

# **Blood Transfusion Safety Act, 2002**

(Act No. XII of 2002)

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# **Blood Transfusion Safety Act, 2002**

(Act No. XII of 2002)

[10 April, 2002]

**An Act to regulate collection of safe blood, preservation thereof and the system of blood transfusion into the body of a patient.**

WHEREAS it is expedient and necessary to regulate collection of safe blood, preservation thereof and the system of blood transfusion into the body of a patient;

It is hereby enacted as follows:-

## **Chapter 1**

### **Preliminary**

**1. Short title and commencement.-** (1) This Act may be called the Blood Transfusion Safety Act, 2002.

(2) It shall come into force on such date as the Government may, by notification in the official Gazette, appoint.

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

- (a) “unauthorised person” means any person who does not have any recognised qualification for collection or transfusion of blood, or is not authorised to do so;
- (b) “unscreened blood” means such blood, blood component or plasma product which has not been screened or tested negative for germs responsible for blood-borne diseases such as AIDS, hepatitis B, hepatitis C, syphilis, malaria etc.;
- (c) “bad ordering of blood collection and transfusion” means collection of blood through wrong procedures, improper preservation of blood, transfusion of time-expired blood, not following cold chain, transfusion of blood in wrong process, or collection and transfusion of blood without following such other processes or methods as may be prescribed by rules for transfusion of blood;
- (d) “Council” means the National Safe Blood Transfusion Council constituted under section 4 of this Act;
- (e) “cold chain” means the process of collection, preservation, transportation and reaching of blood or blood components to the user in +20 to +80 degrees centigrade temperature;

- (f) “doctor” means a person holding minimum MBBS or any equivalent degree, and having been registered with the Bangladesh Medical and Dental Council;
- (g) “prescribed” means prescribed by rules;
- (h) “inspection committee” means the inspection committee constituted under section 15 of this Act;
- (i) “selection committee” means the selection committee constituted under section 11 of this Act;
- (j) “prescription” means the advice note given to a patient by a doctor;
- (k) “Bangladesh Medical and Dental Council” means the Bangladesh Medical and Dental Council constituted under the Medical and Dental Council Act, 1980 (XVI of 1980);
- (l) “blood bag” means a bag approved by the Government containing anticoagulant and used for collecting blood, blood components or plasma product from the donor and preservation and distribution thereof;
- (m) “person” includes any company, institution, partnership business, association and society;
- (n) “private blood transfusion centre” means any private blood transfusion centre, blood bank, or any other institution or centre, by whatever name it may be called, licensed under section 9 of this Act;
- (o) “wrong prescription” means any prescription given by a doctor for blood transfusion treatment, without mentioning the patient’s or blood receiver’s exact requirement, nature of blood components, patient’s or blood receiver’s present physical condition and the type or process of blood transfusion;
- (p) “Director-General” means the Director-General, Directorate of Health Service, and in his absence, any official performing the duties of the Director-General;
- (q) “blood” means whole human blood;
- (r) “blood component” means any component separated and obtained from blood, such as plasma, Red Blood Cell (RBC), White Blood Cell (WBC), platelet, etc.;
- (s) “plasma product” means albumin, immunoglobulin, cryoprecipitate, factor-VIII, factor-I, factor-II, V, VII, IX, X and any other product which has been prepared by separating from plasma;

- (t) “patient or blood receiver” means the person who receives blood as per doctor’s prescription;
- (u) “blood transfusion expert” means any doctor holding MBBS or any equivalent degree and holding additional degrees, such as diploma on blood transfusion medicine DBS&T, MTM, MD, PhD;
- (v) “licence” means any licence issued under section 9 of this Act for establishing and operating any private blood transfusion centre;
- (w) “Licensing Authority” means the Director-General, Directorate of Health Services;
- (x) “requisition for blood” means any requisition for blood or blood components issued by a doctor for supplementing the deficiency of blood or blood components of a patient;
- (y) “disposable items” mean syringes, needles, lancets, blood bags, blood transfusion sets, slides, test-tubes and other one-time items used in collection and preservation of blood and in different examinations for blood transfusion;
- (z) “rules” means rules made under this Act;
- (za) “Chairman” means the Chairman of the National Safe Blood Transfusion Council constituted under section 4 of this Act;
- (zb) “Vice-Chairman” means the Vice-Chairman of the National Safe Blood Transfusion Council constituted under section 4 of this Act;
- (zc) “recognised qualifications” means the qualifications recognised by the Bangladesh Medical and Dental Council;
- (zd) “blood transfusion services” means services relating to collection, tests, separation of blood components, preparation of plasma products and blood transfusion provided by any doctor or any private blood transfusion centre for the treatment of a patient.

**3. Act to override any other law.-** Notwithstanding anything contained in any other law for the time being in force, the provisions of this Act shall have effect.

## **Chapter II**

### **National Safe Blood Transfusion Council**

**4. National Safe Blood Transfusion Council.-** (1) For the purposes of this Act, there shall be a Council to be called the National Safe Blood Transfusion Council.

(2) The Council shall consist of the following members, namely:-

- (a) Minister in charge of the Ministry of Health and Family Welfare, who shall also be its Chairman;

- (b) Secretary, Ministry of Health and Family Welfare, who shall also be its Vice-Chairman;
- (c) one Vice-Chancellor of any University nominated by the Government;
- (d) Chairperson, Department of Blood Transfusion, Bangabandhu Sheikh Mujib Medical University;
- (e) Chairman, Technical Committee, Bangladesh National AIDS Committee;
- (f) Commandant, Armed Forces Institute of Pathology;
- (g) Director-General, Department of Social Services;
- (h) Chairman, Bangladesh Red Crescent Society;
- (i) Directors, all government medical college hospitals;
- (j) Director, National Institute of Diseases of the Chest and Hospital;
- (k) Director, Public Health Institute;
- (l) Departmental heads, Department of Blood Transfusion, all government medical college hospitals;
- (m) Chairperson, Bangladesh Medical Association;
- (n) Chairperson, Jatiyo Mohila Sangstha;
- (o) National Commissioner, Bangladesh Scouts;
- (p) National Commissioner, Bangladesh Girls' Guide Association;
- (q) District Governor, Bangladesh Rotary International;
- (r) District Governor, Bangladesh Lions Club International;
- (s) A professor experienced in blood transfusion, nominated by the Government;
- (t) Chairperson, Bangladesh Sangbad Sangstha (BSS);
- (u) Director-General, Directorate of Health Service, who shall also be its member secretary;

(3) The nominated members of the Council shall hold office for two years from the date of such nomination:

Provided that the Government may cancel such nomination at any time.

(4) Any nominated member may resign his office by writing under his hand addressed to the Government.

**5. Duties and responsibilities of the Council.-** The Council shall have the following duties and responsibilities, namely:-

- (a) to formulate policies for protecting human body from all kinds of blood-borne diseases, including Human Immuno Deficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Malaria and Syphilis;
- (b) to determine the procedures for collection, preservation and transfusion of safe blood;
- (c) to formulate policies to promote blood donors for voluntary blood donation, donating blood to relatives, and donating blood in exchange of blood;
- (d) to formulate policies for regulating private blood transfusion centres;
- (e) to determine the procedures for maintaining statistics of blood donors;
- (f) to formulate policies for gradually discouraging professional blood donors from donating blood;
- (g) to formulate policies for regulating the blood transfusion centres of different government hospitals; and
- (h) to give advice to the Government on such other ancillary issues as may be arisen from the matters mentioned in clauses (a) to (g).

**6. Meetings of the Council.-** (1) The Council may determine the procedures of its meetings.

(2) The meetings of the Council shall be held at such times and places as may be determined by the Chairman.

(3) All meetings of the Council shall be presided over by the Chairman and, in his absence, by the Vice-Chairman of the Council.

(4) To constitute a quorum at a meeting of the Council, one-third members of the Council shall have to be present.

(5) Decisions shall be taken by a majority of votes of the members present at the Council meeting and in the event of equality of votes, the person presiding shall have a second or casting vote.

(6) No act or proceeding of the Council shall be invalid or be called in question merely on the ground of any vacancy in, or any defect in the constitution of, the Council.

### Chapter III

#### Establishment and Operation of Private Blood Transfusion Centres, Licence, Etc.

**7. Establishment and operation of private blood transfusion centres.-** Any person may establish and operate a private blood transfusion centre upon securing a licence under section 9 of this Act.

**8. Conditions for establishing and operating a private blood transfusion centre.-** The conditions for establishing and operating a private blood transfusion centre shall be prescribed by rules.

**9. Licence for establishing and operating a private blood transfusion centre.-** (1) Any person willing to establish and operate a private blood transfusion centre may make an application to the Licensing Authority in such manner and form as may be prescribed by rules.

(2) The Licensing Authority shall, upon receiving any application under sub-section (1), send it to the selection committee for verification of the information mentioned in the application within seven days of receiving such application.

(3) Upon receiving the application under sub-section (2), the selection committee shall make local inspection of the place mentioned in the application and, after examining all information received, and making enquiry of all relevant matters, submit a complete report thereof to the Licensing Authority within 60 days of receiving the application.

(4) Upon verifying the report received under sub-section (3), the Licensing Authority shall,-

- (a) if satisfied that the applicant is capable of fulfilling the conditions prescribed by rules for establishing and regulating a private blood transfusion centre, issue a licence to the applicant upon collecting from him the licence fees prescribed under section 13 of this Act; or
- (b) if of the opinion that the applicant should be given opportunities for fulfilling the conditions prescribed by rules, give the applicant such time which may extend to 30 (thirty) days to fulfill such conditions; and
  - (i) after being satisfied that the applicant has been able to fulfill all the conditions within the given time, grant the application and issue a licence to the applicant within the next 15 (fifteen) days; or
  - (ii) if the applicant has failed to fulfill the required conditions within the given time, reject the application and notify it to the applicant; or
- (c) if of the opinion that the applicant has failed to fulfill most of the conditions prescribed by rules, and there is no possibility to fulfill the



conditions by the applicant though he is given any opportunity under clause (b), directly reject the application and notify it to the applicant within 15 (fifteen) days.

(5) Any person who has established a private blood transfusion centre immediately before the commencement of this Act may, in the manner and form prescribed under sub-section (1), make an application to the Licensing Authority within 30 (thirty) days after this Act coming into force.

(6) Upon receiving the application under sub-section (5), the Licensing Authority shall follow the procedures laid down in sub-sections (2), (3) and clauses (a) and (b) of sub-section (4).

(7) Notwithstanding anything contained in clause (a) of sub-section (4), in the case of an application received under sub-section (5), the applicant shall be given a time of 180 (one hundred and eighty) days to fulfill the conditions, if there is any to be satisfied.

(8) If no application is made under sub-section (5) for a licence to operate any private blood transfusion centre existing immediately before the commencement of this Act, the Licensing Authority may issue an order to suspend all activities of such private blood transfusion centre immediately.

(9) If any application for a licence is made under sub-section (5), and the applicant fails to fulfill the conditions for securing the licence within the time prescribed under this section, the Licensing Authority shall reject such application and issue an order to suspend all activities of such private blood transfusion centre immediately.

**10. Licensing Authority.-** For the purposes of this Act, the Director-General, Directorate of Health Services shall be the Licensing Authority.

**11. Selection Committee.-** For the purposes of this Chapter, in every district there shall be a Selection Committee comprising of such persons as may be prescribed by rules.

**12. Expiry and renewal of licence.-** (1) The licence issued for establishing and operating a private blood transfusion centre shall be valid for three years from the date of issuance thereof, and it shall be renewable at every three years.

(2) For renewal of the licence, an application shall be made to the Licensing Authority in such form and accompanied with such renewal fees as may be prescribed, before 90 (ninety) days of the expiry date of the licence as mentioned in sub-section (1).

(3) The Licensing Authority shall make local inspection of the concerned private blood transfusion centre within 30 (thirty) days of receiving the application under sub-section (2), and upon such inspection,-

- (i) if the Licensing Authority is satisfied that no condition, applicable for operating the blood transfusion centre, remains to be fulfilled, it shall renew the licence;

- (ii) if the Licensing Authority notices that some of the necessary conditions, applicable for operating the blood transfusion centre, remain to be fulfilled and the applicant has failed to maintain the necessary facilities, it shall reject the application and notify it to the applicant in writing minimum 15 (fifteen) days before the expiry date of the licence.

**13. Licence fees, etc.-** The licence fees, payable under this Act for establishing and operating a private blood transfusion centre, shall be Taka 1 (one) lac, and the renewal fees shall be Taka 50 (fifty) thousand:

Provided that the Government may, by notification in the official Gazette, re-determine the fees increasing the rate thereof.

**14. Fees for blood transfusion services.-** (1) The rate of fees, chargeable to a patient for providing blood transfusion services, shall be prescribed by rules.

(2) Every private blood transfusion centre shall-

- (a) affix a chart of fees payable for various blood tests and blood transfusion services to some conspicuous place and on the wall of the reception room; and
- (b) issue a receipt of fees received for blood test or providing blood transfusion services to the patient or his representative and preserve a copy thereof.

**15. Inspection committee.-** (1) The Government may, by notification in the official Gazette, constitute one or more inspection committees for inspecting private blood transfusion centres.

(2) The number and eligibility of the members of a committee constituted under sub-section (1) shall be determined by the Government.

**16. Power of entry, inspection, etc.-** (1) The inspection committee, the Director-General and any officer authorised by the Director-General may, subject to this Act, rule or any order issued thereunder, inspect any private blood transfusion centre.

(2) During inspection under sub-section (1), if the inspection committee or any officer authorized by the Director-General finds that any private blood transfusion centre is not complying with the conditions prescribed by this Act or rules, or has violated any condition of the licence, the inspection committee shall submit a written report thereon to the Government and, as the case may be, the concerned Officer to the Director-General within 15 days of such inspection.

(3) After verifying the written report submitted under sub-section (2), if the Government is of the opinion that the licence of such private blood transfusion centre requires to be suspended or revoked in the public interest, it shall issue directions to the Director-General to take necessary actions in this regard.

(4) If the Director-General, after making an inspection by himself or verifying the written report submitted under sub-section (2), finds that the private blood transfusion centre has relaxed to fulfill some of the conditions of the licence, the Director-General may issue an order to fulfill such conditions and, in case of failure to comply with the order, may suspend or revoke the licence of such private blood transfusion centre.

(5) The inspection committee, the Director-General and any officer authorised by the Director-General may, at any time, enter any place of a private blood transfusion centre, examine its register, the equipments for blood transfusion services or the papers relating to blood transfusion services and, if necessary, collect any extract of the register or papers.

**17. Appeal.-** (1) Any person aggrieved by the order of the Licensing Authority may prefer an appeal to the Government within 30 (thirty) days of the date of issuing such order, and the Government shall dispose of it within 90 (ninety) days of preferring such appeal.

(2) In case of an appeal preferred under sub-section (1), the decision of the Government shall be final.

## Chapter IV

### Offences and Punishment

**18. Punishment for setting up and operating any private blood transfusion centre without licence.-** (1) No person shall set up or operate any private blood transfusion centre without securing a licence under this Act.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence, he shall be punished with rigorous imprisonment for a term not exceeding 2 (two) years, or with fine not exceeding Taka 1 (one) lac, or with both.

**19. Punishment for giving wrong prescription.-** (1) No person shall give any wrong prescription for blood transfusion treatment which may result in grievous physical damage, loss of limbs, physical disability or death to the patient or blood receiver or cause him affected with blood-borne diseases.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence, he shall be punished with rigorous imprisonment for a term not exceeding 5 (five) years, or with fine not exceeding Taka 5 (five) lac, or with both.

**20. Punishment for blood transfusion in unapproved process.-** (1) For the purpose of blood transfusion treatment, no person shall transfuse blood in such process which may result in grievous physical damage, loss of limbs, physical disability or death to the patient or blood receiver or cause him affected with blood-borne diseases.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence, he shall be punished with rigorous imprisonment for a term not exceeding 5 (five) years, or with fine not exceeding Taka 5 (five) lac, or with both.

**21. Punishment for not disposing of disposable items.-** (1) Any person who is responsible for blood transfusion shall ensure disposal of the disposable items used therein after transfusion of blood.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence, he shall be punished with rigorous imprisonment for a term not exceeding 6 (six) months, or with fine not exceeding Taka 5 (five) thousand, or with both.

**22. Punishment of reusing disposable items.-** (1) No person shall reuse disposable items already used for blood transfusion.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence,-

- (a) he shall be punished with rigorous imprisonment for a term not exceeding 1 (one) year, or with fine not exceeding Taka 10 (ten) thousand, or with both; or
- (b) where such offence results in grievous physical damage, loss of limbs, physical disability or death to the patient or blood receiver or cause him affected with blood-borne diseases, he shall be punished with rigorous imprisonment for a term not exceeding 5 (five) years, or with fine not exceeding Taka 5 (five) lac, or with both.

**23. Punishment for transfusing unscreened blood.-** (1) No person shall transfuse unscreened blood, blood components or plasma product into the body of any patient or blood receiver.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence,-

- (a) he shall be punished with rigorous imprisonment for a term not exceeding 1 (one) year, or with fine not exceeding Taka 10 (ten) thousand, or with both; or
- (b) where such offence results in grievous physical damage, loss of limbs, physical disability or death to the patient or blood receiver or cause him affected with blood-borne diseases, he shall be punished with rigorous imprisonment for a term not exceeding 5 (five) years, or with fine not exceeding Taka 5 (five) lac, or with both.

**24. Punishment of unauthorised collection, production and distribution of blood, blood components and plasma product.-** (1) No person shall collect, produce and distribute blood, blood components and plasma product through any procedure or method except as prescribed by this Act.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence, he shall be punished with

rigorous imprisonment for a term not exceeding 2 (two) years, or with fine not exceeding Taka 50 (fifty) thousand, or with both.

**25. Punishment for transfusing blood by an unauthorised person.-** (1) No unauthorised person shall collect blood from the body of another person or transfuse blood into the body of a person.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence,-

- (a) he shall be punished with rigorous imprisonment for a term not exceeding 1 (one) year, or with fine not exceeding Taka 10 (ten) thousand, or with both; or
- (b) where such offence results in grievous physical damage, loss of limbs, physical disability or death to the patient or blood receiver or cause him affected with blood-borne diseases, he shall be punished with rigorous imprisonment for a term not exceeding 5 (five) years, or with fine not exceeding Taka 5 (five) lac, or with both.

**26. Punishment for using fake identity card of a blood donor.-** (1) No person shall use the identity card of another blood donor or fake identity card.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence, he shall be punished with simple imprisonment for a term not exceeding 6 (six) months, or with fine not exceeding Taka 10 (ten) thousand, or with both.

**27. Punishment for collecting excess service fees.-** (1) No person shall collect any fees for blood transfusion service which is excess to the rate prescribed by rules.

(2) If any person contravenes the provisions of sub-section (1), he shall be deemed to have committed a punishable offence, and for such offence, he shall be punished with simple imprisonment for a term not exceeding 6 (six) months, or with fine not exceeding Taka 10 (ten) thousand, or with both.

## **Chapter V**

### **Miscellaneous**

**28. Blood Transfusion Funds.-** The Government may, by an order published in the official Gazette, create a fund to be called the 'Blood Transfusion Fund' for every government hospital, and the manner in which the income and expenditure and the accounts of the fund have to be maintained shall be prescribed by rules.

**29. Blood transfusion expert committee.-** (1) For the purposes of this Act, the Government may, in consultation with the Council, by notification in the official Gazette, constitute one or more blood transfusion expert committees.

(2) Any committee constituted under sub-section (1) shall perform such duties and may exercise such powers as the Government may confer upon it.

**30. Mobile blood collection camp.-** In cooperation with a private blood transfusion centre or government hospital, any national or international voluntary organisation may, with the prior approval of the Government, in the public interest, organise any mobile blood collection camp to encourage voluntary blood donation.

**31. Offences committed by companies, etc.-** Where any offence under this Act is committed by a company, every such director, manager, secretary, partner, officer and employee thereof who has direct involvement with the offence shall, unless he proves that the offence was committed without his knowledge or that he exercised due diligence to prevent its commission, be deemed to be guilty of such offence.

**Explanation.-** In this section-

- (a) “company” includes any commercial institution, partnership business, society, association and organisation;
- (b) “Director”, in the case of commercial institution, includes any partner or member of its board of directors.

**32. Cognizance of offences.-** All offences under this Act shall be non-cognizable, bailable and compoundable.

**33. Power to take cognizance of offence.-** No court shall, without any written complaint made by the Director-General or any officer authorized by the Director-General or the aggrieved person or his representative, take cognizance of any offence committed under this Act.

**34. Power to make rules.-** (1) For the purposes of this Act, the Government may, in consultation with the Council and by notification in the official Gazette, make rules.

(2) Without prejudice to the generality of the powers conferred under sub-section (1), such rules may provide for the following matters, namely:-

- (a) to prescribe the pre-conditions and procedure for collection, preservation and transfusion of safe blood in government hospitals and private blood transfusion centres;
- (b) to prescribe the duties and responsibilities of a doctor issuing requisition for blood or conducting blood transfusion;
- (c) to regulate the preparation, collection, preservation and distribution of blood, blood components and plasma product;
- (d) to prescribe the standard of the premises of a blood transfusion centre;
- (e) to prescribe the standard of hygienic conditions of the buildings to be used as a blood transfusion centre;
- (f) to determine the necessary infrastructures for establishing a blood transfusion centre;

- (g) to determine the equipments for a blood transfusion centre;
- (h) to determine the necessary instruments, chemicals, kits and reagents for a blood transfusion centre;
- (i) to prescribe the waste disposal system of a blood transfusion centre;
- (j) to prescribe the necessary manpower and their qualifications for a blood transfusion centre;
- (k) to prescribe the categories of blood donors and the procedures of issuing identity cards to them;
- (l) to prescribe the procedures for making categorical lists of blood donors and preserving thereof.

(3) Any fine not exceeding Taka 1 (one) lac may be provided for in the rules made under this section for contravening any provision thereof.

**35. Publication of authentic English text.-** After the commencement of this Act, the Government shall, by notification in the official Gazette, publish an English text of this Act which shall be called the authentic English text of this Act:

Provided that in the event of conflict between this Act and the English text, this Act shall prevail.

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