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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the 28th September, 2011/*Asvina* 6, 1933 (*Saka*)

The following Act of Parliament received the assent of the President on the 27th September, 2011, and is hereby published for general information:—

THE TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT) ACT, 2011

(No. 16 OF 2011)

[27*th September,* 2011.]

An Act to amend the Transplantation of Human Organs Act, 1994.

WHEREAS it is expedient to amend the said law enacted by Parliament relating to regulation of removal, storage and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs;

AND WHEREAS Parliament has no power to make or amend 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 West Bengal to the effect that the aforesaid Act should be amended by Parliament;

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

1. (*1*) This Act may be called the Transplantation of Human Organs (Amendment) Act, 2011. Short title, application and commencement.

(*2*) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and West Bengal 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 West Bengal 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.

Amendment of long title.

2. In the Transplantation of Human Organs Act, 1994 (hereinafter referred to as the principal Act), in the long title, for the words "human organs for therapeutic purposes and for the prevention of commercial dealings in human organs", the words "human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues" shall be substituted. 42 of 19

Amendment of section 1.

3. In section 1 of the principal Act, in sub-section (*1*), for the words "Human Organs", the words "Human Organs and Tissues" shall be substituted.

Substitution of references to certain expressions by certain other expressions.

4. Throughout the principal Act [except clause (*h*) of section 2, sub-section (*5*) of section 9, sub-section (*1*) of section 18 and section 19], unless otherwise expressly provided, for the words "human organ" and "human organs", wherever they occur, the words "human organ or tissue or both" and "human organs or tissues or both" shall respectively be substituted with such consequential amendments as the rules of grammar may require.

Amendment of section 2.

5. In section 2 of the principal Act,—

(*a*) after clause (*h*), the following clauses shall be inserted, namely:—

'(*ha*) "Human Organ Retrieval Centre" means a hospital,—

(*i*) which has adequate facilities for treating seriously ill patients who can be potential donors of organs in the event of death; and

(*ii*) which is registered under sub-section (*1*) of section 14 for retrieval of human organs;

(*hb*) "minor" means a person who has not completed the age of eighteen years;';

(*b*) for clause (*i*), the following clause shall be substituted, namely:—

'(*i*) "near relative" means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter;';

(*c*) in clause (*o*), the word "and" shall be omitted;

(*d*) after clause (*o*), the following clauses shall be inserted, namely:—

'(*oa*) "tissue" means a group of cells, except blood, performing a particular function in the human body;

(*ob*) "Tissue Bank" means a facility registered under section 14A for carrying out any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues, but does not include a Blood Bank;';

(*e*) after clause (*p*), the following clause shall be inserted, namely:—

'(*q*) "transplant co-ordinator" means a person appointed by the hospital for co-ordinating all matters relating to removal or transplantation of human organs or tissues or both and for assisting the authority for removal of human organs in accordance with the provisions of section 3.'.

Amendment of section 3.

6. In section 3 of the principal Act,—

(*a*) after sub-section (*1*), the following sub-sections shall be inserted, namely:—

"(*1A*) For the purpose of removal, storage or transplantation of such human organs or tissues or both, as may be prescribed, it shall be the duty of the registered medical practitioner working in a hospital, in consultation with transplant co-ordinator, if such transplant co-ordinator is available,—

(*i*) to ascertain from the person admitted to the Intensive Care Unit or from his near relative that such person had authorised at any time before his death the removal of any human organ or tissue or both of his body under sub-section (*2*), then the hospital shall proceed to obtain the documentation for such authorisation in such manner as may be prescribed;

(*ii*) where no such authority as referred to in sub-section (*2*) was made by such person, to make aware in such manner as may be prescribed to that person or near relative for option to authorise or decline for donation of human organs or tissues or both;

(*iii*) to require the hospital to inform in writing to the Human Organ Retrieval Centre for removal, storage or transplantation of human organs or tissues or both, of the donor identified in clauses (*i*) and (*ii*) in such manner as may be prescribed.

(*1B*) The duties mentioned under clauses (*i*) to (*iii*) of sub-section (*1A*) from such date, as may be prescribed, shall also apply in the case of registered medical practitioner working in an Intensive Care Unit in a hospital which is not registered under this Act for the purpose of removal, storage or transplantation of human organs or tissues or both.";

(*b*) in sub-section (*4*), the following proviso shall be inserted, namely:—

"Provided that a technician possessing such qualifications and experience, as may be prescribed, may enucleate a cornea.";

(*c*) in sub-section (*6*), in clause (*iii*),—

(*i*) the word "and" shall be omitted; and

(*ii*) the following proviso shall be inserted, namely:—

"Provided that where a neurologist or a neurosurgeon is not available, the registered medical practitioner may nominate an independent registered medical practitioner, being a surgeon or a physician and an anaesthetist or intensivist subject to the condition that they are not members of the transplantation team for the concerned recipient and to such conditions as may be prescribed;".

Amendment of section 9.

7. In section 9 of the principal Act,—

(*a*) after sub-section (*1*), the following sub-sections shall be inserted, namely:—

'(*1A*) Where the donor or the recepient being near relative is a foreign national, prior approval of the Authorisation Committee shall be required before removing or transplanting human organ or tissue or both:

Provided that the Authorisation Committee shall not approve such removal or transplantation if the recipient is a foreign national and the donor is an Indian national unless they are near relatives.

(*1B*) No human organs or tissues or both shall be removed from the body of a minor before his death for the purpose of transplanation except in the manner as may be prescribed.

(*1C*) No human organs or tissues or both shall be removed from the body of a mentally challenged person before his death for the purpose of transplantation.

Explanation.— For the purpose of this sub-section,—

(*i*) the expression "mentally challenged person" includes a person with mental illness or mental retardation, as the case may be;

(*ii*) the expression "mental illness" includes dementia, schizophrenia and such other mental condition that makes a person intellectually disabled;

(*iii*) the expression "mental retardation" shall have the same meaning as assigned to it in clause (*r*) of section 2 of the Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995.'; 1 of 1996.

(*b*) after sub-section (*3*), the following sub-section shall be inserted, namely:—

"(*3A*) Notwithstanding anything contained in sub-section (*3*), where—

(*a*) any donor has agreed to make a donation of his human organ or tissue or both before his death to a recipient, who is his near relative, but such donor is not compatible biologically as a donor for the recipient; and

(*b*) the second donor has agreed to make a donation of his human organ or tissue or both before his death to such recipient, who is his near relative, but such donor is not compatible biologically as a donor for such recipient; then

(*c*) the first donor who is compatible biologically as a donor for the second recipient and the second donor is compatible biologically as a donor of a human organ or tissue or both for the first recipient and both donors and both recipients in the aforesaid group of donor and recipient have entered into a single agreement to donate and receive such human organ or tissue or both according to such biological compatibility in the group,

the removal and transplantation of the human organ or tissue or both, as per the agreement referred to above, shall not be done without prior approval of the Authorisation Committee.";

(*c*) for sub-section (*4*), the following sub-section shall be substituted, namely:—

"(*4*) (*a*) The composition of the Authorisation Committees shall be such as may be prescribed by the Central Government from time to time.

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

Amendment of section 10.

8. In section 10 of the principal Act, in sub-section (*1*),—

(*a*) in clause (*b*), the word "and" occurring at the end shall be omitted;

(*b*) in clause (*c*), the word "and" shall be inserted at the end;

(*c*) after clause (*c*), the following clause shall be inserted, namely:—

"(*d*) no Tissue Bank, unless registered under this Act, shall carry out any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues.".

Amendment of section 13.

9. In section 13 of the principal Act, in sub-section (*3*),—

(*a*) for clause (*iii*), the following clause shall be substituted, namely:—

"(*iii*) to enforce such standards, as may be prescribed,—

(*A*) for hospitals engaged in the removal, storage or transplantation of any human organ;

(*B*) for Tissue Banks engaged in recovery, screening, testing, processing, storage and distribution of tissues;";

(*b*) after clause (*iv*), the following clause shall be inserted, namely:—

"(*iva*) to inspect Tissue Banks periodically;".

Insertion of new sections 13A, 13B, 13C and 13D.

10. After section 13 of the principal Act, the following sections shall be inserted, namely:—

Advisory Committees to advise Appropriate Authority.

"13A. (*1*) The Central Government and the State Governments, as the case may be, by notification, shall constitute an Advisory Committee for a period of two years to aid and advise the Appropriate Authority to discharge its functions.

(*2*) The Advisory Committee shall consist of—

(*a*) one administrative expert not below the rank of Secretary to the State Government, to be nominated as Chairperson of the Advisory Committee;

(*b*) two medical experts having such qualifications as may be prescribed;

(*c*) one officer not below the rank of a Joint Director to represent the Ministry or Department of Health and Family Welfare, to be designated as Member-Secretary;

(*d*) two eminent social workers of high social standing and integrity, one of whom shall be from amongst representatives of women's organisation;

(*e*) one legal expert who has held the position of an Additional District Judge or equivalent;

(*f*) one person to represent non-governmental organisations or associations which are working in the field of organ or tissue donations or human rights;

(*g*) one specialist in the field of human organ transplantation, provided he is not a member of the transplantation team.

(*3*) The terms and conditions for appointment to the Advisory Committee shall be such as may be prescribed by the Central Government.

Powers of Appropriate Authority.

of 1908.

13B. The Appropriate Authority shall for the purposes of this Act have all the powers of a civil court trying a suit under the Code of Civil Procedure, 1908 and, in particular, in respect of the following matters, namely:—

(*a*) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;

(*b*) discovery and production of any document or material object;

(*c*) issuing search warrant for any place suspected to be indulging in unauthorised removal, procurement or transplantation of human organs or tissues or both; and

(*d*) any other matter which may be prescribed.

National Human Organs and Tissues Removal and Storage Network.

13C. The Central Government may, by notification, establish a National Human Organs and Tissues Removal and Storage Network at one or more places and Regional Network in such manner and to perform such functions, as may be prescribed.

National registry.

13D. The Central Government shall maintain a national registry of the donors and recipients of human organs and tissues and such registry shall have such information as may be prescribed to an ongoing evaluation of the scientific and clinical status of human organs and tissues.".

Amendment of section 14.

11. In section 14 of the principal Act,—

(*a*) in sub-section (*1*), for the words "No hospital", the words "No hospital (including Human Organ Retrieval Centre)" shall be substituted;

(*b*) after sub-section (*3*), the following sub-section shall be inserted, namely:—

"(*4*) No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant co-ordinator having such qualifications and experience as may be prescribed.".

Insertion of new section 14A.

12. After section 14 of the principal Act, the following section shall be inserted, namely:—

Registration of Tissue Bank.

"14A. (*1*) No Tissue Bank shall, after the commencement of the Transplantation of Human Organs (Amendment) Act, 2011, commence any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues unless it is duly registered under this Act:

Provided that any facility engaged, either partly or exclusively, in any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues immediately before the commencement of the Transplantation of Human Organs (Amendment) Act, 2011, shall apply for registration as Tissue Bank within sixty days from the date of such commencement:

Provided further that such facility shall cease to engage in any such activity on the expiry of three months from the date of commencement of the Transplantation of Human Organs (Amendment) Act, 2011, unless such Tissue Bank 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 Tissue Bank shall be registered under this Act unless the Appropriate authority is satisfied that such Tissue Bank 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.".

Amendment of section 15.

13. In section 15 of the principal Act, in sub-section (*1*), for the words "grant to the hospital", the words "grant to the hospital or to the Tissue Bank, as the case may be," shall be inserted.

Amendment of section 16.

14. In section 16 of the principal Act, for the word "hospital", wherever it occurs, the words "hospital or Tissue Bank, as the case may be," shall be substituted.

Amendment of section 17.

15. In section 17 of the principal Act, after the words, brackets and figure "under sub-section (*6*) of section 9, or any hospital", the words "or Tissue Bank, as the case may be," shall be inserted.

Amendment of section 18.

16. In section 18 of the principal Act,—

(*a*) in sub-section (*1*), for the words "five years and with fine which may extend to ten thousand rupees", the words "ten years and with fine which may extend to twenty lakh rupees" shall be substituted;

(*b*) in sub-section (*2*), for the words "two years", the words "three years" shall be substituted.

(*c*) after sub-section (*2*), the following sub-section shall be inserted, namely:—

"(*3*) Any person who renders his services to or at any hospital and who conducts, or associates with or helps in any manner in the removal of human tissues without authority, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees.".

Amendment of section 19.

17. In section 19 of the principal Act,—

(*a*) after clause (*f*), the following clause shall be inserted, namely:—

"(*g*) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human organs, as a near relative or by reason of affection or attachment towards the recipient.";

(*b*) for the words "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", the words "five years but which may extend to ten years and shall be liable to fine which shall not be less than twenty lakh rupees but may extend to one crore rupees" shall be substituted;

(*c*) the proviso shall be omitted.

Insertion of new section 19A.

18. After section 19 of the principal Act, the following section shall be inserted, namely:—

Punishment for illegal dealings in human tissues.

"19A. Whoever—

(*a*) makes or receives any payment for the supply of, or for an offer to supply, any human tissue; or

(*b*) seeks to find person willing to supply for payment and human tissue; or

(*c*) offers to supply any human tissue for payment; or

(*d*) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human tissue; or

(*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—

(*i*) inviting persons to supply for payment of any human tissue; or

(*ii*) offering to supply any human tissue for payment; or

(*iii*) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (*d*); or

(*g*) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human tissues as a near relative or by reason of affection or attachment towards the recipient,

shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and shall be liable to fine which shall not be less than five lakh rupees but which may extend to twenty-five lakh rupees.".

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Amendment of section 20.

19. In section 20 of the principal Act, for the words "three years or with fine which may extend to five thousand rupees", the words "five years or with fine which may extend to twenty lakh rupees" shall be substituted.

Amendment of section 24.

20. In section 24 of the principal Act, in sub-section (*2*),—

(*a*) after clause (*a*), the following clauses shall be inserted, namely:—

"(*aa*) the human organs or tissues or both in respect of which duty is cast on registered medical practitioner, the manner of obtaining documentation for authorisation under clause (*i*) of sub-section (*1A*) of section 3;

(*ab*) the manner of making the donor or his relative aware under clause (*ii*) of sub-section (*1A*) of section 3;

(*ac*) the manner of informing the Human Organ Retrieval Centre under clause (*iii*) of sub-section (*1A*) of section 3;

(*ad*) the date from which duties mentioned in sub-section (*1A*) are applicable to registered medical practitioner working in a unregistered hospital under sub-section (*1B*) of section 3;

(*ae*) the qualifications and experience of a technician under the proviso to sub-section (*4*) of section 3;";

(*b*) after clause (*b*), the following clause shall be inserted, namely:—

"(*ba*) the conditions for nomination of a surgeon or a physician and an anaesthetist or intensivist to be included in the Board of medical experts under the proviso to clause (*iii*) of sub-section (*6*) of section 3;";

(*c*) after clause (*e*), the following clauses shall be inserted, namely:—

"(*ea*) the manner of removal of human organs or tissues or both from the body of a minor before his death for transplantation under sub-section (*1B*) of section 9;

(*eb*) the composition of the Authorisation Committees under sub-section (*4*) of section 9;";

(*d*) after clause (*i*), the following clauses shall be inserted, namely:—

"(*ia*) the qualifications of medical experts and the terms and conditions for appointment to Advisory Committee under sub-sections (*2*) and (*3*) of section 13A;

(*ib*) the power of the Appropriate Authority in any other matter under clause (*d*) of section 13B;

(*ic*) the manner of establishment of a National Human Organs and Tissues Removal and Storage Network and Regional Network and functions to be performed by them under section 13C;

(*id*) the information in the national registry of the donors and recipients of human organs and tissues and all information under section 13D;";

(*e*) after clause (*k*), the following clauses shall be inserted, namely:—

"(*ka*) the qualifications and experience of a transplant co-ordinator under sub-section (*4*) of section 14;

(*kb*) 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 14A;

(*kc*) 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 Tissue Bank, under sub-section (*3*) of section 14A;";

(*f*) in clause (*l*), for the word "hospital", the words "hospital or Tissue Bank" shall be substituted.

V. K. BHASIN,
Secy. to the Govt. of India.

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