

(100)

GOVERNMENT OF THE PUNJAB,
HEALTH DEPARTMENT.

Dated Lahore 14th May, 2005.

NOTIFICATION

No. SO (PH) 9-78/2002. In exercise of the powers conferred upon him under section 11 of the Punjab Transfusion of Safe Blood Ordinance, 1999 (XXXVI of 1999); the Governor of the Punjab is pleased to direct that the following rules shall be made:-

1. Short title and commencement.- (1) These rules may be called the Punjab Transfusion of Safe Blood Rules, 2005.

(2) They shall come into force at once.

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

(a) "Authority" means the Punjab Blood Transfusion Authority established under section 5 of the Punjab Transfusion of Safe Blood Ordinance, 1999 (XXXVI of 1999);

(b) "committee" means a committee constituted under these rules;

(c) "existing blood bank" means a blood bank operational on the commencement of these rules;

(d) "form" means a form specified in the Schedule;

(e) "Government" means the Government of the Punjab in the Health Department;

(f) "Inspector" includes a person appointed or nominated as Inspector by the Authority;

(g) "license" means a license issued to a blood bank registered under these rules;

(h) "licensee" means a blood bank holding a valid license;

(i) "meeting" means a meeting of the Authority;

(j) "Member" includes the Chairman of the Authority;

(k) "Ordinance" means the Punjab Transfusion of Safe Blood Ordinance, 1999 (XXXVI of 1999);

(l) "Schedule" means Schedule appended to these rules;

(m) "Secretary" means the Secretary of the Authority; and

(n) "Section" means a section of the Ordinance.

3. Functions.-The Authority shall perform the following functions, namely:-

(a) Develop uniform policy covering all aspects of safe blood transfusion based on current developments in the field;

(b) Register and issue licenses to blood banks;

(c) allow renewal of licenses issued to the blood banks annually on payment of fees and after satisfying it self that instructions issued by it for safe blood transfusion were being followed by the blood banks;

(d) Fix service charges of blood and blood products;

(e) Ensure of the bio-safety measures specified by the Authority are strictly adhered to by the blood banks;

(f) ensure that the blood banks are managed and run by qualified professionals preferably having post graduate qualifications in blood transfusion, Hematology or Clinical Pathology recognized by the Pakistan Medical and Dental Council established under the Medical and Dental Council Ordinance, 1962 (Ordinance No. XXXII of 1962); and

HRG's

(g). Monitor the working of the blood banks and carry out periodical inspections where necessary.

Authority. - (1) The Chairman and the Members of the Authority shall hold ex-officio offices.

(2) Unless determined otherwise, the Chairman and Members of the Authority shall hold office for a period of three years.

5. Secretary. - (1) The Secretary shall be appointed either by initial appointment or by transfer on deputation.

(2) The Secretary shall, in case of an appointment by transfer, be an employee of the Government holding at least BPS-19.

(3) The Secretary of the Authority shall be a person having postgraduate or equivalent qualifications in hematology blood transfusion.

6. Secretariat. - The Secretariat of the Authority shall be located at the Institute of Hematology and Blood Transfusion Services, Punjab, Lahore.

7. Appointment of officers, etc.- The Authority may, from time to time, appoint or employ such officers, advisors and staff members as may be deemed necessary for carrying out purposes of the Ordinance.

8. Registration. - (1) A blood bank shall be registered and a license issued under section 4 of the Ordinance on submission of an application on Form MOH-99 accompanied by documents provided thereunder and such other documents as may be required by the Authority

(2) The Authority shall, before issuing a license, publish notices in at least two national newspapers for the registration of blood bank.

(3) Application forms shall be available in the Secretariat and may be obtained against payment of one hundred rupees for each form.

(4) A manual called 'ALARM' containing the requirements of blood banks shall be provided at request along with the application form on payment of two hundred rupees for each copy of the manual.

(5) An existing blood bank desirous of continuing its operation shall, within forty-five days of the commencement of these rules, and every person intending to establish a new blood bank may, in the like manner, apply for registration under sub-rule (1):

Provided that in case of exceptional circumstances or good ground, a grace period of not more than ninety days may be allowed to a blood bank to get itself registered and obtain a license from the Authority, where after, no blood bank not so registered with the Authority shall be allowed to operate in the Province or within the territorial jurisdiction of the Authority.

(6) An existing blood bank may, subject to sub-rule (5), continue to function until its application is rejected or where an appeal is preferred against that rejection, till the decision of that appeal.

(7) The Authority may, on receipt of an application under sub-rule (1), constitute a committee or nominate an Inspector to enquire if the blood bank or a person intending to establish a new blood bank, as the case may be, fulfils and complies with the conditions mentioned in section 7 and in respect of such other matters as may be specified by it.

(8) The committee constituted or an Inspector nominated under sub-rule (7) shall submit the inspection report within fifteen days of such constitution or nomination which may, inter alia, relate to registration, licensing or renewal of the license, as the case may be.

(9) The Authority may, after considering the report of the committee or the Inspector and after making such further enquiry as it considers necessary, grant a license or reject the application.

(10) The blood bank or the person intending to establish a new blood bank shall be issued license or shall be informed about the detailed technical reasons, for rejection of the application.

ARaj's

9. License.- (1) Where an application for registration has been accepted by the Authority under rule 8, it shall issue a license in form at ANNEX- 'E' on payment of non-refundable license fee of five thousand rupees for a period of one year from the date of the registration on such terms and conditions as may be specified by the Authority.

(2) The Authority shall maintain a register containing full description and particulars of the licensee.

(3) The Authority shall, in relation to a blood bank, have the exclusive power to register and grant, extend, modify, amend, suspend, or revoke a license in respect of creation, operation and any of its other related matters.

(4) Subject to the provisions of the Ordinance, a license issued by the Authority shall be subject to such terms and conditions as may be determined by the Authority.

(5) A license issued by the Authority shall be non-transferable and specified for a blood bank at a particular location and shall be valid only within the territorial limits of the Authority.

(6) The licensee shall not operate any other blood bank by proxy, other than the one for which a specific license has been issued by the Authority.

(7) No licensee shall operate its branches anywhere.

(8) The licensee shall, in case of continuance of its operation every year, apply for renewal of license thirty days prior to its expiry, whereupon, the Authority shall, subject to its satisfaction, renew the license for a period of one year on payment of non-refundable renewal fee of one thousand rupees.

(9) In case of any change in the license including change of address or name of the qualified person, etc; the licensee shall immediately report to the Authority, whereupon, the required change where permissible shall be made on the payment of non-refundable fee of one thousand rupees for each such change.

10. Monitoring and Inspection.- (1) The Authority may appoint, nominate or depute as many persons designated as "Inspectors", as may be required to inspect all the blood banks in their respective territorial jurisdiction or an area authorized in that behalf who shall, as and when called for, monitor or report for the purpose of evaluation, registration, licensing and annual renewal of blood banks.

(2) All the blood banks shall be inspected periodically at least twice in a calendar year.

(3) Without prejudice to sub-rule (2), the Authority may conduct spot check of any blood bank at any time either on its own accord or on specific complaint or information.

(4) The Authority may, where any inspection of the blood bank is conducted or otherwise, pass an order requiring the licensee to remove any deficiency or comply with the provisions of the Ordinance and the rules made thereunder and the licensee shall comply with such order and within such period as may be specified therein.

11. Cancellation or suspension of license.- (1) Any person may make a complaint in writing to the Chairman against any licensee for contravening the provisions of the Ordinance or the rules made hereunder.

(2) The Chairman, on receipt of a complaint under sub-rule (1), shall initiate an action and may constitute an enquiry committee where, in the opinion of the Chairman, substantial evidence is available and the case is fit for holding an enquiry.

(3) Notwithstanding anything contained in any law for the time being in force, a person making any complaint hereunder shall not be entitled to any compensation.

(4) Where a complaint filed against a licensee is prima facie correct after physical verification of the blood bank, hospital, clinic, patients, blood donors, blood recipients and all other places and individuals, reasonably deemed to be source of

ARRA

197

fact finding, the Chairman shall, in his discretion, take appropriate action as provided in sub-section (2) of section 9 of the Ordinance.

(5) Where the Authority is satisfied that sufficient grounds exist for proceeding against any licensee or a blood bank contravening the provisions of the Ordinance, the Chairman shall file a complaint before a court of competent jurisdiction under section 10 of the Ordinance.

(6) For every cancellation or suspension of a license, the Authority shall issue orders in writing.

(7) In sequence to the order of authority for suspension/cancellation, the blood bank shall immediately cease to function till the appeal is decided and license is restored. The blood bags/products and other perishable items shall be shifted immediately to a nearby licensed blood bank.

12. Appeal.- Where the Authority rejects an application for registration or suspends or cancels the license, the aggrieved person may, within 30 days from the date of the order, prefer an appeal to the Government and any order passed thereon shall be final.

13. Contravention.- No court shall take cognizance of any contravention under the Ordinance except on a complaint in writing made by the Chairman or a person authorized by him in this behalf.

14. Annual report.- The licensee shall furnish to the Authority each year a report on annual audit and accounts including normal activities of the licensee during the preceding year and such other information relating to its activities as may be required by the Authority.

15. Transaction of business.- (1) The Authority shall dispose of its official business in its meetings which may be held from time to time in accordance with the provisions herein contained.

(2) The Authority shall hold at least one meeting in each quarter of every calendar year.

(3) The Secretary shall, on the directions of the Chairman, convene the meetings of the Authority.

(4) Notice of the meetings along with agenda shall be served on all the Members at least seven days ahead of schedule of the meeting.

(5) The Secretary shall cause the agenda prepared in the following order, namely:-

- (i) confirmation of minutes of the previous meeting;
- (ii) all matters deferred in the previous meetings;
- (iii) business to be transacted at the meeting including the direction of the Government, if any; and
- (iv) report of a committee, etc.

(6) The Chairman shall preside over every meeting and in his absence, any Member nominated by the Chairman in this behalf.

(7) Any Member who absents from three consecutive meetings of the Authority shall cease to be a Member.

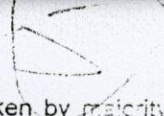
(8) A Member may, at any time, resign from the membership of the Authority by tendering his resignation in writing to the Government.

(9) Unless otherwise directed by the Chairman no meeting shall be adjourned till the business agenda is disposed of.

(10) Any expert or advisor may be invited to attend a meeting but he shall not be entitled to cast a vote.

16. Quorum.- Majority of the total Members shall constitute a quorum for the meeting of the Authority.

Handwritten signature or initials.



17. Decisions.- (1) All decisions of the Authority shall be taken by majority of Members present and voting; provided that in case of a tie, the Chairman or the Chairperson shall have a casting vote.

(2) Action on the decision in a meeting shall be taken after confirmation of the relevant minutes saves in the exceptional cases where the Chairman may, by an order in writing, otherwise direct.

18. Proceeding of the meeting.- (1) Minutes of the proceedings of each meeting shall be drawn by the Secretary.

(2) The minutes shall comprise of the names of Members present at the meeting and the number of items and their brief notes and the decisions taken.

(3) The minutes shall be submitted to the Chairman for his approval whereafter a copy thereof shall be supplied to each Member.

(4) A copy of the minutes of the proceedings of each meeting duly confirmed shall be recorded in a minute book maintained for the purpose by the Secretary.

19. Committee.- (1) The Authority may from time to time constitute such committees or sub-committees as it may deem necessary to facilitate in the discharge of its functions.

(2) The business of every committee so constituted under sub-rule (1) shall be conducted in such manner as the Authority may determine.

(3) Every committee or sub-committee constituted or assigned any function under this rule shall be headed by a convener appointed by the Chairman.

(4) The convener of committee shall preside at the meeting of the committee or in his absence, the members of the committee shall elect one of them to preside and the member so elected shall exercise all powers of the convener under these rules.

(5) The proceedings or reports of the committee shall be submitted to the Chairman within seven days of its meeting for placing it before the Authority.

20. Quality assurance and procedure for operation of blood banks and bio-safety measures for practice in blood banks.- (1) For the purpose of section 7 of the Ordinance, the licensee shall follow the instructions contained in the Manual (First Edition) namely, "Standards and Guidelines for Blood Transfusion Services 1999, BTS (Pakistan) 01/99 published by the Ministry of Health, Government of Pakistan, Islamabad.

(2) The Authority may provide for policy guidelines, standards for equipment, premises, personnel and matters related to the establishment, creation and operation of a blood bank to ensure transfusion of safe blood and blood products in human beings:

Provided that such provisions may be provided in the regulations as may be made by the Authority after it is satisfied with their validity and public safety.

(3) The licensee shall be responsible for ensuring that every procedure in the blood bank is carried out according to the Standard Operating Procedures.

(4) The Standard Operating Procedures shall be developed by the licensee or a person intending to establish a new blood bank and submitted to the Authority alongwith the application for registration of the blood bank and issue of license.

(5) The Standard Operating Procedures shall be developed in view of the status, functions and responsibilities of respective blood bank conforming to the Standards and Guidelines for Blood Transfusion Services, 1999, specified in sub-rule (1).

(6) The Standard Operating Procedures shall contain both the technical and managerial instructions for all steps to be taken by the blood bank including screening and examination of blood and blood products for detection of infectious agents so that it may fall within the meaning of "safe blood" specified under clause (b) of section 2 of the Ordinance.

M. R. J.

198

(7) The Standard Operating Procedures shall contain tools and information about quality assurance management and bio-safety procedures which shall be based on the instructions issued by the Authority and conforming to the Standards and Guidelines for Blood Transfusion Services, 1999, specified in sub-rule (1).

(8) The Authority shall notify and issue the guidelines for quality assurance and maintenance of effective Anti-HIV Hepatitis-B, Hepatitis-C Malaria, Syphilis and other viruses and infective agents for screening.

(9) The Bio-Safety measures specified in the schedule shall be adhered to by all blood banks.

(10) The blood banks shall ensure and satisfy the Authority by providing documentary proof regarding safe and effective disposal of all the biological and chemical waste produced and generated by the blood bank during and after technical procedures.

21. **Service Charges:-** (1) Notwithstanding the recognized principle of non-remunerated voluntary blood donation, the Authority may allow fixation of service charges both for the public and private blood banks after due consultation with all stakeholders.

(2) The services charges shall be fixed on the basis of technical costs of the expenditures of blood banks:

Provided that the Authority shall maintain uniformity in service charges pertaining to various procedures relating to blood and blood products within the territorial limits of the Authority.

(3) Every licensee shall abide by such service charges as may be fixed or regulated by Authority.

22. **Movement of Blood & Blood Products:-** (1) For any blood or blood products intended to be shipped, transferred or exported for any purpose beyond the territorial jurisdiction of the Authority, an applicant shall seek such permission from the Authority at time of registration.

(2) Any person or blood bank seeking permission under sub-rule (1) shall have to satisfy the Authority that it is limited to the scope of helping patients.

(3) No large scale fractionation or products making in any facility in the Province, country or abroad shall be undertaken except with a valid permission.

(4) The Authority may in its discretion and without assigning any reason, allow or disallow movement of blood or blood products.

23. **Safe Blood Donation Committees:-** (1) The Government may from time to time constitute committees for the purpose of creating awareness for availability of safe blood and motivation of voluntary donations.

(2) Committees so constituted under sub-rule (1) shall comprise of such number of members or at such administrative level as may be considered necessary by the Government:

Provided that such committees may comprise of philanthropists, social workers and such other persons as the Government may deem appropriate.

(3) The Authority may, for the purpose of facilitating and formation of committees, provide or recommend panels to the Government.

(4) The Government may dissolve any such committees at anytime after its constitution without assigning any reason.

(5) The members of such committees shall work on honorary basis and shall not be entitled to any remuneration in any manner whatsoever.

24. **Budget.-** (1) An annual budget as may be allocated by the Government shall be utilized by the Authority to meet operational charges in connection with its functions under the Ordinance including the payment of salaries and other remuneration and allowances to the persons engaged and employed therefor.

(2) The budget shall be disbursed through the Accountant General Punjab, Lahore.

(3) To the credit of the Authority all funds including the budget so received by the Authority shall be placed under such heads as may be necessary which may consist of-

- (a) grants obtained from the Federal Government;
- (b) grants obtained by the Authority from other sources;
- (c) grants made by the Provincial Government;
- (d) income from registration fees, license or renewal fees, royalty or income from sale proceeds and published material such as forms, etc., or any other incomes; and
- (e) foreign aids, grants and loans to the Authority.

(4) The Authority shall observe General Financial Rules (GFR) of the Government of Punjab for maintenance and audit of its financial records and system.

25. Accounts.- (1) The Authority shall, in consultation with the Controller General of Accounts, maintain, complete and accurate books of accounts of its actual expenses and receipts and submit to Government auditor for its audit as and when directed.

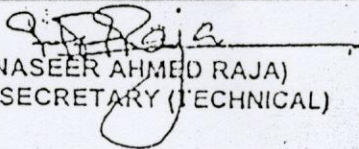
(2) The Accounts of the Authority shall be audited by the Auditor General, Punjab.

SECRETARY TO
GOVERNMENT OF THE PUNJAB
HEALTH DEPARTMENT
Dated Lahore the 14th May 2005.

No. & Date Even.

A copy is forwarded for information and necessary action to the:-

1. Secretary Health, Ministry of Health, Islamabad.
2. Principal Secretary to Chief Minister Punjab.
3. All the Administrative Secretaries to Govt. of Punjab.
4. Registrar, Supreme court of Pakistan, Islamabad.
5. Registrar, Lahore High Court, Lahore.
6. All the District and Session Judges in the Punjab.
7. Inspector General of Police Punjab, Lahore.
8. All the District Coordination Officers in Punjab.
9. Secretary to Provincial Ombudsman Punjab, Lahore.
10. Director General Health, Ministry of Health, Islamabad.
11. Director General Public Relation Punjab, Lahore.
12. Director General Health Service Punjab, Lahore.
13. All the Principals/Heads of Autonomous Medical Institutions in Punjab.
14. Director Blood Transfusion, Lahore.
15. Surgeon Medicolegal Punjab, Lahore.
16. All the Heads of attached departments.
17. All the Executive District Officers (Health) in Punjab.
18. Manager, Govt. Printing Press Punjab, Lahore.
19. All the Medical Superintendents of DHQ/Teaching Hospital in Punjab.
20. PSO to Minister for Health Punjab.
21. PSO to Chief Secretary Punjab, Lahore.
22. PSO to Additional Chief Secretary Punjab, Lahore.
23. PSO to Secretary Health, Government of the Punjab.
24. PA to Technical Advisor (Health) and PA to Additional Secretary (Admen. / Establishment / Development) Health Department


(DR. NASEER AHMED RAJA)
DEPUTY SECRETARY (TECHNICAL)