

**[ DOH ADMINISTRATIVE ORDER NO. 2012 – 0001,  
January 26, 2012 ]**

**NEW RULES AND REGULATIONS GOVERNING THE LICENSURE  
AND REGULATION OF DIALYSIS FACILITIES IN THE  
PHILIPPINES**

**I. RATIONALE/ BACKGROUND**

The Philippine Renal Disease Registry (PRDR) Annual Report for 2011 revealed that of the nine thousand seven hundred sixteen (9,716) patients that started dialysis in 2010, 9,133 (94%) patients were on hemodialysis (HD) and 583 (6%) patients on peritoneal dialysis (PD). There was an 8.9% increase in the number of patients on dialysis from 8,922 in 2009 to 9,716 in 2010.

A listing of dialysis facilities in 2010 as reported by the Renal Disease Control Program (REDCOP) showed a total of 423 dialysis facilities nationwide of which 355 were HD and 68 were PD facilities. To obtain a snapshot of the level of compliance of Hemodialysis Clinics (HDC), the Department of Health (DOH) through the Bureau of Health Facilities and Services (BHFS) conducted a rapid assessment in March 2009 of selected HDC which revealed gaps in standards and requirements such as, but not limited to: a) personnel (inadequate staff); b) equipment (use of refurbished machines with unknown manufacturing dates), supplies and materials (incomplete E-cart medicines, supplies and materials); and c) physical facility (inadequate space for mobility of staff, patients and relatives, and inadequate hand washing areas) that will assure the safety of the foregoing facilities.

Current regulatory issuances on this matter need to be enhanced and updated in order to address the gaps that were noted during the survey. One of these is entitled Administrative Order (A.O.) No. 163 s. 2004 entitled "Revised Rules and Regulations Governing the Licensure and Regulation of Dialysis Clinics in the Philippines" and A.O. No. 2006 – 0037, an Amendment of the same. This Order rescinds such issuance in line with the objective of health regulatory reforms to ensure access to safe, quality and affordable health facilities and dialysis services.

**II. OBJECTIVE**

This Order is promulgated to prescribe a revised minimum standard for HDC to ensure safe and effective HD treatments.

**III. SCOPE**

This Order shall apply to all government and private HDC in the Philippines. In cases where PD is also performed in an HDC, DOH through BHFS shall advocate PhilHealth accreditation standards and requirements on PD.

#### IV. DEFINITION OF TERMS

For purposes of this Order, the succeeding terms and acronyms shall have the following definitions:

1. Association for the Advancement of Medical Instrumentation (AAMI) – an organization which promotes knowledge and use of medical instrumentation. It creates standards, educates and certifies technicians, and publishes technical documents, books, periodicals and software. Its Recommended Practices and Standards are considered to be a major resource of healthcare guidelines and noncompliance with these standards is cited by regulatory organizations that inspect health care facilities.
2. Advanced Cardiac Life Support (ACLS) – a group of interventions used to treat and stabilize victims of life-threatening cardio-respiratory emergencies and to resuscitate victims of cardiac arrest. It also refers to a training course sponsored by the American Heart Association that instructs healthcare providers in the basic and advanced techniques of resuscitation.
3. Adverse Event – injury caused by medical management (and not necessarily the disease process) that either caused death, prolonged hospitalization, or produced a disability at the time of discharge.
4. Applicant – a natural or juridical person who is applying for a license to operate an HDC.
5. Bureau of Health Facilities and Services (BHFS) – the regulatory body of DOH charged with the licensing function under these rules and regulations.
6. Board Certified Physician – a physician who is a diplomate and/or a Fellow of a medical specialty and/or subspecialty society recognized by the Philippine Medical Association and certified to by the corresponding medical specialty and/or subspecialty board.
7. Board Eligible Physician – a physician who finished or completed an accredited medical specialty and/or subspecialty residency/fellowship training program which had been approved by the corresponding medical specialty and/or subspecialty board.
8. Center for Health development (CHD) – the regional office of DOH.
9. Certificate of Compliance (COC) – the certificate issued by REDCOP upon compliance of HDC to reporting and participation in PRDR. A COC issued by REDCOP to a participating dialysis unit is a pre-requisite to renewal of LTO.
10. 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. It is a cleansing process using dialyzing equipment (artificial kidney) and appropriately recognized procedures.
11. Dialysis Station – a designated portion of HDC that accommodates the materials and equipment necessary to provide HD. This station has a minimum area of at least 6 square meters capable of accommodating a dialysis chair or patient bed, a dialysis machine and emergency equipment should the need for it arise.
12. Department of Health (DOH)

13. Department of Health – Permit to Construct (DOH-PTC) – issued by DOH through BHFS to an applicant who will establish and operate an HDC upon compliance with required documents set forth in this Order prior to the actual construction of the subject facility. A DOH-PTC is also required for HDC with substantial alteration, expansion or renovation, or increase in the number of HD stations. It is a prerequisite to LTO.
14. End Stage Renal Disease (ESRD) – a now outdated term synonymous with “Stage V Chronic Kidney Disease”, a severe illness with poor life expectancy if untreated. It is the complete or almost complete failure of the kidneys to function.
15. Hemodialysis (HD) – a medical procedure whereby the patient’s blood is delivered by a machine to a dialyzer (blood filter) to remove metabolic wastes and restore fluid and electrolyte balance.
16. Hemodialysis Clinic (HDC) – the list of DOH licensed HDC is posted at DOH website [www.doh.gov.ph](http://www.doh.gov.ph)
17. License to Operate (LTO) – a formal authority issued by DOH to an individual, agency, partnership or corporation to operate a non-hospital based HDC.
18. One-Stop Shop (OSS) – a strategy of DOH to harmonize the licensure of hospitals, their ancillary and other facilities including, but not limited to, HDC. Under the One-Stop Shop, a hospital based HDC is not required to secure a separate LTO. The provision of HD in a hospital shall be reflected in the hospital LTO upon full compliance to this Order.
19. Peritoneal Dialysis (PD) – a means of dialysis using the peritoneum as a dialysis membrane.
20. Physician On Duty (POD) – the Physician On duty in an HDC.
21. Patient – refers to a person admitted to and receiving care in an HDC.
22. Patient Medical Record – a compilation of pertinent facts about a patient’s life and health history including past and present illnesses and treatment written by health care professionals caring for the patient.
23. Philippine Renal Disease Registry (PRDR) – a compilation of data of all dialysis patients in the country. It was institutionalized under the national epidemiology Center of DOH by virtue of A.O. No. 2009 – 0012.
24. Renal Disease Control Program (REDCOP) – the National Kidney Transplant Institute (NKTi) of DOH is the main implementing agency of REDCOP. The Renal Disease Control Program addresses all levels of renal disease prevention (health promotion, primary, secondary, tertiary prevention including prevention of death of ESRD patients through transplantation and organ donation) by conceptualizing planning, implementing projects and activities on research, training, advocacy, service and quality assurance.
25. Refurbished HD Machine – a pre-owned HD machine sent back to the supplier with capability to recondition and calibrate the unit to specifications that will ensure accuracy and safety.
26. Reverse Osmosis (RO) – a filtration method that removes many types of large molecules and ions from solutions by applying pressure to the solution when it is on one side of a selective membrane. The result is that the solute is retained on the pressurized side of the membrane and the pure solvent is allowed to pass to the other side. It represents the ultimate in ultra-filtration.
27. Water Treatment – the process of treating water used for HD

purposes in order to maintain a continuous water supply that meets the provisions of AAMI "Standards for Water for Hemodialysis."

## V. POLICIES

### A. GENERAL POLICIES

1. Hemodialysis (HD) shall be performed only in DOH licensed non hospital based HDC and hospital based HDC under the One-Stop Shop Licensure System for hospitals.
2. If Peritoneal dialysis (PD) is being performed in facilities regulated by DOH such as, but not limited to, hospitals and HDC, DOH shall advocate PhilHealth accreditation standards and requirements on PD.
3. All HDC shall participate in PRDR. All patients on HD shall be registered by these facilities to PRDR.
4. All HDC shall have a continuing patient education program that updates the patient on treatment options and kidney transplant.
5. All HDC shall have linkages with DOH accredited kidney transplant centers.
6. All HDC shall follow the standards, criteria and requirements prescribed in the assessment tool for licensure of HDC.
7. All HDC shall follow this Order and other related and future issuances by DOH.

### B. SPECIFIC POLICIES

#### 1. CLASSIFICATION OF DIALYSIS FACILITIES

##### a. ACCORDING TO OWNERSHIP

1. Government – operated and maintained, partially or wholly, by the national government, a local government unit (provincial, city or municipal), any other political unit or any department, division, board or agency thereof.
2. Private – owned, established and operated with funds through donation, principal, investment or other means by any individual, corporation, association or organization.

##### b. ACCORDING TO INSTITUTIONAL CHARACTER

1. Hospital based – a dialysis facility that operates within a hospital.
2. Non hospital based – a dialysis facility that operates outside of the hospital premises or on its own.

## 2. STANDARDS

Every HDC shall be organized to provide safe, quality, effective and efficient HD services.

### a. PERSONNEL

Every HDC shall have an adequate number of qualified, trained and competent staff to ensure efficient and effective delivery of HD services. The staff composition will depend on the workload and the services being provided.

#### 1. Head of HDC

a. Every HDC shall have a Medical Director who is duly licensed by the Professional Regulation Commission (PRC) and preferably is a nephrologist certified by the Specialty Board of the Philippine Society of Nephrology (PSN). The Philippine Society of Nephrology shall regularly provide DOH with an updated list of its board certified members.

b. The duties and responsibilities of HDC Medical Director are, but not limited to, the following:

1. Oversees the overall technical and medical operations of HDC;
2. Sees to it that all medical procedures are done in accordance with acceptable norms and standards of medical practice;
3. Develops and adopts internal medical protocol, policies and procedures on dialysis and related treatment in accordance with the standards formulated by DOH in coordination with PSN and oversees the implementation thereof;
4. Sets requirements on education and performance criteria for medical staff including hiring of the same;
5. Requires training program for HDC staff for certification, continuous improvement of skills and knowledge;
6. Oversees the conduct and completion of tasks within HDC;
7. Initiates, supports and implements Quality Assessment and Performance Improvement (QAPI) activities;
8. Ensures strict compliance to infection control and surveillance practices;
9. Assures water safety based on the standards of AAMI including, but not limited to, the following:

- a. Ensures programs and policies to ascertain safe mixing of water and dialysate;
- b. Ensures monitoring of safe water regulations and specifications;
- c. Ensures that the manufacturer or supplier of a complete water treatment and distribution system