



Article Content

Title : Human Organ Transplant Act CH

Amended Date : 2015-07-01

Category : Ministry of Health and Welfare (衛生福利部)

- Article 1 In order to resume patient's organ function or to save lives, this Act is enacted to permit physicians to remove organs either from a corpse or a living person. For those subject matters not stipulated in this Act, other relevant laws shall apply.
- Article 1-1 The competent authorities referred to in this Act are: the Department of Health, Executive Yuan at the central level; and the county (city) government at the county (city) level.
- Article 2 Additional appropriate medical solutions shall be performed in priority before any transplant operations which are based on proven medical knowledge and conform to the development of medical technology in Taiwan can be performed.
- Article 3 The organs referred to in this Act shall include tissues. The scope of transplantable organs, subject to actual needs, shall be designated by the central competent health authority.
- Article 4 When performing a transplant operation by removing an organ from a corpse, the organ donor shall be certified dead by his/her attending physician before the operation can be performed. If the donor is certified as being dead due to brain death, the procedures prescribed by the central competent health authority shall apply.
- Article 5 The physician certifying the death as mentioned in the previous Article shall not be involved in removing an organ or in the transplant operation.
- Article 6 One of the following criteria shall be met before a physician can remove an organ from a corpse:
- (1) The deceased has consented in writing or in a will before death.
 - (2) The deceased's next of kin has consented in writing.
- The consent as mentioned in Item 1 of the previous paragraph shall include the person's written consent in the national health insurance document (the "NHI Card" hereinafter), in the format specified by the central competent authority. The central competent authority shall make a remark on his/her NHI Card once written consent is obtained. The remark shall have the same effect as the original written consent. However, at any time the consenter may withdraw his/her consent in writing and shall request the central competent authority for cancellation of the remark.
- Should the remark on the NHI Card be different from the

expressive organ donation willingness during the clinical treatment process, the later shall prevail.

The medical care institution or the health authority shall scan the written consent mentioned in Item 1 of Paragraph 1 and preserve the electronic file in the central competent authority's database.

The central competent authority shall command the National Health Insurance Administration to take charge. The Administration, the household offices and the motor vehicle supervision offices shall work together and enquire the adults coming forward for applying for or replacing identity card, driver license or NHI Card about their willingness of organ donation. The willingness remark and cancellation procedure shall be done in accordance with the provisions of Paragraphs 2 to 4.

Article 7 No organ shall be removed from the remains of a person who has not died from disease or is suspected not to have died from disease until the corpse has legally undergone a postmortem examination and further examination is deemed unnecessary. However, if the non-disease cause of death is not related to the organ or organs to be removed as determined by the attending physician, the organ/organs may still be removed by the prosecutor's and the next of kin's written consent if completion of the postmortem examination may result in missing the best time for removing the organ/organs.

Article 8 Hospital removing an organ from a living body for a transplant operation shall abide by the following provisions, unless otherwise stipulated in Paragraph 2:

1. The donor should be aged 20 or above, and has sound mental capacity.
2. The donor has presented a written consent under his/her free will, as well as the next of kin's written proof.
3. The donor is confirmed to meet the criteria of donation subject to professional psychological, social, and medical assessments and the approval of the Medical Ethics Committee review.
4. The recipient should be restricted to no more than fifth degree of kinship, or the spouse of the donor.

Adults or married minors aged over 18 years may donate part of their liver organ to relatives no more than fifth degree of kinship; unmarried minors aged over 18 years may donate part of their liver organ to blood relatives of no more than fifth degree of kinship with the written consent of their statutory representative.

The Medical Ethics Committee of a hospital as mentioned in Item 3 of Paragraph 1 shall consist of at least five members, including legal experts and other impartial parties of society, and the external members should account for two third more in the committee; members of either sex should not be less than one third of all committee members. The organization, proceedings, review procedures and scope, principle of recusal, supervision,

and management of the committee, as well as regulations concerning other matters for compliance shall be set down by the central competent authority.

The spouse as mentioned in Item 4 of Paragraph 1 should have children with the donor and have been married to the donor for at least two years. However, the above does not apply to those who are diagnosed as requiring an organ transplant by a physician after being married for one year.

For patients who are unable to meet Item 4 of Paragraph 1 but await kidney transplant, once appropriate lawful donors have been sought and ready, different two pairs of donors/recipients may re-match, exchange, and donate their organs within the scope of the spouse of the recipients and the specified degree of kinship. Transplant operations may be performed without the restriction set by the provision.

The operational procedures of the aforesaid organ re-matching, exchange, and donation, as well as regulations concerning other matters for compliance as stated in the previous paragraph shall be laid down by a dedicated agency as specified in Paragraph 2 of Article 10-1, and be reported to the central competent authority for approval and promulgation.

- Article 8-1 The next of kin stipulated in the previous 3 articles shall include the following:
1. Spouse
 2. Lineal blood descendants
 3. Parents
 4. Siblings
 5. Grandparents
 6. Great grandparents or third-degree collateral blood relatives
 7. First-degree lineal relatives by marriage

The aforesaid next of kin's written consent as specified in Item 2 of Article 6 or in the proviso of Article 7 shall not be in conflict with the deceased's expressed desire before death.

The aforesaid written consent shall be given by one next of kin; in case of disagreement between the next of kin, the priority order as laid down in the items of Paragraph 1 shall be followed. When a person of lower priority has given a written consent, one with higher priority shall express his/her disagreement in writing before the organ is removed.

- Article 9 Before removing an organ from a living body, the physician shall pay attention to the health and safety of the donor, and shall explain the objective, method of implementation, success rate, organ(s) to be taken, process of the operation, and the potential complications and dangers of the operation to the donor and his/her family in a comprehensible way.
- When conducting an organ transplant, the physician shall exercise his/her duty of necessary medical care.
- When regular follow-up examinations are required for the donor after such organ donation, the transplanting hospital or physician shall help arrange the examinations.

Article 10 Hospitals and physicians may only remove organs and perform transplant operations with the central competent authority's approval of their qualifications and only for organs in the categories approved. However, removing corneas for the national cornea bank as established by Paragraph 2 of Article 10-1 may be performed by a eye bank technician.

The requirements on the aforesaid hospitals, qualifications of the physician and the cornea recovery technician, application procedures, deadline for approval, revocation, and regulations concerning other matters for compliance as stated in the previous paragraph shall be determined by the central competent authority.

Hospitals performing organ transplants should report the following details every six months in the manner and format announced by the central competent authority.

1. The categories of organs removed.
2. Basic information about the donors and recipients.
3. Survival status of the recipients.
4. Functional status of the transplanted organs.
5. Names of the physicians or eye bank technicians who removed the organs and performed the transplant operation.
6. Other items specified by the central competent authority.

Patients who have received an organ transplant outside the R.O.C. and are going to receive post-transplant follow-up treatment in a domestic hospital shall provide the hospital with the following information in writing: category of the organ transplanted, name of the country in which they received the transplant, name of the hospital where the transplant took place, and name of the physician who performed the transplant; the hospital may report the case according to the provisions in the previous paragraph.

Article 10-1 Medical care institutions shall report the relevant information about the persons who desire to donate organs and those awaiting organ transplants to the central competent authority; the method of reporting shall be determined by the central competent authority.

The central competent authority shall subsidize the establishment of a dedicated agency to promote organ donation, deal with the allocation of organs, and attend to matters concerning the reports, preservation, and application of items mentioned in the previous paragraph and Paragraphs 3 and 4 of the previous Article. National organ banks may be established when necessary. Regulations concerning the content, criteria, and operating procedures of organ allocation, as well as other matters for compliance shall be laid down by the central competent authority.

The competent authority, medical care institutions, related organizations and groups, and their staff members who come to know the names and relevant information of the persons who desire to donate organs, those awaiting organ transplants, and those who have received organ transplants shall not disclose such information without reason.

To promote the ethos of organ donating, hospitals shall take initiatives to establish a donation soliciting mechanism to ask the family members of potential donors of suitable organs about their desire for organ donation, and hence expand the sources of organ donation.

The central competent authority may subsidize a certain amount of funeral expenses for the family members of deceased donors; the amount of subsidization shall be determined by the central competent authority.

Article 11 Medical care institutions that remove an organ shall include the complete medical record in the donor's records, and shall exercise the necessary duty of medical and customary care. The medical care institution where the organ donor is staying shall provide the donor's transplant-related examination report in writing to the medical care institution where the organ recipient is staying before the transplant operation is performed. The medical care institution where the recipient is staying shall also include the aforesaid report in the recipient's medical record for safekeeping.

Article 12 Any organ for transplantation shall be provided or acquired free of charge.

Article 13 Any organ to be transplanted that is subsequently evaluated unsuitable for transplant shall be handled in a way stipulated by the central competent health authority.

Article 14 A removed organ and its derivatives preserved for transplant shall be kept in an organ bank. The establishment of the organ bank stated in the previous paragraph shall be approved by the central competent authority; the regulations concerning the bank founder's qualifications, conditions, application procedures, required facilities, review and revocation of permit, and other matters for compliance shall be laid down by the central competent authority. Organ banks may charge reasonable fees for keeping an organ; the fees shall be approved by the municipal or county (city) competent authority.

Article 14-1 Organs, tissues, or cells may be imported or exported only with the approval of the central competent health authority. Regulations concerning the application requirements, procedures, and other matters for compliance regarding importing or exporting organs, tissues, or cells in the previous paragraph shall be determined by the central competent health authority.

Article 15 Municipal or county (city) governments may commend the family members of donors who donate organs for transplant, and provide funeral expense subsidies for families in straitened circumstances.

Article 16 Persons who broker organ transplants or the provision and acquisition of organs and are found to be in violation of the provisions in Article 12 shall be subject to imprisonment of at

least one year and up to five years, in addition to a fine between NT\$300,000 and NT\$1,500,000.

R.O.C. nationals committing the aforesaid offence outside R.O.C. territory shall be dealt with according to the provisions in this Act, regardless of whether the offense is punishable or not under the law of the area where the crime is committed.

For medical personnel found to be in serious violation of the provision in Paragraph 1, their professional certificates may be revoked.

In any one of the following circumstances, a fine of between NT\$ 200,000 and \$1,000,000 may be imposed. If the violator is a medical personnel member and the violation is severe, his/her professional certificates may be revoked.

1. Physicians violating the provisions in Paragraph 1 of Article 4, or Article 5.

2. Medical care institutions reporting the information as mentioned in Paragraph 1 of Article 10-1 with fake or fraudulent content.

3. Violating the provision in Paragraph 1, Article 14.

For violations of the provisions in Item 1 or 2 of the previous paragraph, the central competent authority may also revoke the hospital's or physician's credentials for the removal of organs and performing organ transplant operations.

Article 16-1 In any one of the following circumstances, a fine of between NT\$ 60,000 and \$300,000 will be imposed. The imported organs, tissues, or cells shall be sealed immediately, and be returned and shipped out, confiscated, or destroyed on the spot within one month.

1. Import or export of organs, tissues, and cells that without obtaining approval from the central competent authority.

2. Selling, supplying, transporting, storing, brokering, transferring, or displaying for the purpose of selling imported or exported organs, tissues, or cells that have not obtained the approval document from the central competent authority.

Hospitals, physicians, or patients committing any of the following shall be fined between NT\$30,000 and \$150,000:

1. Violating the provision in Paragraph 1 of Article 9.

2. Violating the provision in Paragraph 3 or 4 of Article 10.

3. Violating the organ allocation criteria laid down in Paragraph 2 of Article 10-1 or the provisions in Paragraph 3 of Article 10-1.

4. Violating the provision in Paragraph 2 of Article 11.

5. Violating the provision in Article 13.

Article 17 If a person or hospital meets any one of the following circumstances, a fine of between NT\$120,000 and \$600,000 will be imposed; if the person is a physician, he/she shall be subject to the suspension of practice from one month to one year, or revocation of his/her practice license:

1. Applying for approval for removing an organ or performing an organ transplant operation with fake or fraudulent documents of qualifications or conditions.

2. Violating the provision in Paragraph 1 of Article 10.
3. Violating the regulations concerning matters for compliance regarding hospitals, physicians, and eye bank technicians as provided in Paragraph 2 of Article 10.
4. Violating the regulations concerning the organ allocation content and other matters for compliance laid down in Paragraph 2 of Article 10-1.

The central competent authority may revoke the qualification of a hospital, physician, or eye bank technician to remove organs or perform organ transplant operations if the provision in Item 1, 3, or 4 of the previous paragraph is violated.

- Article 18 In any one of the following circumstances, a fine of between NT\$90,000 and \$450,000 will be imposed:
1. A hospital or physician violating the provisions in Paragraph 1 of Article 6, Article 7, or Article 8.
 2. Disseminating, broadcasting, or publishing organ sales/purchases, other trade or brokerage information in advertisements, publications, on radio, TV, via electronic signals, computer networks or other media.
- The same applies to media operators who violate the provisions in Item 2 of the previous paragraph.

- Article 18-1 In any one of the following circumstances, a fine of between NT\$100,000 and \$500,000 will be imposed, with an order to improve the circumstance or return the collected fee by a specified date; if no improvement or refund is made by the specified date, consecutive fines may be given, and the permit may be revoked for severe violations:
1. Violating the provisions concerning the conditions of establishing an organ bank, the required facilities of an organ bank, and other matters for compliance as stated in Paragraph 2 of Article 14.
 2. Violating the provisions on fees, charging excessive fees or making up various titles for charges as stated in Paragraph 3 of Article 14.

- Article 19 Violating the provisions in this Act which involve criminal liability shall be dealt with in accordance with the relevant laws.

- Article 20 Fines specified in this Act shall be borne by the chief physician if it is a non-corporate private hospital.

- Article 21 Fines, suspensions and revocations of the practice licenses stipulated in this Act shall be imposed by the municipal or county (city) competent health authority.

- Article 22 Fines specified in this Act shall be paid by the deadline; otherwise, the case shall be transferred for compulsory execution.

- Article 23 Organ transplant operations as a part of human subject experiments shall be conducted according to the relevant provisions in the Medical Care Act.

Article 24 The enforcement rules of this Act shall be formulated by the central competent health authority.

Article 25 This Act comes into effect on the date of promulgation.

Web site : Laws & Regulations Database of The Republic of China