

THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

ACT NO. 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 in 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; 2 BE it enacted by Parliament in the Forty-fifth Year of the Republic of India as follows:-

CHAP PRELIMINARY CHAPTER I PRELIMINARY

Short title, application and commencement.

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 [date] 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.

Definition. 2. Definition.- 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; (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 cardiopulmonary 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 subsection (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; 3 (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 hcost 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 recognized medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 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.

CHAP AUTHORITY FOR THE REMOVAL OF HUMAN ORGANS CHAPTER II AUTHORITY FOR THE REMOVAL OF HUMAN ORGANS

Authority for 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.

Removal of human organs not to be authorised in certain cases.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.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).

Authority for removal of human organs from bodies sent for postmortem examination for medicolegal or pathological purposes. 6. Authority for removal of human organs from bodies sent for postmortem examination for medicolegal or pathological purposes.- Where the body of a person has been sent for postmortem 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 postmortem 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.

Preservation of human organs.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.

Savings.

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).

Restrictions on removal and transplantation of human organs.

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. CHAP REGULATION OF HOSPITALS CHAPTER III REGULATION OF HOSPITALS

Regulation of hospitals conducting the removal, storage or transplantation of human organs.

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. 7

(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.

Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purposes. 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.

Explaining effects, etc., to donor and recipient. 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.

CHAP APPROPRIATE AUTHORITY CHAPTER IV APPROPRIATE AUTHORITY

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 subsection (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. 8 CHAP REGISTRATION OF HOSPITALS CHAPTER V

REGISTRATION OF HOSPITALS

Registration of hospital engaged in removal, storage or transplantation of human organs.

14. Registration of hospital 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.

Certificate of registration.

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 requirement, 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.

Suspension or cancellation of registration.

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: 9 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.

Appeals. 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. CHAP OFFENCES AND PENALTIES CHAPTER VI OFFENCES AND PENALTIES

Punishment for removal of human organ without authority.

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.

Punishment for commercial dealings in human organs. 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.

Punishment for contravention of any other provision of this Act. 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.

Offences by companies.

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.

Cognizance of offence.

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. CHAP MISCELLANEOUS CHAPTER VII MISCELLANEOUS

Protection of action taken in good faith.

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.

Power to make rules.

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 incharge of the management or control of the hospital or prison, under sub-section (1) of section 5; 12 (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 he 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. 13

Repeal and savings.

25.Repeal and savings.- (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.

K. L. MOHANPURIA, Secy. to the Govt. of India.
