



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. 2010- 0018

JUN 23 2010

SUBJECT: Revised National Policy on Living Non-Related Donation and Transplantation and its Implementing Structure Amending for the Purpose Administrative Order No. 2008-0004-A

I. RATIONALE

Administrative Order 2008-0004-A is hereby amended to articulate the commitment of the Department of Health (DOH) to abide by the rules set forth by the RA 9208 (Anti-Human Trafficking Act), the Declaration of Istanbul on Organ Trafficking and Transplant Tourism and the WHO Guiding Principles on Organ Transplantation by not permitting the Non-directed Living Non-Related Donation (LNRD). Furthermore, the amendments shall include the changes in the nomenclature of National Human Organ Preservation Effort (NHOPE) to Philippine Network for Organ Sharing (PHILNOS) and a clarification of its scope of function. Also included is the transfer of the function of PhilNETDAT to the existing Philippine Organ Donation and Transplantation Program (PODTP) as a result of the abolition of non-directed LNRD and the creation of the PHILNOS.

II. COVERAGE

The following, whether public or private, shall be governed by this Order:

1. Kidney and other organ donors and recipients.
2. All health and health-related professionals and individuals engaged or have any participation in the conduct of transplantation and donation.
3. All Offices/Bureaus, including attached agencies and field offices of the DOH.
4. All health and health-related facilities such as but not limited to hospitals, laboratories.
5. Other government and non-government agencies and organizations, such as but not limited to foundations organized to promote and support transplantation and donation programs and associations such as medical and specialty societies.

III. DEFINITION OF TERMS

1. Living Related Donors (LRDs) - related to the recipient by blood within the fourth-degree of consanguinity (e.g. parents, children, siblings, nephews/nieces, first cousins).
2. Living Non Related Donors (LNRDs) - not related to the recipient by blood but have the willingness and intention to donate a kidney based on certain reasons.

These donors are classified into:

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- a. Voluntary Donors –Those who are not related by blood to the recipient but bear close emotional ties with him/her. (e.g., spouses, relatives by affinity, friends, employers/employees of long standing, colleagues, fiancé /fiancée and adoptive parents or children).
- b. Commercial Donors— Also known as kidney/organ vendors who offer their kidneys and other organs for sale. They usually engage the services of a broker or agent. Payment or a promise of payment is a precondition and pre-requisite to the organ donation.
 - 2.a.1 Directed Kidney/Organ Donor - someone who has a specific recipient in mind whom he would want to donate to. This follows the principle known as donor designation wherein the donor’s wishes are given due consideration.
 - 2.a.2 Non-Directed Kidney/Organ Donor – a donor who would donate to whoever he/she matches on a list of waiting patients for organ transplant.
3. Board – refers to Philippine Board for Organ Donation and Transplantation (PBODT)

IV. GUIDING PRINCIPLES

The Philippine Organ Donation and Transplantation Program (PODTP) shall be guided by these principles:

1. Equity - Non-directed donated organs belong to the community. Such organs must be allocated fairly among transplant centers and among recipients. Determination of priority shall be based on medical need and probability of success.
2. Justice - The criteria to be adopted in determining allocation of organs must be objective and independent of gender, race, creed, culture and socio-economic status.
3. Benevolence - Only organs that are voluntarily donated with full informed consent by a competent adult shall be subject for transplantation. All health and health related facilities shall not allow the trade or commerce of kidneys/organs.
4. Non-maleficence - No harm should occur to the donor or recipient in the process of transplantation whether immediate or post transplantation.
5. Solidarity - All stakeholders shall have a common and shared objective of safeguarding the health of both the recipient and the donor.
6. Altruism - Organ donation must be done first and foremost out of selflessness and philanthropy to save and ensure the quality of life of the beneficiary.
7. Volunteerism - Organ donation must be done out of the donor’s:
 - Competence (decision-making capacity)
 - Willingness to donate
 - Freedom from coercion

- Medical and psychosocial suitability
- Full information of the risks and benefits as a donor
- Full information of the risks, benefits and other alternative treatment available to the recipient

V . GENERAL POLICY STATEMENTS

As the mandated agency to promote and protect the health of the Filipino people, the DOH adopts the following policies in the practice of kidney transplantation from LNRDs. These policies shall cover the transplantation of other organs where applicable.

1. The Department of Health is committed to abide by the WHO Guiding Principles on Organ Transplantation, the Declaration of Istanbul on Organ Trafficking and Transplant Tourism and RA 9208 (Anti-Human Trafficking Act) and its Implementing Rules and Regulations.
2. The safety of both donor and recipient shall be given highest consideration and transparency regarding the risks to both shall be pursued rigorously.
3. Payment as precondition for kidney donation and sale and purchase of kidneys by kidney vendors/commercial donors are strictly prohibited.
4. Kidney transplantation is not part of medical tourism.
5. Foreigners are not eligible to receive organs from Filipino living non-related donors.
6. All health and health –related facilities and professionals shall not allow the trade of kidneys.
7. Directed LNRDs are permitted only when it is voluntary and truly altruistic, without any kind of compensation or gratuity package attached to it. They must be screened and approved by the Hospital Ethics Committee. Non-directed LNRD are not allowed to donate organs for transplantation. No hospital, foundation, organization or agency, public or private, are allowed to keep a list of potential non-directed LNRDs and to utilize non directed LNRD’s for transplantation.
8. All health and health-related facilities shall implement and adopt quality standards and practices in the medical and organizational management of kidney transplantation. The DOH and The Philippine Health Insurance Corporation (PHIC) shall enforce this Administrative Order and monitor these facilities through their licensing and accreditation rules and regulations to ensure accessibility, quality and sustainability of the services.
9. All professional societies related to organ donation and transplantation shall ensure that all their members comply with PODTP guidelines relative to the practice of organ transplantation. The members of professional societies related to this practice shall likewise be accredited by the PHIC for purposes of payment.
10. In no instance shall any kidney/organ be transported or exported for transplantation abroad.

11. A Philippine Board for Organ Donation and Transplantation (PBODT) is hereby created for the purpose of overseeing the implementation of policies related to organ transplantation. The Philippine Organ Donation and Transplantation Program (PODTP) under the Degenerative Disease Office (DDO) of the National Center for Disease Prevention and Control (NCDPC) shall serve as the overall implementing body for organ donation and transplantation in the country. A Philippine Network for Organ Sharing (PHILNOS) is hereby created to serve as the coordinating body in charge of allocating organs from Deceased donors.

VI. OPERATIONAL STRUCTURES (See Annex 1)

1. Philippine Board for Organ Donation and Transplantation (PBODT)

a. Roles and Functions

- i. Review and approve policies in support of a rational, ethical, accessible and equitable organ transplantation program in the country.
- ii. Approve the issuance of the Certificate of Accreditation of transplant facilities.

b. Composition

- i. Secretary of Health, who shall act as the Chairperson
- ii. Undersecretary for Policy and Standard Development Team (PSDT) for Service Delivery – Vice chairperson
- iii. Chairman of National Transplant Ethics Committee (NTEC)
- iv. PHIC Representative designated by the PHIC President
- v. Representative from a government transplant facility designated by the Secretary of Health (DOH)
- vi. Representative from a private transplant facility designated by the private transplant facilities on a rotational basis to a term of 2 years.
- vii. Representative from the professional societies involved in transplantation – Philippine Society of Transplant Surgeon (PSTS), Philippine Society of Nephrology (PSN), Philippine Urology Association (PUA) designated by the societies on a rotational basis to a term of 2 years.
- viii. Representative from Professional Regulation Commission (PRC) designated by the Chair of the PRC
- ix. Representative designated by the Secretary of Health per recommendation of the PBODT.

The Secretary of Health may appoint additional members based on the recommendation of the PBODT and PODTP. He may also appoint additional members to the National Transplant Ethics Committee (NTEC) and the Philippine Network for Organ Sharing (PHILNOS) based on the recommendation of the PODTP.

The Executive Committee of the Department of Health will serve as oversight of the Board.

The National Center for Disease Prevention and Control shall serve as the Secretariat of the Board.

2. Philippine Organ Donation and Transplantation Program (PODTP)

Roles and Functions

- i. Overall implementing body of the organ donation and transplantation system in the country.
- ii. Monitor compliance of transplant facilities to policies set forth by this order and other operational guidelines that may be formulated.
- iii. Perform such other function as may be ordered by the Secretary of Health related to its primary functions.

3. National Transplant Ethics Committee (NTEC)

Roles and Functions

- i. Formulate national ethical standards/guidelines on organ donation and transplantation for approval by the PBODT.
- ii. Assist the PBODT in the resolution of ethical issues.
- iii. Assist in the monitoring of transplant facilities to ensure compliance with ethical standards/guidelines.
- iv. Perform such other functions as maybe ordered by the Secretary of Health or PBODT for those related to ethical issues.

4. Philippine Network for Organ Sharing (PHILNOS)

Roles and Functions

- i. Act as the central coordinating body to ensure that all donor kidneys/organs from Deceased donors are allocated according to established criteria.
- ii. Implement the policies on deceased donor allocation.
- iii. Maintain 3 national registries, with data coming from each local transplant facility, to include:
 - a. Registry of all kidney transplants performed in the country.
 - b. Registry of all placed living donors – LRD and directed LNRD.
 - c. Registry of all patients seeking kidney transplantation (national waiting list).
- iv. Perform such other functions as may be ordered by the Secretary of Health and PBODT for those related to its primary functions.

5. Bureau of Health Facilities and Services (BHFS)

Roles and Functions

- i. Inspect and monitor transplant facilities.
- ii. Issue Certificate of Accreditation.
- iii. Implement sanctions to non-compliant transplant facilities.
- iv. Perform such other functions as may be ordered by the Secretary of Health and PBODT related to its primary functions.

6. Philippine Health Insurance Corporation (PHIC)

Roles and Functions

- i. Issue accreditation of health facilities and professional.
- ii. Implement sanctions to non-compliant transplant facilities.
- iii. Serve as a member of inspection and monitoring team.
- iv. Perform such other functions as may be ordered by the Secretary of Health and PBODT related to its primary functions.

7. Hospital Ethics Committee (HEC)

Roles and Functions

- i. Monitor and resolve ethical issues that may arise in the process of organ donation and transplantation in the hospital.
- ii. Recommend sanctions for violation of the guidelines to the hospital administration. The hospital shall determine the proper sanction to be given to whoever is deemed culpable for the violation in accordance with the

Administrative Order on LNRD's Violations and corresponding sanctions shall be reported to PODTP.

- iii. Report to the NTEC.
- iv. Perform such other functions as may be ordered by NTEC related to its primary functions.

8. Hospital Transplant Coordinating Office (HTCO)

Roles and Functions

- i. In charge of maintaining the 3 registries at the transplant hospital level
- ii. Report to the PHILNOS.
- iii. Perform such other functions as may be ordered by PHILNOS related to its primary functions.

9. Kidney Donor Monitoring Unit (KDMU)

Roles and Functions

- i. In-charge of follow-up donor protection and long-term monitoring of donors after donation based on specific guidelines.
- ii. Report activities of the transplant facility to the PODTP.
- iii. Perform such other functions as may be ordered by PODTP related to its primary functions

10. Transplant Facility

- i. Comply with the rules and regulations governing the accreditation and operation of kidney transplant facilities.
- ii. Develop and organize programs and services in support of its transplantation program as required by existing DOH standards and regulations.

Transplant facilities can only be set-up in DOH-licensed hospitals and shall be accredited to perform kidney/organ transplantation. Each transplant facility shall establish its own HEC, HTCO and KDMU to comply with and operationalize the policies on organ transplantation herein promulgated.

VII. FUNDING SUPPORT

The national government will allocate P20 million pesos per year in support of the operations of the organ donation and transplantation program starting 2010. Funds may be augmented from government or private sources to support the program.

VIII. MONITORING AND EVALUATION

The Philippine Organ Donation and Transplantation Program (PODTP) shall take the lead in the conduct of monitoring relative to compliance to rules and regulations of all those covered in this Order. PODTP shall report regularly to the PBODT and provide recommendations related to the practice of organ donation and transplantation.

The PODTP shall call on the support of independent bodies and organizations involved in kidney transplantation to constitute a monitoring and evaluation team involving medical and specialty societies, non-government organizations, the private sector, other professionals and civil society. It shall continually develop and support programs and projects towards achieving a world-class status for the country in renal/organ care and transplantation.

IX. VIOLATIONS AND SANCTIONS

Non-compliance with the standards and policies of the PODTP shall be a ground for suspension or revocation of the license to operate of the hospital or its transplant facility subject to the implementing rules and regulations to be established.

Furthermore, any violations by erring professionals (doctors and members of transplantation team) shall be forwarded to the DOH and to the PRC, PSN, and PSTS and other appropriate professional organizations for appropriate sanctions without prejudice to the filing of appropriate civil or criminal charges whenever warranted.

X. REPEALING CLAUSE


Administrative Order No. 2008-0004 and other provisions or issuance found inconsistent with this Order are hereby repealed and/or modified accordingly.

XI. SEPARABILITY CLAUSE

In the event that any provision or part of this Order be declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

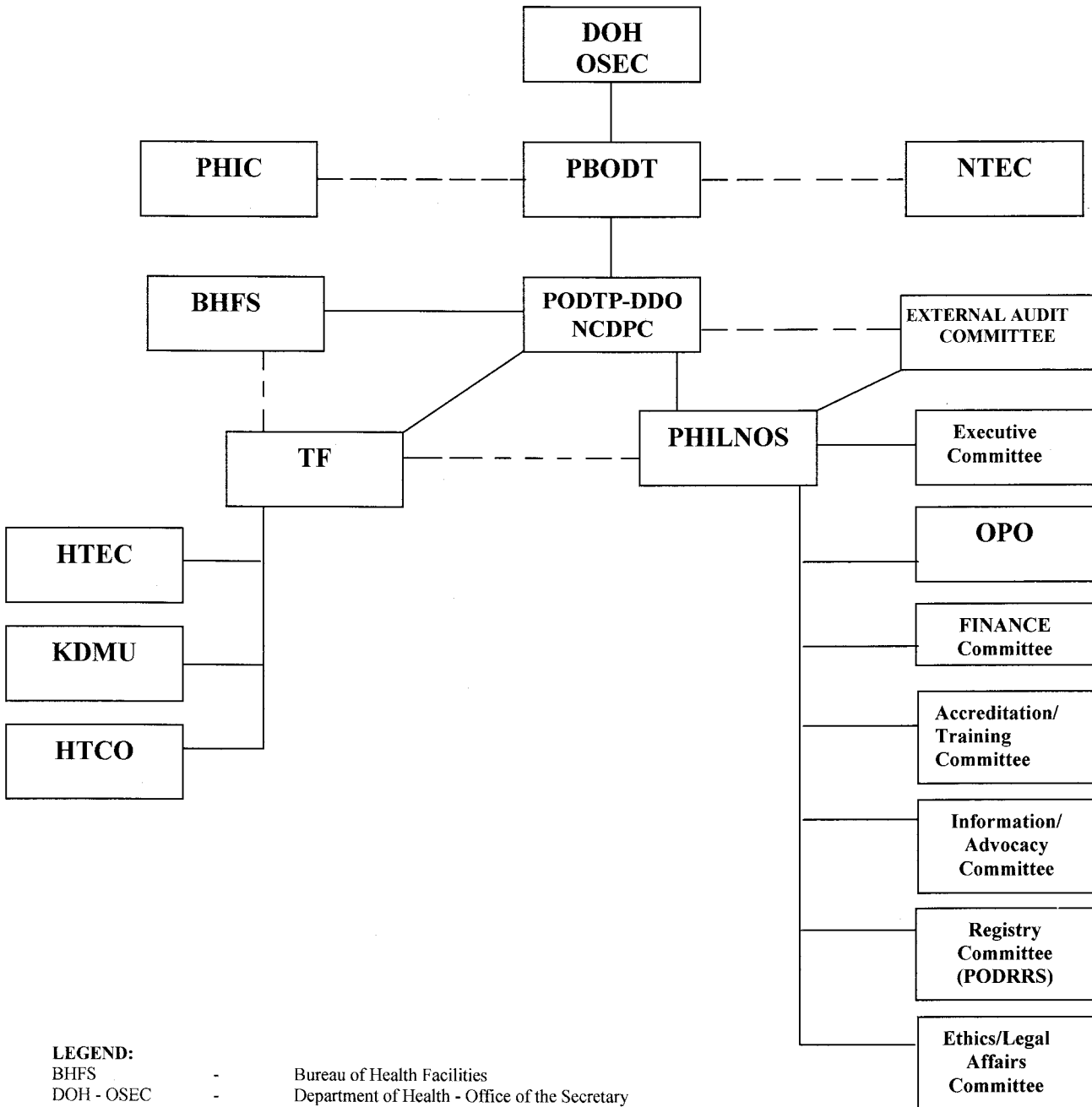
XIII. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication in a newspaper of general circulation.


ESPERANZA I. CABRAL, M.D.
Secretary of Health

ANNEX 1

COMPREHENSIVE ORGANIZATIONAL STRUCTURE FOR
ORGAN DONATION AND TRANSPLANTATION



LEGEND:

- BHFS - Bureau of Health Facilities
- DOH - OSEC - Department of Health - Office of the Secretary
- HTCO - Hospital Transplant Coordinating Office
- HTEC - Hospital Transplant Ethics Committee
- KDMU - Kidney Donor Monitoring Unit
- NCDPC-DDO - National Center for Disease Prevention and Control - Degenerative Disease Office
- NTEC - National Transplant Ethics Committee
- OPO - Organ Procurement Organization
- PBODT - Philippine Board on Organ Donation and Transplantation
- PHIC - Philippine Health Insurance Corporation
- PHILNOS - Philippine Network for Organ Sharing
- PODTP - Philippine Organ for Donation and Transplantation Program
- PODRRS - Philippine Organ Donor and Recipient Registry System
- TF - Transplant Facility

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