

**[DOH ADMINISTRATIVE ORDER NO. 81, S. 2003,
September 01, 2003]**

**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 regulation 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.

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 carry out 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 Nurse
 - 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:
 1. HIV testing laboratory
 2. Blood bank
 3. Dialysis facility
- c. Affiliation contract with a licensed tertiary category clinical laboratory to perform the following examinations:
 1. Immunosuppressive drug level monitoring studies
 2. 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