

Legislative Brief

The Transplantation of Human Organs (Amendment) Bill, 2009

The Bill was introduced in the Lok Sabha on December 18, 2009 by the Ministry of Health and Family Welfare. The Bill was referred to the Standing Committee on Health and Family Welfare (Chairperson: Shri Amar Singh) on Jan 25, 2010. The committee is scheduled to submit its report within three months.

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Highlights of the Bill

- ◆ The Bill amends the Transplantation of Human Organs Act, 1994, which regulates removal, storage and transplantation of human organs.
- ◆ In addition to human organs, the Bill seeks to regulate transplantation of tissues of the human body.
- ◆ The Act permits donations from living persons who are near relatives. The Bill expands the definition of “near relative” to include grandparents and grandchildren in addition to parents, children, brother, sister and spouse.
- ◆ The doctor in an Intensive Care Unit has to inform the patient or relatives of patient about the option of organ donation and ascertain whether they would consent to the donation.
- ◆ A pair of donor and recipient who are near relatives but whose organs do not medically match for transplantation are permitted by the Bill to swap organs with another pair of such persons.
- ◆ The Bill enhances the penalty for unauthorised removal of human organs and for receiving or making payment for human organs.

Key Issues and Analysis

- ◆ The Bill seeks to strengthen provisions to curb commercial trade in human organs while facilitating organ transplantation for needy patients. It is not clear how effective the above measures would be in curbing such commercial trade.
- ◆ Both the donor and recipient shall be penalised if convicted of commercial trade in human organs. Penalising donors who may be forced to sell organs due to financial need may deter them from complaining against commercial trade.
- ◆ Organ donation from a person who is not a “near relative” requires permission of the State Authorisation Committee. It is not clear which State Authorisation Committee shall have jurisdiction if the donor and recipient belong to different states.
- ◆ The Bill provides for establishment of Advisory Committees but does not list its functions.

PART A: HIGHLIGHTS OF THE BILL¹

Context

In India, the availability of medical transplants is lower than the requirement. For example, an estimated 1.5 lakh people are diagnosed with kidney failure every year while about 2,000 to 4,000 transplants are carried out every year.² Also, most donations occur in a few states such as Tamil Nadu, Andhra Pradesh, Gujarat, Maharashtra and Delhi.³

The Transplantation of Human Organs Act, 1994 regulates the removal, storage and transplantation of human organs for therapeutic purposes and prohibits commercial trade in human organs. The Act was initiated at the request of Maharashtra, Himachal Pradesh and Goa and was subsequently adopted by all states except Andhra Pradesh and Jammu and Kashmir, which enacted their own laws.⁴

Despite a regulatory framework, cases of commercial dealings in human organs were reported in the media.⁵ In 2004, the Delhi High Court issued orders to constitute a committee to review the efficacy, relevance and impact of the legal provisions contained in the 1994 Act.⁶ The committee submitted its report on May 25, 2005.⁷

Taking into consideration this report and the Draft Guiding Principles of Organ Transplantation of the World Health Organisation, the Transplantation of Human Organs (Amendment) Bill, 2009 was introduced.

Key Features

- The Bill shall be applicable to Goa, Himachal Pradesh and West Bengal and all the Union Territories. Other states may adopt the amendment by passing a resolution in the state legislatures.
- The 1994 Act allows transplantation of human organs from living donors and cadavers (dead bodies). A living donor is classified as either a near relative or a non-related donor. A near-relative needs permission of the doctor in-charge of the transplant centre to donate his organ. A non-related donor needs permission of an Authorisation Committee established by the state to donate his organs. Additional Authorisation Committees may be formed in hospitals in metros and big cities where more than 25 transplants take place in a year.⁸ Any commercial trade in human organs is prohibited.
- The Act defines a “deceased person” as anyone who has no sign of life due to brain-stem death or in a cardio-pulmonary sense. It also defines “brain-stem death”. The Act stipulates that organs can be removed from cadavers only if the person or his near relative has authorised such removal.
- The 2009 Bill: (a) includes donation of tissues; (b) makes it mandatory for a doctor in an Intensive Care Unit (ICU) to ascertain if a patient wants to donate organs; (c) allows organ swapping; and (d) enhances penalties.

Table 1: Comparison of the 1994 Act with the key amendments in the Bill

	Transplantation of Human Organs Act, 1994	Transplantation of Human Organs (Amendment) Bill, 2009
Scope	Regulates removal, storage and transplantation of human organs.	Regulates removal, storage and transplantation of human organs <i>and tissues</i> .
Definition	“Near relative” means spouse, son, daughter, father, mother, brother, sister. “Tissue” and “Transplant Coordinator” not defined.	Adds grandparents and grandchildren. “Tissue” means a group of cells except blood performing a particular function in the human body. “Transplant coordinator” means a person of the hospital appointed for coordinating matters related to transplantation.
Removal of organs from deceased person	A donor may authorise removal of organs before his death for therapeutic purposes. If no such authorisation was given but no objection was expressed, the person who has legal possession of the body may authorise such removal unless he believes the near relatives of the deceased may object. Brain stem death has to be certified by a board of medical experts consisting of various medical experts.	Adds the provision that a doctor shall ask the patient or relative of every person admitted to the ICU whether any prior authorisation had been made. If not, the patient or his near relative should be made aware of the option to authorise such donation. Adds that if a neurologist or neurosurgeon is not available to be on the board, the doctor in-charge of the hospital may nominate an independent doctor who is a surgeon or a physician and an anaesthetist or intensivist not on the transplant team.

Live donation	The central government has the power to constitute Authorisation Committees for Union Territories.	Authorisation Committees shall be constituted by the state governments and Union Territories. Their composition shall be prescribed by the central government.
	A near relative is permitted to donate his organ without approval of the Authorisation Committee. Any live donation to a non near-relative for reason of affection needs the approval of the Authorisation Committee.	Adds that if the donor or recipient is a foreign national, prior approval of the Authorisation Committee is required. Prohibits removal of organs or tissues from a minor before his death except in a manner to be prescribed.
Organ swapping	No provision	A pair of donor and recipient who are near relatives but whose organs do not medically match for transplantation are permitted to swap with another pair of such persons. The agreement between the two sets has to be approved by the Authorisation Committee.
Powers of Appropriate Authority	The central and state governments shall appoint appropriate authorities in the Union Territories and states to grant or cancel registration of hospitals, enforce standards for these hospitals, investigate complaints of violations and inspect hospitals.	Adds the provision that appropriate authorities shall have the powers of the civil court for summoning any person, producing documents and issuing search warrants.
Advisory Committee	No provision	The central and state governments shall provide for constitution of Advisory Committee for a period of two years to aid and advise the appropriate authority.
Other provisions	No provision	The central govt may establish a National Human Organs and Tissues Removal and Storage Network at any place. Rs 5 crore has been allocated in the Financial Memorandum. The central government shall maintain a registry of the donors and recipients of human organs and tissues.
	No provision	Non-governmental organisations, registered societies and trusts working in the field of organ or tissue removal, storage or transplantation shall apply for registration in the prescribed manner.
Penalties	Penalty for removal of organ without authority is imprisonment for a maximum of five years and a fine of upto Rs 10,000.	Increases penalty to imprisonment for a maximum of ten years and a fine of upto Rs 5 lakh.
	Penalty for making or receiving payment for supplying human organs is imprisonment for 2-7 years and a fine between Rs 10,000 and 20,000.	Increases penalty to imprisonment for 5-10 years and a fine between Rs 5 and 20 lakh. Adds offence of abetting in submission of false documents to prove that donor is a near relative or donating for affection.
	Penalty for contravening any other provisions is imprisonment for a maximum term of 3 years or with fine of upto Rs 5,000.	Increases penalty to imprisonment for a maximum of 5 years or with fine of upto Rs 5 lakh.

Source: The Transplantation of Human Organs Act, 1994, 2009 Bill and PRS.

PART B: KEY ISSUES AND ANALYSIS

Curb on commercial trade in human organs

Adequacy of regulatory framework

Statement of Objects and Reasons

The key objectives of the 1994 Act are to facilitate organ transplantation of needy patients while preventing commercial exploitation of vulnerable people. The Statement of Objects and Reasons of the 2009 Bill states that despite the regulatory framework put in place by the 1994 Act, “there has been a spate of reports in the print and electronic media about thriving human organ trade in India and the consequential exploitation of economically weaker sections of the society.” Furthermore, the conviction rate under the Act is very poor.

Also, the World Health Organisation has expressed fears that shortage of organs may lead to commercial transactions, and has laid down some guiding principles. These include a ban on commercial transactions, and a recommendation that the donor be genetically related to the recipient (except in some cases such as bone marrow transplant).⁹ On the other hand, there is a school of thought that argues against banning commercial trade in face of acute shortage claiming that it only drives the trade underground. They argue in favour of regulated trade with provision for screening, counselling, reliable payment and financial advice.¹⁰

Since the 1994 Act was not able to curb commercial trade, the Bill seeks to achieve this objective while facilitating genuine cases of organ donation. The amendments in the Bill include enhancing penalties for commercial trade, allowing organ swapping and making it mandatory for a doctor in the ICU to ask every patient or his near relative if he is willing to donate his body in case of death. It is not clear if these measures adequately address the factors that lead to commercialization and low levels of conviction.

Recommendations of the Committee to review the 1994 Act

Clause 2(i) The Rules under the 1994 Act state that it is the responsibility of the doctor (in-charge of transplant centre) to ascertain whether a donor is a “near relative” of the recipient. A Review Committee set up to review the Transplantation of Human Organs Act pointed out that there were several instances where the donors were projected to be “near relative” in order to avoid scrutiny. Therefore, the Review Committee recommended that instead of placing the responsibility of certifying a donor as “near relative” on a doctor, the Authorisation Committees should certify a “near relative” keeping in mind the larger objective of ruling out commercial considerations. This recommendation has not been implemented in the Bill.

Some of the other recommendations of the Review Committee to curb trade and increase donations are not included in the Bill: (a) incentives should be given to family of cadaver donor; (b) live donors should get benefits such as life long follow up care where donation took place, and customised Life Insurance Policy; and (c) constitute a fund to promote cadaver organ donation.

Penalties

Clause 19 The Bill increases the penalty for commercial dealings in human organs. The penalty provision in the Act is applicable to both donors and recipients if they are convicted of commercial trade. It is not clear if increasing penalty provision would curb commercial dealings given the low rate of conviction. Also, having penalty for donors who may be forced to sell organs due to financial need may deter them from complaining against commercial trade.¹¹

Jurisdiction of Authorisation Committees

Clause 9(4)(a) All organ donations between non-relatives require the permission of the Authorisation Committee established by the state government. It is not clear in the Bill which State Authorisation Committee shall have jurisdiction under certain circumstances. These include (a) the donor and recipient may belong to different states; or (b) one or both of them hail from states which do not have an Authorisation Committee. It is also unclear whether the Authorisation Committee of the state where transplantation is taking place shall retain some jurisdiction (for medical evidence) in case the donor and the recipient belong to other states.

There have been disputes over the jurisdiction of Authorisation Committees. For example, in 2005, a petition was filed in the Supreme Court where both the donor and the recipient belonged to Punjab while the hospital where the transplant was to take place was located in Tamil Nadu. The Supreme Court gave a judgement directing that the Authorisation Committee of Punjab shall examine the donor and the recipient.¹²

Role of Advisory Committees

Clause 13(A) The Bill provides for establishment of Advisory Committees to aid and advise the Appropriate Authority. However, the Bill does not lay down the specific functions of the Advisory Committee nor does it state that the functions shall be laid down in the Rules. The Ministry of Health and Family Welfare mentions in its “Note on Amendments Proposed in the Transplantation of Human Organs Act, 1994” that the Advisory Committee shall “function on a reference to be made by the Appropriate Authority and payment of remuneration shall be on per sitting basis.”² However, the Bill does not specify this provision.

The Advisory Committee will be appointed for a period of two years. It is not clear who would perform this role after this period.

Definition of Human Organ Removal Centre

Clause 3(1A)(iii) Hospitals may register under the Act to remove, store and transplant organs. The Bill makes it mandatory for medical practitioners in all hospitals (regardless of whether they have this registration) to ask all patients in an ICU or their relative whether the patient wants to donate organs.

If a patient in the ICU or his relative agrees to donate his organs or tissues on his death, the Bill requires the medical practitioner to inform the hospital which in turn has to inform the “Human Organ Removal Centre” for

removal, storage and transplantation of human organs or tissues. However, the Bill does not define or specify the composition or functions of the “Human Organ Removal Centre”. Also, the Bill states that Rules shall specify only the manner of informing the “Human Organ Removal Centre”.

Regulation in other countries

The laws in different countries differ in three broad ways: (a) type of consent necessary to transplant organs if a person is dead; (b) type of donors; and (c) whether commercial sale is permitted. Table 2 describes the system and the law in some countries.

Table 2: Regulatory framework in various countries

Law	Regulatory Framework	Deceased donors
India		
Transplantation of Human Organs Act, 1994	Type of consent: Opting in/family consent* Type of donor: Live donation from “near relatives” and un-related donors; Cadaver donor (brain stem death and cardiac death or non heart beating donor); Prohibits sale of human organs.	N.A.
USA		
National Organ Transplantation Act, 1984 Uniform Anatomical Gift Act, 1967	Type of Consent: Opting in/ family consent Type of donor: Live donation through organ swapping; Cadaver donor: (brain death and cardiac death); Prohibits sale of human organs	26.2 (per million of population or pmp)
U.K.		
The Human Tissues Act, 2004 (repeals Human Organ Transplantation Act, 1989 and Anatomy Act, 1984)	Type of Consent: Opting in/ family consent or nominated representative Type of donor: Live donation from genetically or emotionally related donors. Also from paired and altruistic donations. Cadaver donation from brain stem death and non heart beating donors. Prohibits sale of human organs.	14.7 pmp
Spain		
Transplantation Law 1979 and Royal Decree updating law 1999	Type of Consent: Opting out/ Presumed consent† Type of donor: Live donation with voluntary consent from relatives or emotionally related donors. Allows organ swapping. Cadaver donation Prohibits sale of human organs.	34.2 pmp
Austria		
Austrian Hospitals Law 1982	Type of Consent: Opting out/ Presumed consent Type of donor: Allows donation from brain dead cadaver donors, non-heart beating cadaver donors and living donors. Prohibits sale of human organs.	20.1 pmp
Pakistan		
The Transplantation of Human Organs and Tissues Act, 2009	Type of Consent: Opting in/consent of family Type of donor: Live donations from close blood relative and non-close blood relative. Cadaver donations of brain dead patients. Prohibits sale of human organs.	N.A.
Singapore		
Human Organ Transplant Act, 2009 (HOTA) and Medical (Therapy, Education and Research) Act	Type of Consent: Opt out for 4 organs (kidney, liver, heart and cornea); Opt in for any organ or tissue not covered by HOTA. Both donor and his next of kin can pledge organ. Type of donor: Live donations (related and non-related). Cadaver donation (brain death and cardiac death). Prohibits sale of human organs.	NA
Iran		
Organ Transplantation and Brain Death Act, 2000	Type of Consent: Opting in/consent from family Type of donor: Cadaver donation (brain death and cardiac death) Live donation (regulated paid donor system or a monetary gift as a “token of appreciation” by central govt)	2.9 pmp

Sources: The National Organ Transplantation Act, 2008 and The Revised Uniform Anatomical Gift Act, 2006 (USA); Human Tissues Act, 2004 (U.K.); European Transplant Coordinators Organisation <http://www.eurotransplantcoordinators.org/NKMDData/pdf/spain.pdf> (Spain); “Consent System for Post Mortem Organ Donation in Europe,” Sjeff Gevers, Anke Janssen & Roland Friele, European Journal of Health Law, 2004, vol 11, pp 175-186 (Austria); The Transplantation of Human Organs and Tissues Act, 2009 (Pakistan); Human Organ Transplant Act, 2009 and Medical (therapy, Education and Research) Act (see <http://www.moh.gov.sg/mohcorp/legislations.aspx?id=1672>) (Singapore); “Living unrelated kidney donor transplantation in Iran,” Ali Nobakht Haghighi and Nasrollah Ghahramani, Nature Clinical Practice Nephrology, 2006, vol 2, no. 12 (Iran), International Registry of Organ Donation and Transplantation (IRODaT), 2008.

* Consent of patient or family is necessary to remove organs once the patient is dead.

† Consent of patient to donate organs on his death is presumed unless he has specifically opted out.

Notes

1. This Brief has been written on the basis of the Transplantation of Human Organs (Amendment) Bill, 2009, which was introduced in the Lok Sabha on December 18, 2009. The Bill was referred to the Standing Committee on Health and Family Welfare (Chairperson: Shri Amar Singh), which is scheduled to submit its report within three months.
2. Note on the Amendments Proposed in the Transplantation of Human Organs Act, Ministry of Health and Family Welfare, Govt of India (see <http://www.mohfw.nic.in/THOA%20-%20Cabinet%20Note%20Modified.pdf>).
3. "Organ Donation and Transplantation in India: Legal Aspects and Solutions to Help with Shortage of Organs," Sunil Shroff, *Journal of Nephrology and Renal Transplantation*, 2009, vol 2, pp. 23-34.
4. Since "public health" is a State List subject, under Article 252 of the Constitution of India, Parliament may enact a law if legislatures of two or more states pass resolutions empowering the Parliament to enact a law on their behalf. The Act may be applicable only in these states and other states may adopt it by a legislation passed in those states.
5. Illegal trade in human organs, Letter by the Chairperson of National Human Rights Commission to the Prime Minister, January 29, 2004.
6. *Balbir Singh vs the Authorisation Committee and Others* case, WP(C) 813/2004.
7. The Report of Transplantation of Human Organs Act Review Committee, Ministry of Health and Family Welfare, Govt of India, May 25, 2005 (see <http://www.mohfw.nic.in/thoa.htm>).
8. The Transplantation of Human Organs Rules, 1995 (amended in 2008)
9. Draft Guiding Principles on Human Organ Transplantation, World Health Organisation.
10. "The case for allowing kidney sales," Radcliffe-Richards J, Daar AS, Guttman RD, Hoffenberg R, Kennedy I, Lock M, Sells RA, Tilney N for International Forum for Transplant Ethics, *Lancet*, June 27, 1998, vol 351, pp 1950-2; "The case for a regulated system of living kidney sales," Abdullah S. Daar, *Nature Clinical Practice Nephrology*, 2006, vol 2, pp 600-601; Resolutions passed by participants attending International Congress on Ethics in Organ Transplantation, December 10-13, 2002, Munich, Germany (see http://findarticles.com/p/articles/mi_m0YUG/is_1_13/ai_n18615099/).
11. "The Vienna Forum to Fight Trafficking 13-15 Feb 2008," Austria Centre Vienna Background Paper, UNODC (see <http://www.unodc.org/documents/human-trafficking/Marika-Misc/BP011HumanTraffickingfortheRemovalofOrgans.pdf>).
12. *Kuldip Singh & another vs State of Tamil Nadu and others*, Appeal (civil) 156 of 2005, March 31, 2005.

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