

No. S-12011/15/2008-MG II/MS
GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
313, 'D' Wing, Nirman Bhawan, New Delhi - 110108
Email: soms-mohfw@nic.in, ☎: 011-23061313

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Dated 27.04.09

To

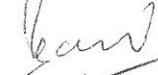
Secretary (Health & FW),
Department of Health & Family Welfare,
Government of Bihar,
Secretariat, Patna - 800 001.,
Bihar

Subject:- Transplantation of Human Organs Rules, 1995- Amendment regarding.

Sir,

I am directed to inform you that THO Rules, 1995 have been amended and notified. An amended copy of THO Rules, 1995, (as amended vide notification dated 31st July, 2008, and published in the extraordinary gazette of India part II- section 3- sub section (I) dated 4th August, 2008) is enclosed for information and further necessary action. A copy of the same is also available on the Ministry's website i.e. www.mohfw.nic.in.

Yours faithfully


(Jai Prakash)

Under Secretary to the Government of India

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TRANSPLANTATION OF HUMAN ORGANS RULES, 1995, AS AMENDED VIDE NOTIFICATION DATED 31ST JULY, 2008, (PUBLISHED IN THE EXTRAORDINARY GAZETTE OF INDIA PART II – SECTION 3 – SUB-SECTION (i) DATED 4TH AUGUST, 2008

[Original notification was published in the Gazette of India Extraordinary Part II – Section 3 – Sub-Section (i) vide G. S. R. 51 (E) dated the 4th February, 1995

First amendment notified and published in the Gazette of India Extraordinary Part II – Section 3 – Sub-Section (i) vide G. S. R. 571 (E) dated the 4th August, 2008]

MINISTRY OF HEALTH AND FAMILY WELFARE

G.S.R. 51(E)-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 here by 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;
- ¹(d) "National Accreditation Board for Laboratories" (NABL) means a Board set up by the Quality Council of India (set up by the Government of India) for undertaking assessment and accreditation of testing and calibration of laboratories in accordance with the international standard ISO / IEC 17025 and ISO 15189;
- ²(e) the Registered Medical Practitioner, as defined in clause (n) of section 2 of Transplantation of Human Organs Act, 1994 includes an allopathic doctor with MBBS or equivalent degree under the Medical Council of India Act.

¹ Inserted vide Gazette notification dated 04.08.2008

² Inserted vide Gazette notification dated 04.08.2008

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³(f) words and expression 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 authorize 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 ⁴Form 1(A), 1(B) and 1(C).

4. DUTIES OF THE MEDICAL PRACTITIONER

⁵(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 authorization in appropriate Form 1(A) or 1(B) or 1(C).
 - (b) that the donor is in proper state of health and is fit to donate the organ, and the registered medical practitioner shall sign a certificate as specified in Form 2.
 - (c) that the donor is a near relative of the recipient, as certified in Form 3, who has signed Form 1(A) or 1(B) as applicable to the donor and that the donor has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority and that the necessary documents as prescribed and medical tests, if required, to determine the factum of near relationship, have been examined to the satisfaction of the Registered Medical Practitioner i.e. Incharge of transplant centre.
 - (d) that in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 1(B) and has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority under provisions of sub-rule(2) of rule 4A.
 - (e) In case of a donor who is other than a near relative and has signed Form 1(C) and submitted an application in Form 10 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained.
- (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 witness (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

³ Re-numbered as clause (f) vide Gazette notification dated 04.08.2008, of the earlier clause (d)

⁴ Amended vide Gazette notification dated 04.08.2008

⁵ Substituted vide Gazette notification dated 04.08.2008

