

**[DOH ADMINISTRATIVE ORDER NO. 2008-0034,
November 13, 2008]**

**REVISED RULES AND REGULATIONS GOVERNING
ACCREDITATION OF HOSPITALS ENGAGED IN KIDNEY
TRANSPLANTATION**

I. Background/Rationale

In 2003, the “Rules and Regulations Governing Accreditation of Hospitals Engaged in the Conduct of Kidney Transplantation”, was approved and implemented. Since then, the BHFS has accredited twenty two (22) kidney transplantation facilities.

With the issuance of Administrative Order No. 2008-0004 “Revised National Policy on Living Non-Related Organ Donation and Transplantation and Its Implementing Structures”, there were changes in policies that affected the operational structure for regulation as well as the standards and technical requirements for the accreditation of kidney transplantation facilities.

In view of the above and in line with the Formula One for Health, which aim to make regulation more rational and client responsive, the need to revise AO No. 81 s. 2003 to redirect and to improve the services being provided by the regulatory bodies becomes a crucial.

II. Objective

This Order is promulgated to strengthen the regulation of hospitals engaged in kidney transplantation to ensure public health and safety.

III. Coverage

This Order shall apply to all government and private hospitals that are and will be performing kidney transplantation.

IV. Definition of Terms

Accreditation - a formal authorization issued by the DOH to an individual, partnership, corporation or association to operate a hospital that performs kidney transplantation. It refers to compliance with standards set for a particular purpose. These standards shall cover input/structural, process, and outcome/output standards.

BHFS - acronym for Bureau of Health Facilities and Services; a regulatory body under the Department of Health.

DOH - acronym for Department of Health

DOJ - acronym for Department of Justice

In-house - refers to the members of the transplant team who are accredited/affiliated with the hospital and should be readily available and accessible to attend to patient's needs. He/she lives within the locality of the hospital.

NTEC - acronym for National Transplant Ethics Committee

PBODT - acronym for Philippine Board for Organ Donation and Transplantation

PhilHealth - acronym for Philippine Health Insurance Corporation

PhilNETDAT - acronym for Philippine Network for Organ Donation and Transplantation

PODTP - acronym for Philippine Organ Donation and Transplantation Program

PRC - acronym for Philippine Regulation Commission

Quality Assurance Program - an organized plan of activities that aims to provide the best possible care and services for all kidney transplant patients.

V. Guidelines

1. Only DOH licensed government and private hospitals shall be eligible to apply for accreditation.

2. A Certificate of Accreditation shall be granted to the hospital performing kidney transplantation in compliance with the standards and technical requirements embodied in the survey/monitoring tools as posted in the DOH website www.doh.gov.ph. Compliance with these rules and regulations shall be maintained at all times.

3. The hospital shall provide ancillary/support services such as, but not limited to, the following:

3.1 HIV testing;

3.2 Blood Banking;

3.3 Dialysis;

3.4 Laboratory diagnostic capability in virology, post immuno-suppression, infection, tissue typing and DNA typing (*affiliation with other facilities will be considered if unable to provide the service*);

3.5 Immunosuppressive drug level monitoring studies (*affiliation with other facilities will be considered if unable to provide the service*);

3.6 Imaging facility to include at least an ultrasound machine with Doppler capability, and CT scan or nuclear medicine facility (*affiliation with other facilities within the locality will be considered if unable to provide the service*).

4. There shall be well-ventilated, well-lighted, clean and spacious rooms with isolated air handling system to accommodate the activities of the service.

5. There shall be provisions for appropriate, adequate and well-maintained equipment to effectively carry out kidney transplantation.

6. The hospital shall have surgical and medical expertise of practitioners earned through training, specialization, and recognition by medical specialty societies. The

following personnel, among others, shall be members of their in-house transplant team:

- 6.1 Transplant Surgeon accredited by the Philippine Society of Transplant Surgeons;
- 6.2 Donor Surgeon accredited by the Philippine Urologic Association;
- 6.3 Nephrologist accredited by the Philippine Society of Nephrology;
- 6.4 Anesthesiologists accredited by the Philippine Society of Anesthesiology;
- 6.5 Infectious Disease Consultant accredited by the Philippine Society of Microbiology and Infectious Disease;

The hospital shall also provide, among others, the following personnel:

- 6.6 Operating Room nurses with at least one (1) year work experience as OR nurse;
- 6.7 Competent 24 hours duty physicians who can provide care for post transplantation patients.

7. The hospital shall set up an Organ Transplantation Program in accordance with the operational guidelines of the PODTP.

8. The hospital shall have an Ethics Committee on Organ Donation/ Transplantation that shall be guided by the ethical standards set forth by the NTEC.

9. The hospital shall have a Manual of Operations based on the operational guidelines set by the PODTP which include, among others, the following:

- 9.1 Policies and ethical standards;
- 9.2 Protocol for quality control;
- 9.3 Protocol for screening donors and recipients;
- 9.4 Protocol for pre-operative work-up of donors and recipients;
- 9.5 Protocol for intra-operative procedures;
- 9.6 Protocol for post-operative management of donors and recipients to include among others pain management.

10. The hospital shall accomplish and submit the Transplant Registry Form to the Philippine Renal Disease Registry Office (REDCOP, National Kidney and Transplant Institute).

11. There shall be an advocacy plan to implement the different preventive and promotive activities relative to organ donation and transplantation. The hospital transplant service shall have an active program on deceased organ donation in terms of advocacy, existing guidelines or protocol on deceased organ donor procurement, creation of team who shall convince relatives of donor, retrieve the organs, and other relevant activities.

12. The hospital shall establish a Quality Assurance Program on organ donation and transplantation.

13. All policies, standards, and proceedings of the different committees shall be properly documented. These documents shall be kept and made available for review by the survey and monitoring teams during their visit.

VI. Procedural Guidelines

A. Certificate for Initial/Renewal of Accreditation

1. Application for Initial/Renewal of Accreditation

1.1 Applicant requests for relevant information and prescribed form from the PhilNETDAT in person or through mail, e-mail or internet.

1.2 Applicant accomplishes required documents and submits them to the PhilNETDAT every October to November prior to expiry date.

Documentary requirements:

- a. Duly accomplished and notarized application form.
- b. Photocopy of a valid License to Operate a hospital including the following services:

- b.1 HIV testing laboratory;
- b.2 Blood Bank;
- b.3 Dialysis facility;
- b.4 Imaging facility to include at least an ultrasound machine with Doppler capability, and CT scan or nuclear medicine facility

- c. Memorandum of Agreement with the referral facility if the following examinations are not provided by the hospital:

- c.1 Immunosuppressive drug level monitoring studies
- c.2 Diagnostic virology and post immuno-suppression infection studies
- c.3 Imaging Facility - CT scan or nuclear medicine facility

- d. List of personnel and appropriate permits (valid Professional Regulation Commission Identification Card, valid PhilHealth Accreditation Identification Card, Certificates of the Specialty/Subspecialty Board).

- e. List of Equipment

- f. Documentation of the Quality Assurance Program

1.3 The PhilNETDAT reviews the documents for completeness, authenticity and compliance with accreditation requirements.

1.4 The PhilNETDAT informs the applicant if all the documentary requirements were met then schedules the survey of the hospital.

2. Payment of Fees

2.1 The PhilNETDAT prepares the order of payment.

2.2 A non-refundable application fee of thirty eight thousand pesos (P38,000.00) shall be paid by the applicant to the DOH cashier in cash or through postal money order payable to the DOH.