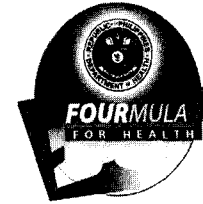




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March 3, 2008

ADMINISTRATIVE ORDER

No. 2008- 0004

SUBJECT: Revised National Policy on Kidney Transplantation from Living Non-Related Organ Donor and its Implementing Structures

I. RATIONALE

With the increasing number of end stage renal disease (ESRD) in many countries including the Philippines, the demand for transplantation has also increased. For a transplant operation to materialize, an organ donor becomes an urgent need for an ESRD patient. With the overwhelming demand for organ donors, the potential abuse in sourcing them out has become a local and worldwide concern.

There are 10,000 to 12, 500 Filipinos nationwide who develop ESRD annually. It is estimated that 50-60 percent of these patients are suitable kidney transplant candidates but only less than 10% are actually transplanted because of insufficient organ supply and the unaffordability of the operative procedure to most patients. Based on the Philippine Renal Disease Registry 2006 Report, 90% of kidney transplants in the Philippines are from living donors while only 10% come from deceased donors. Of the total living donors, 68% are from LNRDs. This is a marked change from the figures 15 years ago and it is expected to increase yearly because of a rising need for transplantation and the unavailability of preferred donors coming from Living Related Donors (LRDs) and brain dead individuals. However, the deceased organ donation and living related organ donation are the top preferred modes of the government.

Advances in technology during the past decade have made transplantation from LNRDs better than those coming from best-matched deceased donors. Kidney transplantation has become the preferred option for most patients with ESRD because it offers a better quality of life compared with dialysis. Furthermore, the latter is costly wherein a 2-3 session per week of dialysis treatment costs P48,000 – 96,000 per month. As a modality of treatment on a long-term basis, this amount is unaffordable for an average income earning Filipino especially today.

Culturally, LNRDs are also becoming to be acceptable in the country as evidence by a survey conducted by the Philippine Information Agency – Public Opinion Research Division and the University of the Philippines Institute of Clinical Epidemiology National Institutes of Health – Philippines. Based on the Nationwide Survey on the People's Knowledge and Opinions About Organ Donation in 2001 and 2005, 44% and 53% respectively, of the respondents agree that LNRDs are acceptable sources of organs.

However, recent media reports on transplantation using LNRDs have highlighted the potential for abuse and manipulation of these donors who are mostly poor. Both the

organ donor and potential recipient are easy and vulnerable targets of organ sale and brokering. It has generated controversy that needs urgent action and attention.

The initial step of the Department of Health (DOH) to counter the commercialization of organ donors was the formulation of the National Policy on Kidney Transplantation from Living Non-Related Donors (LNRDs) through Administrative Order No. 124 series 2002. A.O. 124 s. 2002 has likewise considered the tenets of Republic Act no. 7170 otherwise known as the Organ Donation Act of 1991, which addresses the issue of brain dead donors. However, it does not include provisions for the acceptance and management of living organ donors, the regulation of which has become imperative.

Having this premise, there is a need to strengthen the guiding policy governing organ donors to curb the reported cases of “backdoor” operations that currently defy ethical and medical standards in transplantation. Regulation of health tourism is likewise seen as a relevant strategy to inhibit illegal organ trafficking.

This Order therefore sets the general guidelines and ethical principles whereby the act of donation and conduct of transplantation using non-related donors shall be managed and regulated.

II. COVERAGE

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

1. Kidney 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 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) -They are related to the recipient by blood within the fourth-degree of consanguinity (i.e. parent, children, siblings, nephews/nieces, first cousins).
2. Living Non Related Donors (LNRDs) - They are 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:
 - a. Voluntary Donors –Those who are not related by blood to the recipient but bear close emotional ties with him/her. (i.e. spouses, relatives by affinity, friends, colleagues, fiancé /fiancée and adoptive parents or children).
 - b. Commercial Donors— Also known as kidney vendors who offer their kidneys 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.

3. 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.
4. Non-Directed Kidney Organ Donor – a donor who would donate to whoever he/she matches on a list of waiting patients for organ transplant.
5. Board – to refer to Philippine Board for Organ Donation and Transplantation.
6. Network – to refer to Philippine Network for Organ Donation and Transplantation (PhilNETDAT)

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 organ 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 kidney vendors.
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
 - Free from coercion
 - Medical and psychosocial suitability
 - Fully informed of the risks and benefits as a donor
 - Fully informed 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:

1. Filipino recipients shall be given priority in the donor allocation. Ability to pay should not be a deterrent for their prioritization and delivery of services.
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 kidney organs by kidney vendors are strictly prohibited.
4. Kidney transplantation is not part of medical tourism.
5. All health and health –related facilities and professionals shall not allow the trade of kidney.
6. Directed or non-directed LNRDs are permitted only in cases when it is voluntarily made. All non-directed kidney organ donors should be obtained from the National-Human Organ Preservation Effort (NHOPE) or its component HOPE facility. Directed kidney organ donor should be reported to the NHOPE or its component HOPE facility, after being favorably endorsed by the Ethics Committee of the facility.
7. Foreign patients may receive organs from local donors subject to the guidelines and limitations formulated for this purpose by the Philippine Network for Organ Donation and Transplantation (Phil NETDAT) as approved by the Board.
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 PHIC, whichever is applicable, shall enforce 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.
10. In no instance shall any kidney be transported or exported abroad.
11. Existing foundations involved in processing kidney donors should be an affiliated member of Phil NETDAT.
12. A Philippine Board for Organ Donation and Transplantation shall be created for this purpose to serve as overseer in the implementation of policies related to organ transplantation. A national network for organ donation and transplantation shall likewise be created to serve as the overall implementing body for organ donation and transplantation. This shall be called Philippine Network for Organ Donation and Transplantation or PhilNETDAT. PhilNETDAT may also create composite teams as necessary and appropriate to run the various aspects of the organ donation program.

VI. OPERATIONAL STRUCTURES

A. Roles and Functions

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

- a. Roles and Functions
 - i. Reviews and approves policies in support of a rational, ethical, accessible and equitable organ transplantation program in the country.
 - ii. Approves 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 & Standards Development Team (PSDT) for Service Delivery – Vice chairperson
 - iii. Chairman of NTEC
 - iv. President of Phil NETDAT
 - v. PHIC Representative
 - vi. Representative from a government transplant facility
 - vii. Representative from a private transplant facility (rotational basis)
 - viii. Representative from the professional societies involved in transplantation – Philippine Society of Transplant Surgeon (PSTS), Philippine Society of Nephrology (PSN), Philippine Urology Association (PUA)
 - ix. Representative from Professional Regulation Commission
 - x. Representative designated by Secretary of Health per recommendation of the Board

The Secretary of Health may likewise appoint additional members based on the recommendation of the component group. He may also appoint additional members to the National Transplant Ethics Committee and NHOPE 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 Network for Organ Donation and Transplantation (PhilNETDAT)

- a. Roles and Functions
 - i. Overall implementing body of the organ donation and transplantation system in the country.
 - ii. Oversees the conduct of inspection for the accreditation of transplant facilities
 - iii. Monitors compliance of transplant facilities to policies set forth by this order and other operational guidelines that may be formulated.

b. **Composition**

The PhilNETDAT may also be composed of different teams to run the various aspects of the system and shall include competent representatives from professional organizations, PHIC, NTEC and BHFS.

3. National Transplant Ethics Committee (NTEC)

- i. Formulates national ethical standards/guidelines on organ donation and transplantation for approval by the PBODT.
- ii. Assists the PBODT in the resolution of ethical issues.
- iii. Assists in the monitoring of transplant facilities to ensure compliance with ethical standards/guidelines.

4. National Human Organ Preservation Effort (NHOPE)

- i. Acts as the central coordinating body to ensure that all donor kidneys are allocated according to established criteria.
- ii. Implements the policies on donor allocation.
- iii. Maintains 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 LNRDs and those waiting to be placed
 - c. Registry of all patients seeking kidney transplantation (national waiting list).

5. Bureau of Health Facilities and Services (BHFS)

- i. Inspects and monitors transplant facilities.
- ii. Issues Certificate of Accreditation.
- iii. Implements sanction to transplant facilities.

6. Philippine Health Insurance Corporation (PHIC)

- i. Issue accreditation of health facilities and professional
- ii. Implement sanctions to transplant facilities
- iii. Serve as a member of inspection and monitoring team

7. Hospital Ethics Committee (HEC)

- i. Monitor 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.

Human Organ Preservation Effort (HOPE)

- i. In charge of donor allocation following set guidelines.
- ii. Reports to the NHOPE.

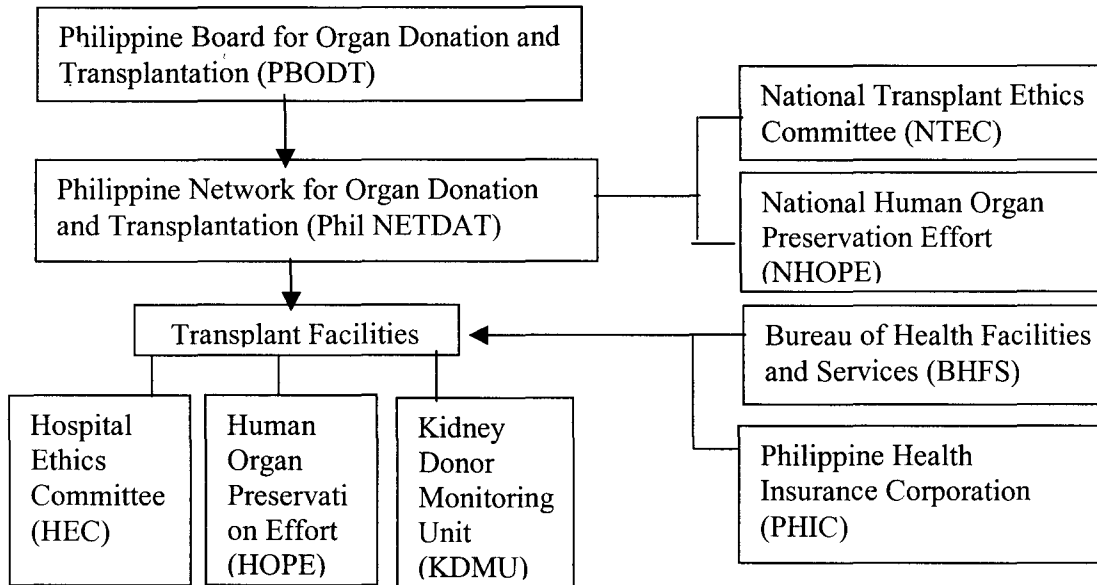
Kidney Donor Monitoring Unit (KDMU)

- i. In-charge of follow-up donor protection and long-term monitoring donors after donation based on specific guidelines.
- ii. Reports activities of the transplant facility to the Phil NETDAT.

8. Transplant Facility

- i. Complies with the rules and regulations governing the accreditation of kidney transplant facilities.
- ii. Develops and organizes programs and services in support of its development and improvement as required by existing DOH standards and regulations.

B. Organizational Structure and Linkages



The Health Secretary shall create the Phil NETDAT. Several committees will be formed to run the various aspects of the organ donation program. The Health Secretary shall appoint membership to the following committees based on the recommendation of the DOH-PODTP:

1. NTEC
2. NHOPE

Transplant facilities can only be set-up in DOH-licensed hospitals and shall be accredited to perform kidney transplantation. Each transplant facility shall establish the HEC, HOPE and KDMU.

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 2008. Other funding sources may be tapped to support the program.

VIII. MONITORING AND EVALUATION

The Phil NETDAT shall take the lead in the conduct of monitoring relative to compliance to rules and regulations of all those covered in this Order. Phil NETDAT shall report regularly to the PBODT and provide recommendations related to the practice of organ donation and transplantation.

The Phil NETDAT 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 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 of the hospital or its transplant facility subject to the implementing rules and regulations to be established.

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

X. TRANSITORY PROVISION

While the Phil NETDAT is being organized, the DOH will task any existing foundation to take charge of the donor gratuity and formulation of implementing guidelines subject to approval of the PBODT. The selection of the foundation will be through a screening process based on criteria set forth by the Board.

Specific operational guidelines shall be formulated to allow for a smooth implementation of this Order as these relate to the management, regulation and conduct of transplantation from LNRDs and all other types of donors as conditions warrant.

XI. REPEALING CLAUSE

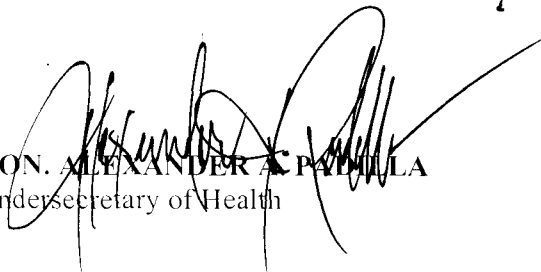
Any existing provision or issuance found inconsistent with this Order shall be repealed.

XII. SEPARABILITY CLAUSE

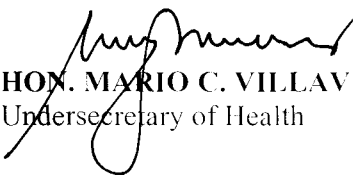
In the event that any provision or part of this Order be declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

XIII. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication in the official gazette or newspaper of general publication. This Order shall be followed and implemented until such time that a national legislation regarding Living Non-Related Donor's is passed.



HON. ALEXANDER C. PADILLA
Undersecretary of Health



HON. MARIO C. VILLAVERDE
Undersecretary of Health



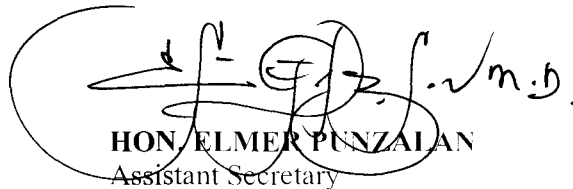
HON. JADE F. DEL MUNDO
Undersecretary of Health



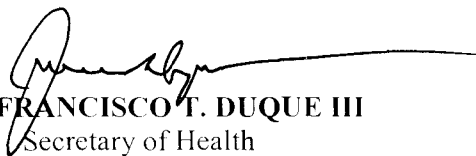
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