

THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

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THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

INTRODUCTION

With the advance of science and technology particularly in the field of medicine and surgery it has become possible to remove organs from living as well as deceased persons and to transplant such organs to save the lives of suffering human beings. This advancement brought its evils as well. Commercial dealings in human organs especially kidneys, started increasing. Thus a need for a comprehensive legislation for regulating the removal of organs from cadavers and living persons and prohibiting commercial dealings in human organs, was felt as the matter has been agitated by the parliamentarians as well as by various national bodies, medical, legal and social experts. On the other hand, in the absence of any law the removal of organs from persons suffering brain-stem death has not been possible. Transplantation of organs like liver and heart for which latest technology is available in the country, had been impeded. Under the circumstances it became necessary to enact a comprehensive law. The Transplantation of Human Organs Bill, 1992 was introduced in the Lok Sabha on 20th August, 1992. After being discussed by both the Houses of Parliament it was referred to a Select Committee of both the Houses. The Select Committee presented its report on 21st December, 1993. On the recommendations of the Select Committee the Bill was again discussed in both the Houses of Parliament.

STATEMENT OF OBJECTS AND REASONS

At present, there is no comprehensive legislation to regulate the removal of organs from living as well as deceased persons and transplantation of such organs. In the Union territory of Delhi, there are two enactments in force, namely, the Eyes (Authority for use for Therapeutic Purposes) Act, 1982 and the Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 which regulate the removal and transplantation of cornea, ear drum and ear bones. In Maharashtra, the Maharashtra Kidney Transplantation Act, 1982 and the Bombay Corneal Grafting Act, 1957 regulate the transplantation of kidneys and corneas respectively. Thus, there is a need for a comprehensive legislation for regulating the removal of organs from cadavers and living persons and prohibiting commercial dealings in human organs.

2. There has been a persistent demand for such a legislation in Parliament, and from various national bodies, medical, legal and social experts, particularly when reports about the commercial dealing in human organs, especially kidneys, have increased. There has been persistent demand for prohibiting this unethical practice. On the other hand, in the absence of any legal sanction the removal of organs from persons suffering brain-stem death has not been possible. It has impeded transplantation of organs like liver and heart for which the necessary technology is available in the country. In order to reach a broad consensus of opinion in this regard, a series of seminars were held in the four metropolitan cities of the country. A report was also prepared by a Committee of medical and legal experts headed by Dr. L.M. Singhvi.

3. Against this background, it is considered necessary to enact a comprehensive law for regulating the removal and transplantation of human organs and for preventing commercial dealings in organs by providing punishment for such dealings.

4. The Bill seeks to achieve the above objects.

ACT 42 OF 1994

The Bill was passed by both the Houses of Parliament and it received the assent of President on 8th July, 1994. After it was assented it became THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994 (42 of 1994).

THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

(42 of 1994)

[8th July, 1994]

An Act to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto.

WHEREAS it is expedient to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs;

AND WHEREAS Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in Articles 249 and 250 of the Constitution;

AND WHEREAS in pursuance of clause (1) of Article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and Maharashtra to the effect that the matters aforesaid should be regulated in those States by Parliament by law;

BE it enacted by Parliament in the Forty-fifth Year of the Republic of India as follows :—

CHAPTER I PRELIMINARY

1. **Short title, application and commencement.**—(1) This Act may be called the Transplantation of Human Organs Act, 1994.

(2) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and Maharashtra and to all the Union territories and it shall also apply to such other State which adopts this Act by resolution passed in that behalf under clause (1) of Article 252 of the Constitution.

(3) It shall come into force in the States of Goa, Himachal Pradesh and Maharashtra and in all the Union territories on such date¹ as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, means the date on which this Act comes into force in such State or Union territory.

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

- (a) “advertisement” includes any form of advertising whether to the public generally or to any section of the public or individually to selected persons;
- (b) “Appropriate Authority” means the Appropriate Authority appointed under section 13;

1. Came into force on 4th February, 1995, vide S.O. 80(E), dated 4th February, 1995.

- (c) "Authorisation Committee" means the committee constituted under clause (a) or clause (b) of sub-section (4) of section 9;
- (d) "brain-stem death" means the stage at which all functions of the brain-stem have permanently and irreversibly ceased, and is so certified under sub-section (6) of section 3;
- (e) "deceased person" means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place;
- (f) "donor" means any person, not less than eighteen years of age, who voluntarily authorises the removal of any of his human organs for therapeutic purposes under sub-section (1) or sub-section (2) of section 3;
- (g) "hospital" includes a nursing home, clinic, medical centre, medical or teaching institution for therapeutic purposes and other like institution;
- (h) "human organ" means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body;
- (i) "near relative" means spouse, son, daughter, father, mother, brother or sister;
- (j) "notification" means a notification published in the Official Gazette;
- (k) "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 human organ from his body;
- (l) "prescribed" means prescribed by rules made under this Act;
- (m) "recipient" means a person into whom any human organ is, or is proposed to be, transplanted;
- (n) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956 (102 of 1956), and who is enrolled on a State Medical Register as defined in clause (k) of that section;
- (o) "therapeutic purposes" means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and
- (p) "transplantation" means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes.

COMMENTS

The definition requires to be interpreted broadly so as to give effect to the legislative intention envisaged under the Act: *Rajeev Metal Works v. The Mineral and Metal Trading Corporation of India Ltd.*, 1996(1) Supreme 140.

CHAPTER II

AUTHORITY FOR THE REMOVAL OF HUMAN ORGANS

3. Authority for removal of human organs.—(1) Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organ of his body for therapeutic purposes.

(2) If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall, unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor.

(3) Where no such authority as is referred to in sub-section (2), was made by any person before his death but no objection was also expressed by such person to any of his human organs being used after his death for therapeutic purposes, the person lawfully in possession of the dead body of such person may, unless he has reason to believe that any near relative of the deceased person has objection to any of the deceased person's human organs being used for therapeutic purposes, authorise the removal of any human organ of the deceased person for its use for therapeutic purposes.

(4) The authority given under sub-section (1) or sub-section (2) or, as the case may be, sub-section (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ; but no such removal shall be made by any person other than the registered medical practitioner.

(5) Where any human organ is to be removed from the body of a deceased person, the registered medical practitioner shall satisfy himself, before such removal, by a personal examination of the body from which any human organ is to be removed, that life is extinct in such body or, where it appears to be a case of brain-stem death, that such death has been certified under sub-section (6).

(6) Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following, namely:—

- (i) the registered medical practitioner, in charge of the hospital in which brain-stem death has occurred;
- (ii) an independent registered medical practitioner, being a specialist, to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority;
- (iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; and
- (iv) the registered medical practitioner treating the person whose brain-stem death has occurred.

(7) Notwithstanding anything contained in sub-section (3), where brain-stem death of any person, less than eighteen years of age, occurs and is certified under sub-section (6), any of the parents of the deceased person may give authority, in such form and in such manner as may be prescribed, for the removal of any human organ from the body of the deceased person.

4. Removal of human organs not to be authorised in certain cases.—(1) No facilities shall be granted under sub-section (2) of section 3 and no authority shall be given under sub-section (3) of that section for the removal of any human organ from the body of a deceased person, if the person required to grant such facilities, or empowered to give such authority, has reason to believe that an inquest may be required to be held in relation to such body in pursuance of the provisions of any law for the time being in force.

(2) No authority for the removal of any human organ from the body of a deceased person shall be given by a person to whom such body has been entrusted solely for the purpose of interment, cremation or other disposal.

5. Authority for removal of human organs in case of unclaimed bodies in hospital or prison.—(1) In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remains unclaimed may be given, in the prescribed form, by the person in charge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof.

(2) No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even though such near relative has not come forward to claim the body of the deceased person within the time specified in sub-section (1).

6. Authority for removal of human organs from bodies sent for post-mortem examination for medico-legal or pathological purposes.—Where the body of a person has been sent for post-mortem examination—

- (a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause; or
- (b) for pathological purposes,

the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, authorise the removal, for therapeutic purposes, of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.

7. Preservation of human organs.—After the removal of any human organ from the body of any person, the registered medical practitioner shall take such steps for the preservation of the human organ so removed as may be prescribed.

8. Savings.—(1) Nothing in the foregoing provisions of this Act shall be construed as rendering unlawful any dealing with the body or with any part of the body of a deceased person if such dealing would have been lawful if this Act had not been passed.

(2) Neither the grant of any facility or authority for the removal of any human organ from the body of a deceased person in accordance with the provisions of this Act nor the removal of any human organ from the body of a deceased person in pursuance of such authority shall be deemed to be an offence punishable under section 297 of the Indian Penal Code (45 of 1860).

9. Restrictions on removal and transplantation of human organs.—(1) Save as otherwise provided in sub-section (3), no human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.

(2) Where any donor authorises the removal of any of his human organs after his death under sub-section (2) of section 3 or any person competent or empowered to give authority for the removal of any human organ from the body of any deceased person authorises such removal, the human organ may be removed and transplanted into the body of any recipient who may be in need of such human organ.

(3) If any donor authorises the removal of any of his human organs before his death under sub-section (1) of section 3 for transplantation into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such human organ shall not be removed and transplanted without the prior approval of the Authorisation Committee.

(4)(a) The Central Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the Central Government on such terms and conditions as may be specified in the notification for each of the Union territories for the purposes of this section.

(b) The State Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the State Government on such terms and conditions as may be specified in the notification for the purposes of this section.

(5) On an application jointly made, in such form and in such manner as may be prescribed, by the donor and the recipient, the Authorisation Committee shall, after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements of this Act and the rules made thereunder, grant to the applicants approval for the removal and transplantation of the human organ.

(6) If, after the inquiry and after giving an opportunity to the applicants of being heard, the Authorisation Committee is satisfied that the applicants have not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for approval.

CHAPTER III REGULATION OF HOSPITALS

10. Regulation of hospitals conducting the removal, storage or transplantation of human organs.—(1) On and from the commencement of this Act,—

- (a) no hospital, unless registered under this Act, shall conduct, or associate with, or help in, the removal, storage or transplantation of any human organ;
- (b) no medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, any activity relating to the removal, storage or transplantation of any human organ at a place other than a place registered under this Act; and
- (c) no place including a hospital registered under sub-section (1) of section 15 shall be used or cause to be used by any person for the removal, storage or transplantation of any human organ except for therapeutic purposes.

(2) Notwithstanding anything contained in sub-section (1), the eyes or the ears may be removed at any place from the dead body of any donor, for therapeutic purposes, by a registered medical practitioner.

Explanation.—For the purposes of this sub-section, “ears” includes ear drums and ear bones.

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

12. Explaining effects, etc., to donor and recipient.—No registered medical practitioner shall undertake the removal or transplantation of any human organ unless he has explained, in such manner as may be prescribed, all possible effects, complications and hazards connected with the removal and transplantation to the donor and the recipient respectively.

CHAPTER IV APPROPRIATE AUTHORITY

13. Appropriate Authority.—(1) The Central Government shall appoint, by notification, one or more officers as Appropriate Authorities for each of the Union territories for the purposes of this Act.

(2) The State Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purposes of this Act.

(3) The Appropriate Authority shall perform the following functions, namely:—

- (i) to grant registration under sub-section (1) of section 15 or renew registration under sub-section (3) of that section;
- (ii) to suspend or cancel registration under sub-section (2) of section 16;

- (iii) to enforce such standards, as may be prescribed, for hospitals engaged in the removal, storage or transplantation of any human organ;
- (iv) to investigate any complaint of breach of any of the provisions of this Act or any of the rules made thereunder and take appropriate action;
- (v) to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed; and
- (vi) to undertake such other measures as may be prescribed.

CHAPTER V

REGISTRATION OF HOSPITALS

14. Registration of hospitals engaged in removal, storage or transplantation of human organs.—(1) No hospital shall commence any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes after the commencement of this Act unless such hospital is duly registered under this Act:

Provided that every hospital engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement:

Provided further that every hospital engaged in any activity relating to the removal, storage or transplantation of any human organ shall cease to engage in any such activity on the expiry of three months from the date of commencement of this Act unless such hospital has applied for registration and is so registered or till such application is disposed of, whichever is earlier.

(2) Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.

(3) No hospital shall be registered under this Act unless the Appropriate Authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed.

15. Certificate of registration.—(1) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder, grant to the hospital a certificate of registration in such form, for such period and subject to such conditions as may be prescribed.

(2) If, after the inquiry and after giving an opportunity to the applicant of being heard, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(3) Every certificate of registration shall be renewed in such manner and on payment of such fees as may be prescribed.

16. Suspension or cancellation of registration.—(1) The Appropriate Authority may, *suo moto* or on complaint, issue a notice to any hospital to show cause why its registration under this Act should not be suspended or cancelled for the reasons mentioned in the notice.

(2) If, after giving a reasonable opportunity of being heard to the hospital, the Appropriate Authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, without prejudice to any criminal action that it may take against such hospital, suspend its registration for such period as it may think fit or cancel its registration:

Provided that where the Appropriate Authority is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any hospital without issuing any notice.

17. Appeals.—Any person aggrieved by an order of the Authorisation Committee rejecting an application for approval under sub-section (6) of section 9, or any hospital aggrieved by an order of the Appropriate Authority rejecting an application for registration under sub-section (2) of section 15 or an order of suspension or cancellation of registration under sub-section (2) of section 16, may, within thirty days from the date of the receipt of the order, prefer an appeal, in such manner as may be prescribed, against such order to—

- (i) the Central Government where the appeal is against the order of the Authorisation Committee constituted under clause (a) of sub-section (4) of section 9 or against the order of the Appropriate Authority appointed under sub-section (1) of section 13; or
- (ii) the State Government, where the appeal is against the order of the Authorisation Committee constituted under clause (b) of sub-section (4) of section 9 or against the order of the Appropriate Authority appointed under sub-section (2) of section 13.

CHAPTER VI OFFENCES AND PENALTIES

18. Punishment for removal of human organ without authority.—(1) Any person who renders his services to or at any hospital and who, for purposes of transplantation, conducts, associates with, or helps in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.

(2) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

19. Punishment for commercial dealings in human organs.—Whoever—

- (a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;
- (b) seeks to find a person willing to supply for payment any human organ;

- (c) offers to supply any human organ for payment;
- (d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;
- (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,—
 - (a) inviting persons to supply for payment of any human organ;
 - (b) offering to supply any human organ for payment; or
 - (c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d),

shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees:

Provided that the court may, for any adequate and special reason to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees.

COMMENTS

Moral conviction must be replaced by legal conviction; *State of West Bengal v. Bhola Devi*, (1996) 1 Crimes 427 (Cal DB).

20. Punishment for contravention of any other provision of this Act.—Whoever contravenes any provision of this Act or any rule made, or any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, shall be punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees.

21. Offences by companies.—(1) Where any offence punishable under this Act has been committed by a company, every person who, at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided 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.

(2) Notwithstanding anything contained in sub-section (1), where any offence punishable under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section,—

- (a) “company” means any body corporate and includes a firm or other association of individuals; and
- (b) “director”, in relation to a firm, means a partner in the firm.

22. Cognizance of offence.—(1) No court shall take cognizance of an offence under this Act except on a complaint made by—

- (a) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or the State Government or, as the case may be, the Appropriate Authority; or
- (b) a person who has given notice of not less than sixty days, in such manner as may be prescribed, to the Appropriate Authority concerned, of the alleged offence and of his intention to make a complaint to the court.

(2) No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

(3) Where a complaint has been made under clause (b) of sub-section (1), the court may, on demand by such person, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

CHAPTER VII MISCELLANEOUS

23. Protection of action taken in good faith.—(1) No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

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

24. Power to make rules.—(1) The Central Government may, by notification, make rules for carrying out the purposes of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

- (a) the manner in which and the conditions subject to which any donor may authorise removal, before his death, of any human organ of his body under sub-section (1) of section 3;
- (b) the form and the manner in which a brain-stem death is to be certified and the conditions and requirements which are to be satisfied for that purpose under sub-section (6) of section 3;
- (c) the form and the manner in which any of the parents may give authority, in the case of brain-stem death of a minor, for the removal of any human organ under sub-section (7) of section 3;
- (d) the form in which authority for the removal of any human organ from an unclaimed

dead body may be given by the person in charge of the management or control of the hospital or prison under sub-section (1) of section 5;

- (e) the steps to be taken for the preservation of the human organ removed from the body of any person under section 7;
- (f) the form and the manner in which an application may be jointly made by the donor and the recipient under sub-section (5) of section 9;
- (g) the manner in which all possible effects, complications and hazards connected with the removal and transplantation is to be explained by the registered medical practitioner to the donor and the recipient under section 12;
- (h) the standards as are to be enforced by the Appropriate Authority for hospitals engaged in the removal, storage or transplantation of any human organ under clause (iii) of sub-section (3) of section 13;
- (i) the other measures as the Appropriate Authority shall undertake in performing its functions under clause (vi) of sub-section (3) of section 13;
- (j) the form and the manner in which an application for registration shall be made and the fee which shall be accompanied, under sub-section (2) of section 14;
- (k) the specialised services and the facilities to be provided, skilled manpower and the equipments to be possessed and the standards to be maintained by a hospital for registration, under sub-section (3) of section 14;
- (l) the form in which, the period for which and the conditions subject to which certificate of registration is to be granted to a hospital, under sub-section (1) of section 15;
- (m) the manner in which and the fee on payment of which certificate of registration is to be renewed under sub-section (3) of section 15;
- (n) the manner in which an appeal may be preferred under section 17;
- (o) the manner in which a person is required to give notice to the Appropriate Authority of the alleged offence and of his intention to make a complaint to the court, under clause (b) of sub-section (1) of section 22; and
- (p) any other matter which is required to be, or may be, prescribed.

(3) Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

25. Repeal and saving.—(1) The Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 (28 of 1982) and the Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 (29 of 1982) are hereby repealed.

(2) The repeal shall, however, not affect the previous operation of the Acts so repealed or anything duly done or suffered thereunder.

THE TRANSPLANTATION OF HUMAN ORGANS RULES, 1995¹

In exercise of the powers conferred by sub-section (1) of section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following rules, namely:—

1. Short title and commencement.—(1) These rules may be called the Transplantation of Human Organs Rules, 1995.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions.—(a) “Act” means the Transplantation of Human Organs Act, 1994 (42 of 1994);

(b) “Form” means a form annexed to these Rules;

(c) “Section” means a section of the Act;

(d) words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. Authority for Removal of Human Organ.—Any donor may authorise the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and on such conditions as specified in Form 1.

4. Duties of the Medical Practitioner.—(1) A registered medical practitioner shall, before removing a human organ from the body of a donor before his death, satisfy himself—

(a) that the donor has given his authorisation in Form 1;

(b) that the donor is in proper state of health and is fit to donate the organ, and shall sign a certificate as specified in Form 2.

(c) that the donor is a near relative of the recipient, and shall sign a certificate as specified in Form 3 after carrying out the following tests on the donor and the recipient, namely:—

(i) tests for the antigenic products of the Human Major Histocompatibility system HLA-A, HLA-B and HLA-DR using conventional serological techniques;

(ii) tests to establish HLA-DR beta and HLADQ beta gene restriction fragment length polymorphism;

(iii) where the tests referred to in sub-clause (i) and sub-clause (ii) do not establish a genetic relationship between the donor and the recipient, tests to establish DNA polymorphisms using at least two multi-locus gene probe;

(iv) where the tests referred to in sub-clause (iii) do not establish a genetic relationship between the donor and the recipient further tests to establish DNA polymorphisms using at least five single locus polymorphic probes.

(d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that they are so related and shall sign a certificate in Form 4.

1. *Vide* G.S.R. No. 51(E), dated 4th February, 1995, published in the Gazette of India, Extra., Pt. II, Sec. 3(i), dated 4th February, 1995.

(2) A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself—

- (a) that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority aforesaid;
- (b) that the person lawfully in possession of the dead body has signed a certificate as specified in Form 6 or Form 7.

(3) A registered medical practitioner shall, before removing a human organ from the body of a person in the event of his brain-stem death, satisfy himself—

- (a) that a certificate as specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of section 3 of the Act;
- (b) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person.

5. Preservation of Organs.—The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the Authorisation Committee as specified in Form 10.

7. Registration of Hospital.—(1) An application for registration shall be made to the Appropriate Authority as specified in Form 11. The application shall be accompanied by a fee of rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.

(2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 12 and shall be valid for a period of five years from the date of its issue and shall be renewable.

8. Renewal of Registration.—(1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee of rupees five hundred payable to the Appropriate Authority by means of a bank draft or postal order.

(2) A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years.

(3) If, after an inquiry including inspection of the hospital and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and the Rules made thereunder

and conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

9. Conditions for grant of Certificate of Registration.—No hospital shall be granted a certificate of registration under this Act unless it fulfils the following requirement of manpower, equipment, specialised services and facilities as laid down below :—

General Requirement

1. Surgical Staff
2. Cardiology Staff
3. Nursing Staff
4. Communication System
5. Intensivist
6. Medical Social Worker
7. Perfusionist.

Various Departments

1. Microbiology
2. Mycology
3. Pathology
4. Virology
5. Nephrology
6. Neurology
7. Psychology
8. G.I. Surgery
9. Anaesthesiology
10. Imaging Facilities
11. Paediatrics
12. Physiotherapy
13. Immunology
14. Haematology
15. Blood Bank
16. Clinical Chemistry
17. Cardiology.

Non-transplantation Programme Team

1. Neurologist
2. Neurosurgeon
3. Medical Superintendent
4. And Other Hospital Staff.

Basic Equipment

Operating Room facilities for routine open heart surgery which includes heart lung machine and accessories.

Additional Equipment Required for Transplantation Programme

1. Cell Saver.
2. Assist devices like IABP, Centrifugal Pump and various assist devices, both pneumatic and electric operated.
3. Mobile C-arm, image intensifier for routine biopsies in the sterile operating room.
4. Eact/Alert System for early detection of any infection.
5. Radioimmunoassay for measuring Cyclosporin levels.
6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasmosis and other Mycology Tests.

Experts

(A) Kidney Transplantation

M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised centre in India or abroad and having attended to adequate number of renal transplantation as an active member of team.

(B) Transplantation of liver and other abdominal organs

M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established centre with a reasonable experience of performing liver transplantation as an active member of team.

(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation

M. Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least 3 years experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-valve surgery.

10. Appeal.—(1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9, or by an order of the Appropriate Authority under sub-section (2) of section 15 and section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government.

(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

FORM 1

(See rule 3)

I, aged s/o, d/o, w/o Shri.
 resident of
 hereby authorise to remove for therapeutic purposes/consent to donate my organ, namely,
 to

(i) Shri/Smt./Km. s/o, d/o, w/o Shri.
 aged resident of
 who happens to be my near relative as defined in clause (i) of section 2 of the Act.

OR

(ii) Shri/Smt./Km. s/o, d/o, w/o Shri.
 aged resident of
 towards whom I possess special affection or attachments, or for any special reason (to be specified).

I certify that the above authority/consent has been given by me out of my own free will without any undue pressure, inducement, influence or allurement and that the purposes of the above authority/donation and of all possible complications, side-effects, consequences and options have been explained to me before giving this authority or consent or both.

Signature of the Donor

FORM 2

[See rule 4(1)(b)]

I, Dr. possessing qualification of
 registered as medical practitioner at Serial No. by the
 Medical Council, certify that I have examined Shri/Smt./Km. s/o, d/o,
 w/o Shri. aged whose free and informed
 consent about donation of the organ, namely to
 Shri/Smt./Km. s/o, d/o, w/o Shri. who is near relative of
 the donor and that the said donor is in proper state of health and is
 medically fit to be subjected to the procedure of organ removal.

Signature

Place.....

Dated.....

FORM 3

[See rule 4(1)(c)]

I, Dr. possessing qualification of
 registered as medical practitioner at Serial No. by the
 Medical Council, certify that Shri/Smt./Km. s/o, d/o, w/o Shri.
 aged the donor, and Mr./Mrs.
 s/o, d/o, w/o Shri. aged the recipient of the organ
 donated by the said donor are related to each other as brother/sister/mother/father/son/daughter as per
 their statement and the fact of this relationship has been established by the results of the tests for
 Antigenic Products of the Human Major Hysto-compatibility System, namely,
 by the Authorisation Committee as per the information contained in their letter of approval
 No. dated

Signature

Place.....

Dated.....

FORM 4

[See Rule 4(1)(d)]

I, Dr. possessing qualification of
registered as medical practitioner at Serial No. by the
Medical Council, certify that—

- (i) Shri. s/o Shri.
aged resident of
and Smt. d/o, w/o Shri.
aged resident of are
related to each other as spouse according to the statement given by them and their statement
has been confirmed by means of following evidence before effecting the organ removal from
the body of the said Shri/Smt./Km.
(Applicable only in the cases where considered necessary).

OR

- (ii) The Clinical condition of Shri/Smt.
mentioned above is such that recording of his/her statement is not practicable.

Place

Signature of Registered Medical Practitioner

Dated

FORM 5

[See rule 4(2)(a)]

I, s/o, do, w/o Shri.
aged resident of in the
presence of persons mentioned below hereby unequivocally authorise the removal of my organ/
organs, namely, from my body after my death for therapeutic
purposes.

Signature of the Donor

Dated

(Signature)

1. Shri/Smt./Km.
s/o, d/o, w/o Shri.
aged
resident of

(Signature)

- (2) Shri/Smt./Km. Shri.
s/o, d/o, w/o Shri.
aged
resident of
is a near relative to the donor as

Dated

FORM 6

[See rule 4(2)(b)]

I, s/o, d/o, w/o Shri.
 aged resident of
 having lawful possession of the dead body of Shri/Smt./Km.
 s/o, d/o, w/o Shri. aged resident of
 having known that the deceased has not expressed any objection to his/her organ /organs being removed for therapeutic purposes after his/her death and also having reasons to believe that no near relative of the said deceased person has objection to any of his/her organs being used for therapeutic purposes, authorise removal of his/her body organs, namely,

Signature

Dated

Place

Person in lawful possession of the dead body

Address

FORM 7

[See rule 4(2)(b)]

I, Shri/Smt./Km., having lawful possession of the
 deadbody of Shri/Smt./Km. s/o, d/o, w/o Shri.
 aged resident of
 after having known that no objection was expressed by the deceased
 to any of his human organ being used after his death for therapeutic purposes and also having reason
 to believe that no near relative of the deceased person has objection to any of the deceased person's
 organ being used for therapeutic purposes, hereby authorise the removal of the deceased's organ,
 namely, for therapeutic purposes.

Signature

Name

Address

Time and date

FORM 8

[See rule 4(3)(a) and (b)]

We, the following members of the Board of medical experts after careful personal examination,
 hereby certify that Shri/Smt./Km.
 aged about s/o, d/o, w/o, Shri.
 resident of
 is dead on account of permanent and irreversible cessation of all functions of the brain-stem. The tests
 carried out by us and the findings therein are recorded in the brain-stem death Certificate annexed
 hereto.

Dated

Signature

1. R.M.P., Incharge of the Hospital in which brain-stem death has occurred.
2. R.M.P., nominated from the panel of names approved by the Appropriate Authority.
3. Neurologist/Neuro-Surgeon nominated from the panel of names approved by the Appropriate Authority
4. R.M.P., treating the aforesaid deceased person.

BRAIN-STEM DEATH CERTIFICATE

(A) Patient Details :

1. Name of the patient Shri/Smt./Km.
.....
S.O./D.O/W.O. Shri.
.....
Sex Age
2. Home Address
.....
.....
3. Hospital Number
4. Name and Address of next of kin
or person responsible for the patient
(if none exists, this must be
specified)
5. Has the patient or next of kin agreed
to any transplant?
6. Is this a Police Case? Yes No

(B) Pre-conditions :

1. Diagnosis : Did the patient suffer from any illness or accident that led to irreversible brain damage? Specify details
.....
.....

Date and time of accident/onset of illness

Date and onset of non-responsible coma

2. Findings of Board of Medical Experts :

- (1) The following reversible causes of coma have been excluded :—
Intoxication (Alcohol)

Depressant Drugs

Relaxants (Neuromuscular blocking agents)

	First Medical Examination		Second Medical Examination	
	1st	2nd	1st	2nd
Primary hypothermia				
Hypovolaemic shock				
Metabolic or endocrine disorders				
Tests for absence of brain-stem functions				
(2) Coma				
(3) Cessation of spontaneous breathing				
(4) Pupillary size				
(5) Pupillary light reflexes				
(6) Doll's head eye movements				
(7) Corneal reflexes (Both sides)				
(8) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk				
(9) Gag reflex				
(10) Cough (Tracheal)				
(11) Eye movements on coloric testing bilaterally				
(12) Apnoea tests as specified				
(13) Were any respiratory movements seen ?				

Date and time of first testing :

Date and time of second testing :

This is to certify that the patient has been carefully examined twice after an interval of about six hours and on the basis of findings recorded above.

Shri./Smt./Km. is declared brain-stem dead.

- | | |
|---|--|
| 1. Medical Administrator Incharge of the hospital | 2. Authorised Specialist. |
| 3. Neurologist/Neuro-Surgeon | 4. Medical Officer treating the patient. |

NB. I. The minimum time interval between the first testing and second testing will be six hours.

II. No. 2 and No. 3 will be coopted by the Administrator Incharge of the hospital from the Panel of experts approved by the appropriate authority.

FORM 9

[See rule 4(3)(b)]

I, Shri./Smt.s/o, w/o Shri
resident ofhereby authorise removal of the organ/organs, namely,
.....for therapeutic purpose from the deadbody of my son/daughter
Shri/Km.agedwhose
brain-stem death has been duly certified in accordance with the law.

Signature

Name

Place

Date

FORM 10

APPLICATION FOR APPROVAL FOR TRANSPLANTATION LIVE DONOR OTHER THAN NEAR RELATIVE

Whereas I,s/o, d/o, w/o, Shri
agedresiding at have been informed by
my doctor that I am suffering from and may be benefited by
transplantation of into my body,

and whereas I,s/o, d/o, w/o Shri
agedresiding at by reason of affection and
attachment because:
.....
.....

(reason to be filled in)

would like to donate mytowe.....

(donor)

andhereby apply to authorisation committee for permission for such
transplantation to be carried out.

(Recipient)

We solemnly affirm that the above decision has been taken without any undue pressure
inducement, influence or allurement and that all possible consequences and options of organ
transplantation have been explained to us.
.....
.....

Signature and address of prospective donor.

Signature and address of prospective recipient.

FORM 11

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN TRANSPLANTATION

To

The Appropriate Authority for organ transplantation.....

(State or Union Territory)

We hereby apply to be recognised as an institution to carry out organ transplantation. The required
data about the facilities available in the hospital are as follows:—

(A) Hospital

1. Name
2. Location
3. Govt./Pvt.
4. Teaching/Non-teaching
5. Approached by :

Road :	Yes	No
Rail :	Yes	No
Air :	Yes	No

6. Total bed strength :
7. Name of the disciplines in the hospital
8. Annual budget
9. Patient turnover/year

(B) Surgical Team

1. No. of beds
2. No. of permanent staff members with their designations
3. No. of temporary staff with their designations
4. No. of operations done per year
5. Trained persons available for transplantation (Please specify organ for transplantation)

(C) Medical Team :

1. No. of beds
2. No. of permanent staff members with their designation
3. No of temporary staff members with their designation
4. Patient turnover per year
5. No. of potential transplant candidates admitted per year.

(D) Anaesthesiology :

1. No. of permanent staff members with their designations

2. No. of temporary staff members with their designations
3. Name and No. of operations performed
4. Name and No. of equipments available
5. Total no. of operation theatres in the hospital
6. No. of emergency operation-theatres
7. No. of separate transplant operation theatre

(E) I.C.U./H.D.U. Facilities :

1. ICU/HDU facilities : Present Not present.....
2. No of ICU beds
3. Trained
- Nurses
- Technicians
4. Name and number of equipments in ICU

(F) Other Supportive Facilities :

Data about facilities available in the hospital.

(G) Laboratory Facilities

1. No. of permanent staff with their designations.
2. No. of temporary staff with their designations.
3. Names of the investigations carried out in the Deptt.
4. Name and No. of equipments available.

(H) Imaging Services:

1. No. of permanent staff with their designations.
2. No. of temporary staff with their designations.
3. Names of the investigations carried out in the Deptt.
4. Name and No. of equipments available.

(I) Haematology Services :

1. No. of permanent staff with their designations.
2. No. of temporary staff with their designations.
3. Names of the investigations carried out in the Deptt.
4. Name and No. of equipments available.

(J) Blood Bank Facilities : Yes..... No

(K) Dialysis Facilities : Yes..... No

(L) Other Personnel :

- | | |
|--------------------|--------|
| 1. Nephrologist | Yes/No |
| 2. Neurologist | Yes/No |
| 3. Neuro-Surgeon | Yes/No |
| 4. Urologist | Yes/No |
| 5. G.I. Surgeon | Yes/No |
| 6. Paediatrician | Yes/No |
| 7. Physiotherapist | Yes/No |
| 8. Social Worker | Yes/No |
| 9. Immunologists | Yes/No |
| 10. Cardiologist | Yes/No |

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Draft/Cheque of Rs. 1.000/- is being enclosed.

Head of the Institution

FORM 12**CERTIFICATE OF REGISTRATION**

This is to certify that.....Hospital located at has been inspected by the Appropriate Authority and certificate of registration is granted for performing the organ transplantation of the following organs:—

1.
2.
3.
4.

This certificate of registration is valid for a period of five years from the date of issue.

Signature

Signature

FORM 13

[See sub-rule 8(2)]

OFFICE OF THE APPROPRIATE AUTHORITY

This is with reference to the application, dated from (Name of the hospital) for renewal of certificate of registration for performing organ transplantation, under the Act.

After having considered the facilities and standards of the above said hospital, the Appropriate Authority hereby renews the certificate of registration of the said hospital for the purpose of performing organ transplantation for a period of five years.

Appropriate Authority

Place

Date