prescribed under this rules:

Provided further that the provisions under this Act any rules or any regulations promulgate under this Act shall be applicable on the Blood Banks in both the public and private sectors:

Provided also that, the Authority may, for the reasons to be brought on official and if directed by the Government on public record, declare a specific category of Blood Banks to be exempt from the requirements of registration, or issuance of license, or both, However, this exemption will not be granted for indefinite periods at any given time.

4. (1) As soon as may be, but not later than thirty days, after commencement of this Act, the Government shall, by notification in the official gazette, establish and

authority to be known as the Balochistan Safe Blood Transfusion Authority, comprising of a Chairman, and other members as prescribed hereunder:-

(i) The Secretary, Government of Balochistan, Health Department, shall be Ex-officio Chairman of the Authority;

(ii) The Director General Health Services Balochistan, shall be Ex-officio member of the Authority;

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(iii) | The Provincial Program Manager for safe Blood Transfusion, shall be ex-officio member/ secretary of the Authority;

(iv) The Hematologist/ Transfusionist from CMH Quetta, shall be ex-officio member to the Authority;

(v) One Hematologist from the Hematology section of the Department of Pathology, Bolan Medical College, Quetta, being not below the rank of Assistant Professor Hematology, will be a member to the

Authority;

(vi) | One District Pathologist or District Blood Transfusion Officer will be a member to the Authority;

(vii) One representative from amongst the Private Blood Bank in District Quetta, will be a member to the Authority;

(viii) One representative from amongst the Private Blood Banks in the Province outside District Quetta, will be a member of the Authority;

(ix) Two persons whose expertise are considered beneficial for the purposes of the Authority, will be nominated by the Authority as Co-opted members;

(x) The immediate past Secretary to the Authority, if different from the current nominee, will be a co-opted member for a period of one year from the date of nomination/ appointment as member to the Authority.

(2) Notwithstanding anything contained in this Act, every member shall have at least 10 years of relevant professional experience to his or her credit.

(3) There shall be a Vice Chairman of the Authority, to be designated by the Authority from among its members, on rotation. The tenure of the Vice Chairman shall be one (1) year.

(4) A member shall, excluding the Chairman, unless he/she resigns or is removed from office earlier, shall hold office for a two (2) year term and shall be eligible for reappointment for a similar term.

(5) No Bill or proceeding of the Authority shall be invalid by reason only of the existence of a vacancy in, or defect in the constitution of, the authority.

(6) The Principal Officer of the Authority shall be at Quetta and it may set-up sub-offices at such place or places in the Province as it may deem appropriate.

(7) To facilitate the working and initiation of the Authority, the first members under the provisions of clause (vii) and (viii), section 1, or rule 4, will be nominated by the Government. Thereafter, members to their vacancies shall be nominated by the Private Blood Bank in the province through their consensus, as the case may be. In case of dispute on such subsequent nominations among the Private Blood Banks which does not resolve in stipulated time, the Authority will recommend the required Bill to the Government on the matter of such nominations to the Government for final decision. The decision of the Government in the matter shall be final.

(8) In case of vacancy or vacancies occurring due to

any reason, the Government shall declare appointment of members on recommendations of the Authority as provided under this Act, such appointments shall be declared within

Delegation.

thirty (30) days of a vacancy occurring on the Authority.

(9) A member may resign from office by submitting resignation the Government, or a member may be removed from being a member to the Authority by the Government, if found unable to perform functions of his office because of mental or physical incapability or misconduct.

(10) The Chairman, members, staff, experts, consultants, advisors, and other employees of the Authority, when Billing or purporting to Bill in pursuance of any of provisions of this Act or rules and Regulations made hereunder, shall be deemed to be public servants within meaning of section 21 of Pakistan Penal Code, 1860(Bill SLV of 1860).

(11) To carry out the purposes of this Act the Authority may, from time to time, employ officers, members of its staff, experts, consultants, advisors, and other employees on such terms and conditions as it may deem fit, as prescribed in the rules.

(12) The Chairman, members, staff, inspectors, advisors, consultants, and all such persons who are engaged by the Authority for the purposes of this Act or any rules or any regulations promulgated under this Act, shall be eligible to receive remuneration, on such rates that may be determined by the Authority in consultation with the Government. This shall not be varied to their disadvantage during the term of their services with the Authority.

(13) The Authority may and will appoint person or persons deemed fit for the assignment, as Inspectors to facilitate the achievement of the purposes of this Act, as prescribed in the rules;

Provided that, in case of valid apprehension of prejudice or any other discrimination by any Inspector, an incumbent being inspected may register complaint with the Authority, which will dispose the matter as prescribed in the rules.

5. The Authority may delegate to the Chairman, a member, or professional staff, or a special committee, all or any of its powers, functions, or duties under this Act, except; -

(a) The power to grant, reject, amend, vary or revoke license or registration status or any condition thereof.

(b) The powers to determine or modify fees and charges under this Act.

(c) The powers to make or repeal rules or regulation under this Act.

Funds.

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Authority.

(d) The powers to make orders on applications made for review of its orders and determinations.

6. The operations of the Authority shall be funded from:-

(a) Grants from the Government including initiating grant.

(b) Fees and Fines collected by it as prescribed under the rules.

7. (1) The Authority shall maintain complete and accurate books of accounts of its actual expenses and receipts, as prescribed under the rules.

(2) The accounts of the Authority shall be audited by the Director General Audit Balochistan.

8. (1) Notwithstanding anything repugnant to the spirit and provisions of this Act, the Authority shall have the following — functions and powers, to be implemented in the manner prescribed in the rules:-

(i) To register, and receive applications for, and grant, extend, modify, amend, suspend, renew or revoke registration status and/or license; or declare exemption, for creation, operation and /or any related matter of a Blood Bank in the province.

(ii) To set and implement requirements to be fulfilled for all applications for grant of any registration or license for a Blood Bank.

(iii) To set and implement terms, conditions, restrictions, category, or vary imposition of the provisions of this Act, or any rules or any regulations promulgated under this Act, as may be prescribed in the rules for grant of any registration or license for Blood Banks in the Province.

(iv) To development and enforce guidelines, standards, standard operating procedures, operating procedures in special situation, rules, and regulations, for Blood Banks, their registration and license, including but not limited to requirement of professional qualification and training standard or professional staff or all categories working in a Blood Bank, Management of Blood Banks and matters connected and ancillary thereto in the province.

(v) To maintain a register Blood Banks in the province, and matter connected and ancillary

(vi)

(vii)

(viii)

(ix)

(x)

(xi)

(xii)

(xiii)

(xiv)

(xv)

(xvi)

thereto.

To provide and cause public information in the matter as and if considered necessary, as under the rules

To issue certificates and such other insignia to the registered blood banks to display their registration status with the Authority.

To monitor the working of, and / or cause inspection of, Blood Banks _ regarding compliance with the provisions of this Act, and rules and regulations made hereunder; and to take all measures that may become required, or considered necessary by the Authority for the enforcement and achievement of the objectives of this Act.

To prescribe, review, approve, and regulate tariff for professional fees and charges pertaining to Blood Bank services.

To prescribe, review, approve, and regulate fees, and charges in respect of any of its functions, as under the rules.

To prescribe fines for contravention of the provisions of this Act, as under the rules.

To impose and collect fees, charges, fines, and any other charges in respect of any of its functions, as may have been prescribed under the rules.

To take measures considered necessary to protect legitimate interests of the patients and the public in accordance with the provisions of this Act.

To take measures considered necessary to protect legitimate interests of the individuals and concerns operating and providing services as registered Blood Banks in accordance with the provisions of this Act.

To explore, receive reports, assess, analyze review, hear, and consider cases/ complaints regarding contraventions of the Provision of this Act, and decide the manner of disposal in all such matters.

To review, modify, vary, set aside, or change in any other manner considered fit, its decisions as under the rules.

(xvii) Formulate Committees and Sub-committees and assign appropriate persons as their members to undertake any tasks consequential to the realization of the objectives of this Act.

(xviii) To commission research, investigate, conduct hearing and receive advice on any matter considered necessary.

(xix) To contract out expert services or special assignments, as the case may be for the achievement of the purposes of this Act.

(xx) | Prescribe a minimum standard reporting system for professional services performed, and management of Blood Banks.

(xxi) Develop and implement training programs to improve Blood Bank Service in the Province.

(xxii) Undertake mass awareness and public education campaigns for promotion of Blood Donation, Safe Blood Transfusion, and to promote effective utilization of Blood Bank services by the public and the medical professions in the province.

(xxiii) To establish a Provincial Blood Donation Committee with assigning appropriate persons on it, for furtherance of the cause of Blood Donation in the province, as under the rules.

(xxiv) To prescribe and adopt the rules of business for the smooth functioning of the Authority in all matters connected and ancillary to the purposes of this Act, as under the rules.

(xxv) Tender technical advice to the Government and authorities concerned to improve Blood Bank Services in the province, and on all other such matters as may be required of it.

(xvi) To undertake all such Bills as may be incidental or consequential to the performance of any of its functions or the exercise of any of its powers.

(xxvii) To undertake any assignment directed by the Government.

(2) In performing its functions the Authority, as for

as possible and practicable, protect the interests of the patients, public, and providers of the Blood Bank Services, in the light of the Health Policy and Guidelines for the time being in force, not inconsistent with the provisions of this Act.

(3) As soon as possible, but not later than ninety

Penalties for
Contravention.

(90) days of its establishment, the Authority shall by notification in the official gazette and mass media, declare the rules and regulations on minimum standards for Blood Banks; the requirements for registration and further issuance of license to operate, to Blood Bank in the province, to be amended from time to time in light of internationally and nationally accepted norms, as and when considered in necessary.

(4) A ninety (90) days grace period, or as determined by the Authority, will be allowed from the date of notification of rules and regulation in section (3) of rule 8, for all Blood Bank in the province to register with the Authority and obtain a valid license to operate, after which time no Blood Bank will be allowed to operate which is not so registered with, and is further duly licensed to operate by, the Authority as may be prescribed under the rules.

9. (1) Whoever, himself or by any other person on his behalf, or by any person under his supervision wilfully or recklessly contravenes any of the provisions under this Act or any rule or any regulation promulgated under this Act shall be punishable with imprisonment of either description which may extend to three (3) years; or with fine up to Rupees thirty thousand with a minimum fine of Rupees fifteen thousand; or with both.

(2) Whoever, himself or by any other person on his behalf, or by any person under his supervision wilfully or recklessly contravenes any of the provisions under this Act or any rule or any regulation promulgated under this Act and thereby causes physical injury to the person of another, he shall be punishable with imprisonment of either description which may extend to five (5) years; or with fine up to Rupees one hundred thousand with a minimum fine of Rupees thirty thousand; or with both.

(3) Whoever, himself or by any other person on his behalf, or by any person under his supervision, with out excuse, does any Bill with the intention of interfering, without authorization, with the operations carried out for the purposes of this Act by a licensee, and thereby causes damage to any facility, equipment, material, or person, such a person shall be guilty of an offence punishable with imprisonment of either description — which may extend to three (3) years; or with fine of Rupees fifty thousand with a minimum fine of Rupees twenty thousand; or with both.

(4) Whoever, himself or by any other person on his

behalf, or by any person under his supervision, conceals or
connives to conceal, or falsely presents, any records, material,
procedure s, or situation, without lawful excuse, or obstructs an
Inspector from accessing records, material, or other relevant

evidence in case of an investigation under this under this Act, he will be guilty of an offence punishable with imprisonment; or with fine; or with both.

(5) Whoever, himself or by any other person on his behalf, or by any person under his supervision, having committed an offence under this Act or any rule or any regulation promulgated under this Act, again commits the same offence under this Act or any rule or any regulation promulgated under this Act, he shall be punishable with imprisonment of either description which may extend to five (5) years; or with fine up to Rupees one hundred thousand with a minimum fine of Rupees thirty thousand; or with both.

(6) where person guilty of an offence under this Act or any rule or any regulation promulgated under this Act, is a company group practice, hospital, department, corporation, firm, or institution, every director, partner, and employee of the respective company, group practice, hospital, department, corporation, firm, or institution, shall, unless he proves that the offence was committed without his knowledge or consent, be guilty of the like offence.

(7) If any person is convicted of an offence under this Act or any rule or any regulation promulgated under this Act, it shall be lawful for the Authority to cause the offender's name, place of residence, place of business, the offence which has been convicted, and the penalty inflated upon him, to be published at the expense of such person in such newspaper or in such other manner as the Authority may direct;

Provided that the expenses of such publication shall recoverable in the same manner as a fine is recoverable.

(8) If any person is convicted of an offence under this Act or any rule or any regulation promulgated under this Act, it shall be lawful for the equipment used and any other related materials in respect of which contravention has been made to be confiscated to the Government, to be disposed off in a manner to be decided by the Government.

(9) Notwithstanding anything repugnant to the foregoing powers of the Authority, in case of contravention of provisions under this Act or any Rule or Regulation under this Act, it will be lawful for the Authority if it upon initial review considers it appropriate not to refer the case to a Court of Law and concludes to decide such a case itself. In such a case it shall be law full for the Authority to impose any one or more of the following penalties:-

(i) Issue a warning;

(ii) Issue an adverse report n the Blood Bank;

(iii) | Put the Blood Bank on probation for a

Cognizance of
Contravention.

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Rules.

period to be determined by the Authority;

(iv) Fine of up to Rupees fifty thousand or a minimum of Rupees five hundred;

(v) Seize and confiscate Blood, Blood products, or other material, or equipment, which are in contravention of this Act or any rule or any regulation promulgated under this Act, to be disposed in a manner to be determined by the Authority;

(vi) Temporarily or permanently debar any person or persons to work in a Blood Bank;

(vii) Temporarily or permanently disallow use of any material, equipment, or such other thing which is in contravention or is anticipated to be in contravention of the provisions of this Act or any rule or any regulation promulgated under this Act;

(viii) Temporarily or permanently close down the Blood Bank;

(ix) Temporarily or permanently revoke the license of the Blood Bank;

(x) Temporarily or permanently de-register the Blood Bank.

10. (1) No court shall take cognizance of any contravention under this Act, except on a categorical written complaint made by the Chairman of the Authority or a person authorized by him in this behalf as under this Act or the rules and regulation promulgated under this Act.

(2) The provisions of Chapter XX of the Code of Criminal Procedure, 1898 (Act V of 1898), shall apply to the trial of offences punishable under this Act.

11. Any person aggrieved by an order made or order passed by the Authority under this Act or any rule or any regulation promulgated under this Act, may file a review application with the Chairman of the Authority, within fifteen (15) days of such an order. The Authority shall decide the review application within forty (40) days of date of receipt of such a review application with the Authority.

12. The Authority may, by notification in the official gazette, with approval of the Government, make rules on all aspects of business to be carried out for the purposes of this Act, including but not limited to the minimum standards to be

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observed in matters related to Blood, Blood Products, Standard Operating Procedures Account and Audit, and Rules of Business.

13. The Authority may, by notification in the official gazette, make regulation to carry out its functions, not inconsistent with the provisions of this Act or Rules made hereunder;

Provided that without prejudice to the generality of foregoing powers these regulations may also provide for the establishment matters related to the staff of the Authority.

14. The provisions of this Act shall be in addition to, and not in derogation of any other law or the time being in force.

15. If any difficulty arises in giving effect to any of the provisions of this Act, the Government may make such order, not inconsistent with the provisions of this Act, as may appear to the Government to be necessary for the purpose of removing the difficulty.