



Republic of the Philippines  
Department of Health  
OFFICE OF THE SECRETARY  
Manila



September 1, 2003

**ADMINISTRATIVE ORDER**  
No. 81 s. 2003

**Subject: Rules and Regulations Governing Accreditation of Hospitals Engaged in the Conduct of Kidney Transplantation**

**I- Background/Rationale:**

Based on the review of records done by the Renal Disease Control Program from 2001 to 2002, there were 23 patients with post transplant complications referred to the National Kidney and Transplant Institute by different hospitals.

On May 20, 2003, it was published in the Gulf Daily News, Bahrain that three patients who underwent surgery in Manila developed complications over the past six months and had died upon returning to their country. It was also mentioned in the same article that very often, kidneys bought from donors in the Philippines do not match the recipient.

As promulgated in Administrative Order No.124 s, 2002 'National Policy on Kidney Transplantation from Living Non Related Donors', the Bureau of Health Facilities and Services shall accredit hospitals engaged in the conduct of kidney transplantation. This is to ensure that such health facility has the capability and expertise to perform kidney transplantation.

**II- Coverage:**

These rules and regulations shall apply to all government and private hospitals that are and will be performing kidney transplantation.

**III- Definition of Terms:**

*Accreditation* – a formal authorization issued by the Department of Health 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 standards, process standards and outcome/output/impact standards.

*Accredited kidney transplant hospital* – a facility that performs kidney transplantation and has passed the accreditation of the Department of Health.

Signed AO  
Received in the Records  
Section on 11-26-03

*BHFS* – refers to the Bureau of Health Facilities and Services; A regulatory body under the Department of Health. The BHFS shall exercise accreditation and regulation functions under these rules and regulations.

*DOH* - refers to the Department of Health

*Kidney vendor* – also known as commercial donors for the reason that they offer their kidneys for valuable consideration. They may engage the services of a broker or agent. Payment or a promise of payment is a precondition and pre-requisite to the organ donation.

*Living Non Related Donor (LNRD)* - A person who has the willingness and intention to donate a kidney based on certain reasons but are not related to the recipient by blood.

*Medical expert* – refers to a physician who is an authority in his/her respective line of specialization and who is either a diplomate or fellow of the same subspecialty board.

*Non-accredited kidney transplant hospital* - a facility that refuses to be accredited by or has not complied with the accreditation requirements of the Department of Health.

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

*Second Level Referral Hospital* – a departmentalized hospital that has the following service capability:

- a. Provides clinical care and management on the prevalent diseases in the locality, as well as particular forms of treatment, surgical procedure and intensive care.
- b. Clinical services which include general medicine, pediatrics, obstetrics and gynecology, surgery and anesthesia, as well as specialty clinical care.
- c. Provides appropriate administrative and ancillary services (clinical laboratory, radiology, pharmacy).
- d. Provides nursing care for patients who require immediate, moderate and partial category of supervised care for 24 hours or longer as well as total and intensive skilled care.

#### **IV. Technical and Administrative Requirements:**

1. Only government and private DOH licensed hospitals with at least a Second Level Referral classification shall be eligible to apply for accreditation.
2. A certificate of accreditation shall be granted in accordance with the prescribed accreditation requirements and on the basis of specific conditions and limitations established during the survey.
3. The hospital shall provide the following services:
  - a. Immunosuppressive drug level monitoring studies (*affiliation with other facilities will be considered if unable to provide the service*)
  - b. 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*)

- c. HIV testing
- d. Blood banking
- e. Dialysis
4. There shall be well-ventilated, well-lighted, clean and spacious room to accommodate the activities of the service.
5. There shall be provisions for appropriate, adequate and well-maintained equipment to effectively carryout the service of the hospital.
6. The hospital shall have surgical and medical expertise of practitioners and support staff earned through training, specialization, and recognition by medical specialty societies. The hospital shall employ, among others the following personnel:
  - a. Transplant Surgeon accredited by any transplant societies recognized by the Philippine College of Surgeons
  - b. Donor Surgeon accredited by the Philippine Urologic Association
  - c. Nephrologist accredited by the Philippine Society of Nephrology
  - d. Infectious Disease Consultant accredited by the Philippine Society of Microbiology and Infectious Disease
  - e. Transplant Immunologist (optional)
  - f. Trained Anesthesiologist certified by the Philippine Society of Anesthesiology
  - g. OR Nurses
  - h. OR Surgical Technician
7. The hospital shall set up an Organ Transplant Program in accordance with the operational guidelines of the Philippine Organ Donation Program.
8. The hospital shall have a Donors/Recipients Registry Unit that shall actively coordinate and network with the Kidney Donor Monitoring Unit under the Philippine Organ Donation Program (PODP).
9. The hospital shall create an Ethics Committee on Organ Donation/Transplantation that shall be guided by the ethical standards set forth by the National Transplant Ethics Committee.
10. The hospital shall have a Manual of Operations based on the operational guidelines set by the Philippine Organ Donation Program (PODP) which include, among others, the following:
  - a. Policies and ethical standards
  - b. Protocol for quality control
  - c. Protocol for screening donors and recipients
  - d. Protocol for pre-operative work-up of donors and recipients
  - e. Protocol for intra-operative procedures
  - f. Protocol for post-operative management of donors and recipients to include among others pain management
11. The hospital shall establish a Quality Assurance Program.
12. 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.

**V. Procedural Guidelines:**

**A. Certificate for Initial Accreditation:**

**1. Application for initial accreditation**

- 1.1 Applicant requests for relevant information and prescribed form from the BHFS in person or through mail, e-mail or internet
- 1.2 Applicant accomplishes required documents and submits them to BHFS

Documentary requirements:

- a. Duly accomplished and notarized prescribed application form. The application shall include a statement that the applicant has fully complied with all the requirements for accreditation.
  - b. Photocopy of License to Operate a Second/Third Referral Hospital and Certificate of Accreditation/License to Operate on the following laboratory services:
    - HIV testing laboratory
    - Blood bank
    - Dialysis facility
  - c. Affiliation contract with a licensed tertiary category clinical laboratory to perform the following examinations:
    - Immunosuppressive drug level monitoring studies
    - Diagnostic virology and post immuno-suppression infection studies
  - d. Location map or sketch of the location of the hospital
  - e. List of personnel and appropriate permits (valid Professional Regulation Commission Identification Card, PTR, Certificates of the Specialty/Subspecialty Board)
  - f. List of equipment
  - g. Quality Assurance Program plan
- 1.3 BHFS reviews the documents for completeness, authenticity and compliance with accreditation requirements.
  - 1.4 BHFS shall inform the applicant if all the documentary requirements were met then schedules the survey of the facility.

**2. Payment of Fees**

- 2.1 BHFS prepares the order of payment

- 2.2 Applicant pays the non-refundable application fee of six thousand pesos (P6, 000.00) to the DOH cashier in cash or through postal money order payable to the DOH.
- 2.3 Applicant pays an additional fee of three thousand pesos (P3, 000.00) for every re-survey to be done.

### **3. Survey**

- 3.1 BHFS Director or his duly authorized representative(s), representative(s) from the Transplant Society of the Philippines and Philippine Society of Nephrology survey the health facility. Survey shall be done only after the hospital had conducted self- assessment to determine compliance with the requirements.
- 3.2 BHFS prepares official summary of findings and recommends approval or disapproval after survey.
- 3.3 BHFS Director approves or disapproves the issuance of certificate of accreditation.
  - 3.3.1 If approved, the BHFS registers the hospital and issues the certificate of accreditation.
  - 3.3.2 If disapproved, the BHFS sends a copy of survey findings and recommendations to the applicant. Compliance with the recommendations shall be made within 15 days otherwise the applicant re-files application and pays the corresponding fee.

## **B. Certificate of Renewal of Accreditation**

### **1. Application for Renewal**

- 1.1 Applicant requests for relevant information and prescribed form from the BHFS in person or through mail, e-mail or internet
- 1.2 Applicant accomplishes required documents and submits them to BHFS

#### Documentary requirements:

- a. Duly accomplished and notarized Application Form. The application shall contain a statement that the applicant has complied with the requirements for renewal of accreditation.
- b. List of Personnel
- c. List of Equipment
- d. Quality Assurance Program documentation

1.3 BHFS reviews documents for completeness, authenticity and compliance with accreditation requirements.

1.4 BHFS informs the applicant if all the documentary requirements were met and schedules the survey of the facility.

**2. Payment of Fees**

2.1 BHFS prepares the order of payment

2.2 Applicant pays the application fee of six thousand pesos (P6,000.00) to the DOH in person or through postal money order payable to the DOH. An additional fee of three thousand pesos (P3,000.00) shall be paid for a re-survey.

**3. Survey**

3.1 BHFS Director or his duly authorized representative(s) surveys the health facility.

3.2 BHFS prepares the official summary of findings and recommends approval or disapproval after survey.

3.2.1 If approved, the BHFS renews the certificate of accreditation.

3.2.2 If disapproved, the BHFS sends the findings and recommendations to the applicant for compliance. Compliance with the recommendations shall be made within 15 days otherwise the application shall be automatically denied.

**C. Monitoring:**

1. All hospitals engaged in the conduct of kidney transplantation shall be monitored regularly and records shall be made available to determine compliance with these rules and regulations.

2. BHFS shall be allowed to monitor the facility at any appropriate time without prior notice.

**VI. Validity:**

The certificate of accreditation shall be valid for two (2) years after issuance. However, a self-assessment report shall be submitted to the BHFS on the succeeding year from date of issuance of the certificate. The self-assessment report shall follow the BHFS guidelines.

## **VII. Terms and Conditions:**

1. Compliance with these rules and regulations shall be maintained at all times. Any deficiencies found during the monitoring may be a ground for suspension or revocation of the accreditation.
2. The certificate of accreditation and any right granted under the accreditation shall not be assigned or transferred.
3. An accreditation that is not renewed on the expiry date shall be considered lapsed and registration shall be cancelled. A new application for the issuance of accreditation shall be required before it can be allowed to operate.
4. The Bureau shall be notified of any change in management, name or ownership. In cases of transfer of location, a new application shall be required. Failure to report in writing within fifteen (15) days of any substantial change in the condition of the facility (e.g. changes in the physical plant, equipment or manpower) may be a basis for the suspension or revocation of the accreditation.
5. Separate accreditation shall be required for health facilities or branches thereof, maintained in separate premises even though they operate under the same owner/management.
6. 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.

## **VIII. Violations:**

Violations of these rules and regulations governing accreditation of hospitals engaged in the conduct of kidney transplantation shall include among others the commission of the following acts:

- a. Change of ownership or location of the medical facility without notifying the BHFS.
- b. Operating unauthorized branches other than the accredited facility.
- c. Refusal to allow survey or monitoring of the facility by persons authorized by the BHFS Director during an appropriate time.
- d. Non-implementation of the Quality Assurance Program.
- e. Engaged in the conduct of organ transplantation involving kidney vendors.
- f. Any false statements in the application

Any violation committed/omitted under this Administrative Order and other issuances of agencies under the Department of Health shall be a ground for suspension and/or revocation of the certificate of accreditation. During suspension, the facility shall cease and desist all operations involving kidney transplantation. After due notice and hearing, the Bureau may revoke/cancel the certificate of accreditation for violation of these rules and regulations.

Non-accredited hospitals engaged in the conduct of kidney transplantation shall have their hospital license to operate suspended and/or revoked.

**IX. Investigation of Charges or Complaints:**

The BHFS upon receipt of complaints or charges against an accredited hospital by any person or interested party shall investigate the complaints or charges.

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

**X. Appeal:**

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

**XI. Publication:**

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

**XII. Implementing Mechanisms:**

**A. Bureau of Health Facilities and Services (BHFS)**

The BHFS shall accredit all hospitals engaged in the conduct of transplantation. It shall be primarily responsible for the issuance, suspension or revocation of the accreditation of health facilities engaged in kidney transplantation.

The BHFS to effectively perform its functions shall coordinate with the Philippine Organ Donation Program and its partner agencies in terms of policies, ethical standards and information updates.

**B. Philippine Organ Donation Program**

The Philippine Organ Donation Program shall formulate policies in support of a rational, ethical, accessible and equitable renal health care program in the country in coordination with the National Kidney and Transplant Institute and other organizations, associations and professionals engaged in transplantation and donation programs and activities.



The responsibilities of the Philippine Organ Donation Program are embodied in Administrative Order No. 124 s. 2002 "National Policy on Kidney Transplantation from Living Non-Related Donors".

C. Partner agencies (such as, but not limited to, professional organizations like the Philippine Society of Nephrology and Philippine Society of Transplant Surgeon)

The partner agencies shall assist in the implementation of these rules and regulations by providing technical assistance during survey and monitoring.

The partner agencies shall report non-accredited hospitals engaged in the conduct of kidney transplantation to the BHFS.

The BHFS shall designate partner agencies in regulating kidney transplant facilities.

**XV. Separability Clause:**

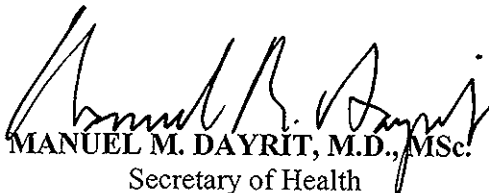
In the event that any rule, section, paragraph, sentence, clause or words of these rules and regulations is declared invalid for any reason, the other provisions thereof shall not be affected thereby.

**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 its publication in the official gazette or in a newspaper of general circulation.

  
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Secretary of Health