

**[DOH ADMINISTRATIVE ORDER NO. 163, S. 2004,
June 14, 2004]**

**REVISED RULES AND REGULATIONS GOVERNING
REGISTRATION, LICENSURE AND OPERATION OF DIALYSIS
CLINICS IN THE PHILIPPINES**

**I
Rationale**

Every year the number of patients undergoing dialysis is continually increasing. Based on the Renal Disease Control Program (REDCOP) report in 2001, 11,250 Filipinos nationwide was estimated to develop End Stage Renal Disease annually. In 2003, there were 5,070 patients who were started on dialysis, of which 83% were on hemodialysis and 17% were on peritoneal dialysis. Compared to 2002 data, there was an increase of 15% in the number of patients undergoing dialysis.

Based on the 2003 data, there were 210 hemodialysis and 51 peritoneal dialysis centers nationwide. These dialysis clinics were either free-standing or institution-based. Pursuant to Executive Order No. 5, s. 1986 and Administrative Order No. 33-A s. 1994 entitled "Rules and Regulations Governing the Licensure and Regulation of Dialysis Clinics", the Department of Health (DOH) is mandated to license dialysis clinics in the country. However, majority of those dialysis centers were operating without a license.

Patients have the right to receive quality health service and this can only be achieved by having all the dialysis clinics comply with the licensing requirements set by the DOH. With the mandate of the Bureau of Health Facilities and Services to set and review regulatory policies and standards, A.O. No. 33-A, s. 1994 shall be amended to ensure the general public of quality service of the dialysis clinics and guide the facility owners with regards to the new licensing requirements.

**II
Scope**

These rules and regulations shall apply to all government and private, freestanding and institution-based dialysis clinics nationwide and describes the technical standards and requirements including the procedural guidelines leading to the licensure of these facilities.

**III
Definition of Terms**

Bureau - refers to the Bureau of Health Facilities and Services

Board Certified Nephrologist - diplomate or fellow of the Philippine Society of Nephrology.

Board Qualified/Eligible Physician - a physician who is a fellow/diplomate of the Philippine College of Physicians and has completed an accredited fellowship-training program in nephrology.

Dialysis - a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semi-permeable membrane. Currently, the two types of dialysis that are commonly in use are hemodialysis and peritoneal dialysis.

Dialysis Station - a designated portion of the dialysis patient treatment area that accommodates the equipment necessary to provide a hemodialysis and/or peritoneal dialysis treatment. This station must have sufficient area to house a chair or bed, the dialysis equipment, and emergency equipment if needed.

Dialysis Clinic - a health facility performing both peritoneal and/or hemodialysis to patients with kidney failure on an outpatient basis. It shall be referred to in this issuance as "Clinic".

Dialysis Technician - a person who, under the direct supervision of a licensed physician or a registered nurse, provides assistance in the treatment of patients who receive dialysis treatment for end stage renal disease.

License to Operate - a formal authority issued by the DOH to an individual, agency, partnership, corporation to operate a dialysis clinic.

Patient - a person admitted to and receiving care in the dialysis clinic.

Permit to Construct - requirement for construction, alteration, expansion or renovation of an existing dialysis clinic. It is a pre-requisite for the issuance of a license to operate.

Water Treatment - the process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets the provisions of the Association for the Advancement of Medical Instrumentation (AAMI) - "Standards for Water for Hemodialysis".

Secondary Care Hospital - (as defined in Administrative Order No. 147, s. 2004) - a departmentalized hospital that provides clinical care and management on the prevalent diseases in the locality, as well as particular forms of treatment, surgical procedure and intensive care.

IV Policies and Guidelines

A. CLASSIFICATION

A.1 According to ownership

A.1.1 Government - operated and maintained partially or wholly by the national, provincial, city or municipal government, or other political unit, or by any department, division, board or agency thereof.

A.1.2 Private - privately owned, established and operated with funds through donation, principal, investment, or other means, by any individual, corporation, association or organization

A. 2 According to institutional character

A.2.1 Institution based- a clinic that operates as part of a health institution (e.g. hospital, multi-specialty clinic, etc.) and is located within its premises

A.2.2 Free-standing - a clinic that operates independently. It may be located outside or inside the premises of a health institution

B. TECHNICAL REQUIREMENTS

B.1 Personnel - There shall be a sufficient number of qualified personnel to carry out the functions of the clinic, which are as follows:

B.1.1. A Board Certified Nephrologist shall be the head of the clinic. In areas where there is no Board Certified Nephrologist, as certified by the Philippine Society of Nephrology, a board-qualified physician shall be the head of the clinic for a maximum period of three (3) years. After this three-year period, a Board Certified Nephrologist must head the clinic.

The head of clinic or at least one of the clinic's medical staff shall be a member of at least a secondary care hospital medical staff in the locality to facilitate referral of complications that may arise from the dialysis procedure.

B.1.2 A Duty Physician who must meet the following requirements:

- Completed an accredited Internal Medicine Residency Program
- Experience in the care of patients with end stage renal disease
- Certificate of training on Basic and Advanced Life Support

He shall be physically available to patients during hours of operation. The ratio of duty physician to patient bed shall be 1:15.

B.1.3 Dialysis Nurse must meet the following requirements:

- Duly licensed
- Current member of Renal Nursing Association of the Philippines (ReNAP) or its equivalent
- Certified IV therapy nurse
- Hospital/clinical work experience for one (1) year
- Certificates of special training on dialysis for not less than thirty (30) days and on Basic and Advanced Life Support.

The ratio of nurse to patient bed shall be 1:4.

In cases where there is more than one (1) nurse, headship shall be by a chief nurse. The qualifications shall be based on the provisions of Republic Act 9173 known as the Philippine Nursing Act of 1992.

B.1.4 Technician shall have certificate of dialysis training and at least one (1) year experience in same field.

B.1.5 There shall be adequate number of administrative personnel to facilitate non-medical work in the facility.

B.1.6 A personnel record folder shall be maintained for each employee. The folder shall contain physical examination, laboratory test results, resume, and current job description that reflect the employee's responsibilities and work assignments.

B.2 Physical Plant

B.2.1 To provide adequate facilities for the cure and comfort of patients, watchers and personnel, each clinic must be planned and designed in a way that the clinic has the following areas listed below. The plan shall be prepared and signed by a licensed engineer or architect, and conforms to applicable laws.

B.2.1.1 Dialysis Service Complex

- Dialysis Station shall be designed to provide adequate space area and safe treatment as well as to ensure the privacy of patients. The area shall not be less than 8 meter² to accommodate a chair or bed, the dialysis equipment and emergency equipment if needed. Separate dialysis machine shall be designated solely for use of Hepatitis B and C patients.
- Nursing Station shall be located in an area that allows adequate surveillance of patients on dialysis machines. It shall also be the releasing area for post-hemodialysis patients.

- Storage area for sterile instrument/supplies and other materials
- Work area that contains a work counter, hand washing sink, storage cabinets
- Toilet facility for the staff/patients with urinal, water closet, and lavatory.
- Water treatment area
- Designated area for central sterilization
- Pre-treatment area and consultation area

B.2.1.2 Non-Treatment Area

- Business area for information service, admitting section, cashier
- Waiting area with sufficient seats for patients and visitors
- Pantry for hygienic purposes.

B.2.2 The facility shall be kept in good operating condition.

B.2.3 Water supply for all purposes shall be adequate in volume and pressure. Water used for dialysis purposes must be analyzed for bacteria at least monthly, for chemicals at least every six months and treated as necessary in accordance with the provisions of Association of Advancement of Medical Instrumentation (AAMI) to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques.

B.2.4 All plumbing shall be installed in such a manner as to prevent back flow or cross-contaminations between potable and non-potable water supplies.

B.2.5 The facility shall be provided with effective and suitable ventilation to maintain comfortable room temperature.

B.2.6 The facility shall be provided with sufficient intensity of illumination to provide effective nursing care.

B.3 Equipment/Supplies

B.3.1 The clinic shall be adequately equipped with the following to provide quality service to the patients and personnel:

- Stethoscope - 3 units*
- Sphygmomanometer - 3 units*
- * One each for regular, Hepatitis B+, and Hepatitis C+ patients
- Examining light
- Oxygen unit with gauge
- Minor surgical instrument set
- Instrument table
- Dialysis machine(s)