



November 13, 2008

**ADMINISTRATIVE ORDER**  
No. 2008 - 0034

**SUBJECT: 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 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](http://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 carryout 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 Anesthesiologist 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.

2.3 An application for renewal filed every October to November prior to expiry date of accreditation shall be granted a ten percent (10%) discount on the renewal fee.

- 2.4 An application for renewal filed after the expiry date of accreditation shall be imposed a surcharge equal to fifty percent (50%) of the renewal fee.
- 2.5 An additional fee of thirty eight thousand pesos (P38,000.00) for every re-survey to be done shall be paid by the applicant.

### 3. Survey

- 3.1 The PhilNETDAT organizes a composite team composed of representatives from the following:
  - Team Leader – representative from PhilNETDAT
  - Members – representatives from:
    - BHFS
    - NTEC
    - Philippine Society of Nephrology
    - Philippine Society of Transplant Surgeons
- 3.2 The composite team conducts survey of the hospital, prepares the official summary of findings and makes recommendation.
- 3.3 The PhilNETDAT forwards/ presents the findings and recommendation of the composite team to the PBODT.
- 3.4 The PBODT approves or disapproves the issuance of Certificate of Accreditation.
  - a) If approved, the BHFS registers the hospital and issues the Certificate of Accreditation.
  - b) If disapproved, the PhilNETDAT sends a copy of survey findings and recommendations to the applicant. Compliance with the recommendations shall be made within fifteen days (15) days otherwise the applicant re-files another application and pays the corresponding fee.

### **B. Monitoring**

1. All hospitals performing kidney transplantation shall be monitored at least once a year and records shall be made available to determine compliance with these rules and regulations.
2. The PhilNETDAT or representatives designated by the PhilNETDAT shall be allowed to monitor the hospital at any appropriate time without prior notice.

### **C. Terms and Conditions**

1. The sale, lease or transfer in any form of the Certificate of Accreditation or rights derived therein shall result to its automatic cancellation/ revocation.
2. An accreditation that is not renewed before the expiry date shall be considered lapsed and registration shall be cancelled. A new Certificate of Accreditation shall be required before it can be allowed to operate.
3. The BHFS shall be notified of any change in management, name or ownership or condition of the facility (e.g. changes in the physical plant, equipment or manpower). Failure to report in writing within fifteen (15) days of any substantial change in the condition of the facility may be a basis for the suspension or revocation of the accreditation.

4. Separate accreditation shall be required for health facilities or branches thereof, maintained in separate premises even though they operate under the same owner/management.
5. The Certificate of Accreditation of the hospital shall be posted in a conspicuous place readily seen by the public within the premises of the medical facility.

## **VII. Validity**

The Certificate of Accreditation shall be valid for three (3) years after issuance, starting from January 1 of the first year to December 31 of the third year. A self-assessment report shall be submitted to the PhilNETDAT on the succeeding year from date of issuance of the certificate.

## **VIII. Violations**

Violation of these rules and regulations governing accreditation of hospitals engaged in the conduct of kidney transplantation, including the commission of the following acts:

1. Refusal to allow survey or monitoring of the facility by persons authorized by the PhilNETDAT during an appropriate time.
2. Non-implementation of the Quality Assurance Program.
3. Conduct of organ transplantation involving organ vendors and organ trafficking.
4. Any false statement in the application.

## **IX. Penalties and Sanctions**

1. The following are the penalties and sanctions:
  - 1.1 First Offense
    - a. Suspension of authority to perform kidney transplantation of not less than three (3) months but not more than six (6) months, **and**
    - b. Administrative fine of not more than two hundred thousand pesos (Php 200,000.00) shall be imposed.
  - 1.2 Second Offense
    - a. Suspension of authority to perform kidney transplant of not less than six (6) months but not more than one (1) year, **and**
    - b. Administrative fine of five hundred thousand pesos (Php 500,000.00) shall be imposed.
  - 1.3 Third Offense
    - a. Revocation of authority to perform kidney transplant, **and**
    - b. Administrative fine of one million pesos (Php 1,000,000.00) shall be imposed.
2. Penalties imposed as fines shall be doubled if kidney transplant is performed on foreigners.

3. Each kidney transplant whether local or foreign shall be considered separate offenses even if performed in a single day.
4. Health facilities performing transplantation without the proper accreditation shall be a ground for the suspension or revocation of the hospital license.
5. The PBODT shall approve the imposition of the penalties and sanctions. The decision of the Board shall be final and executory after ten (10) days from receipt of such Order.
6. The fine imposition procedure shall be as follows:
  - 6.1 An official notice of the imposition of the administrative fine shall be sent to the hospital by registered mail/ courier/ personal delivery.
  - 6.2 The fine shall be paid to the DOH cashier, within ten (10) days after receipt of official notice.
  - 6.3 If the fine is not paid within the ten (10) day period after the receipt of official notice, it shall be considered as another offense and corresponding penalty shall be imposed under this Order.
7. Administrative fines collected shall be used in supporting the deceased donor program.
8. The DOH shall refer cases involving violations committed by professionals to PRC, PhilHealth, DOJ, and concerned professional organizations for their appropriate action.
9. If upon survey or monitoring visits, the hospital is found to be violating the rules and regulations as well as other violations stipulated in this Order, the PBODT may immediately preventively suspend the performance of kidney transplantation. Preventive suspension shall not be more than sixty (60) days.

#### **X. Investigation of Charges or Complaints**

The PhilNETDAT upon receipt of complaints or charges against an accredited hospital by any person or interested party shall refer the complaints or charges to the BHFS or any appropriate organization for investigation.

If upon investigation, a hospital is found violating any of the provisions of these rules and regulations, circulars and orders, the BHFS Director, upon approval of the PBODT, shall impose the corresponding sanctions enumerated therein without prejudice to referring the case to judicial authorities for criminal action.

#### **XI. Appeal**

Any hospital engaged in the conduct of kidney transplantation, or any of its personnel aggrieved by the decision of the PBODT may, within ten (10) days after receipt of the notice of decision, file a notice of appeal to the DOH Executive Committee and serve a copy of the notice of appeal to the PhilNETDAT. Thereupon, the PBODT shall promptly certify and file a copy of the decision, including the transcript of the hearings on which the decision is based, with the DOH Executive Committee, for review. The decision of the DOH Executive Committee shall be final and executory.

## **XII. Publication**

A list of accredited hospitals engaged in kidney transplantation shall be published periodically and shall be made available to any individual, corporation, association, or organization for legitimate purpose.

## **XIII. Implementing Mechanisms**

### **1. PBODT**

- 1.1 Reviews and approves policies in support of a rational, ethical, accessible and equitable organ transplantation program in the country.
- 1.2 Approves the issuance of the Certificate of Accreditation of transplant facilities.

### **2. NTEC**

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

### **3. PhilNETDAT**

- 3.1 Acts as the overall implementing body of the organ donation and transplantation system in the country.
- 3.2 Oversees the conduct of inspection for the accreditation of transplant facilities.
- 3.3 Designates partner agencies in regulating kidney transplant facilities.
- 3.4 Monitors compliance of transplant facilities to policies set forth by this Order and other operational guidelines that may be formulated.

### **4. BHFS**

- 4.1 Issues the Certificate of Accreditation, upon approval of the PBODT, to all hospitals engaged in the conduct of kidney transplantation.
- 4.2 Suspends or revokes accreditation of hospitals to perform organ transplantation.
- 4.3 Suspends or revokes License to Operate the hospital.
- 4.4 Refers cases involving violations committed by professionals to the DOJ, PRC, PhilHealth, and/or professional organizations, as the case may be, for their appropriate action.

### **5. PhilHealth**

Acts on cases referred to it by the DOH relative to violations committed by accredited professionals.

### **6. DOJ**

Acts on cases referred to it by the DOH relative to violations of RA 9208 and its Implementing Rules and Regulations.



7. PRC

Acts on cases referred to it by the DOH relative to violations committed by professionals.

8. Partner agencies (such as, but not limited to, professional organizations like the Philippine Society of Nephrology, NTEC, Philippine Urologic Association, Philippine Society of Transplant Surgeons, and the Philippine Society of Anesthesiologists)

- 8.1 Acts on cases referred to it by the DOH relative to violations committed by its respective members and imposes due sanctions as determined by its society.  
8.2 Assists in the implementation of these rules and regulations by providing technical assistance during survey and monitoring.  
8.3 Reports non-accredited hospitals engaged in the conduct of kidney transplantation to the PhilNETDAT.

**XIV. Transitory Provisions**

The BHFS shall assume the responsibility, authority, accountability, and functions of the PhilNETDAT until such time that the latter has been fully established.

**XV. Separability Clause**

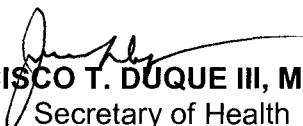
In the event that any rule, section, paragraph, sentence, clause or words of these rules and regulations is declared invalid for any reason, the other provisions thereof shall not be affected thereby.

**XVI. Repealing Clause**

These rules and regulations shall repeal and supersede all administrative orders and other issuances inconsistent thereof.

**XVII. Effectivity**

These rules and regulations shall take effect fifteen (15) days after the completion of its publication in the official gazette or in a newspaper of general circulation.

  
**FRANCISCO T. DUQUE III, M.D., MSc.**  
Secretary of Health