

Regulations on Human Organ Transplantation of the PRC

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Chapter I — General Provisions

Article 1 — These Regulations are formulated for the purpose of regulating human organ transplantation, safeguarding the health of citizens, and protecting the lawful rights and interests of donors and recipients.

Article 2 — The term "human organ transplantation" as used in these Regulations refers to the medical activity of collecting an organ from a donor and transplanting it into a recipient, including the collection, storage, distribution, and transplantation of the organ. The donation, collection, and transplantation of human organs within the territory of the People's Republic of China shall be governed by these Regulations.

Article 3 — The State shall encourage and support the donation of human organs, and shall protect the lawful rights and interests of organ donors. Any form of trading in human organs shall be prohibited.

Article 4 — The health administrative department of the State Council shall be in charge of the supervision and administration of human organ transplantation throughout the country. The health administrative departments of the local people's governments at or above the county level shall be in charge of the

supervision and administration of human organ transplantation within their respective administrative areas.

Article 5 — Medical institutions engaged in human organ transplantation shall meet the conditions prescribed by the State and shall obtain the corresponding qualifications. Medical institutions without the corresponding qualifications shall not engage in human organ transplantation.

Article 6 — The State shall implement a system of allocation of human organs, and shall distribute human organs in a fair, just, and transparent manner in accordance with the principles of medical need and clinical urgency.

Chapter II — Donation of Human Organs

Article 7 — A citizen may donate his or her organs voluntarily. Organ donation shall be voluntary and free of charge.

Article 8 — A citizen with full capacity for civil conduct may donate his or her organs during his or her lifetime, and shall express his or her willingness to donate in writing, and may revoke the expression of willingness to donate at any time.

Article 9 — A citizen may, in writing, express his or her willingness to donate organs after death. Where a citizen does not object to organ donation during his or her lifetime, after the death of the citizen, his or her spouse, adult children, and parents may jointly decide to donate the organs of the deceased in writing.

Article 10 — No organization or individual may force, deceive, or induce another person to donate organs, and shall not donate organs in a disguised form of trading. Organ donors shall not receive any compensation or remuneration for their donation.

Chapter III — Collection of Human Organs

Article 11 — Medical institutions engaged in the collection of human organs shall meet the conditions prescribed by the State and shall obtain the corresponding qualifications. Medical institutions without the corresponding qualifications shall not collect human organs.

Article 12 — Collection of organs from a living donor shall meet the following conditions: the donor has full capacity for civil conduct; the donor donates voluntarily; the donor is the spouse, a lineal blood relative, or a collateral blood relative within three generations of the recipient, or a person who has formed a special relationship of mutual care with the recipient; and other conditions prescribed by the State.

Article 13 — Collection of organs from a deceased donor shall be carried out only after the death of the donor has been determined by qualified physicians in accordance with the standards and procedures prescribed by the State.

Article 14 — The collection of human organs shall respect the body of the donor, and after collection, the appearance of the body shall be restored in accordance with the relevant provisions.

Article 15 — Physicians who participate in the determination of the death of a donor shall not participate in the collection or transplantation of the organs of the donor.

Chapter IV — Transplantation of Human Organs

Article 16 — Medical institutions engaged in human organ transplantation shall meet the conditions prescribed by the State, including having physicians, equipment, and facilities that conform to the provisions, and shall obtain the corresponding qualifications.

Article 17 — Human organs shall be allocated in accordance with the State's system of organ allocation, and shall not be allocated on the basis of factors unrelated to medical need.

Article 18 — Before performing an organ transplant, a medical institution shall explain the risks and consequences of the transplantation to the recipient and shall obtain the written consent of the recipient or his or her family members.

Article 19 — Medical institutions engaged in human organ transplantation shall establish and preserve complete medical records, and shall keep the information of donors and recipients confidential.

Article 20 — Medical institutions shall not engage in organ transplantation with medical institutions without the corresponding qualifications, and shall not conduct organ transplantation activities that violate the provisions of these Regulations.

Chapter V — Legal Liability

Article 21 — Where a medical institution engages in the collection or transplantation of human organs without obtaining the corresponding qualifications, the health administrative department shall order it to stop the unlawful activity and shall confiscate the unlawful gains, and may impose a fine; where the circumstances are serious, the relevant approval shall be revoked in accordance with law.

Article 22 — Where a unit or individual engages in trading in human organs, the health administrative department shall order it to stop the unlawful activity and shall confiscate the unlawful gains, and may impose a fine; where a crime is constituted, criminal liability shall be investigated in accordance with law.

Article 23 — Where a medical institution or a member of its staff forces, deceives, or induces a person to donate organs, or collects organs in violation of the provisions of these Regulations, the health administrative department shall impose penalties in accordance with law; where a crime is constituted, criminal liability shall be investigated in accordance with law.

Article 24 — Where a medical institution fails to obtain the informed consent of the recipient or fails to keep the information of donors and recipients confidential in accordance with the provisions, the health administrative department shall order it to make corrections and may impose a fine.

Article 25 — Where a staff member of a health administrative department neglects his or her duties, abuses power, or engages in malpractices for personal gain in the supervision and administration of human organ transplantation, sanctions shall be imposed in accordance with law; where a crime is constituted, criminal liability shall be investigated in accordance with law.

Chapter VI — Supplementary Provisions

Article 26 — The transplantation of human tissues, cells, and other materials shall be administered with reference to the provisions of these Regulations.

Article 27 — These Regulations shall come into force as of May 1, 2007.

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