



**Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU**

ASSESSMENT TOOL FOR LICENSING A DIALYSIS CLINIC

I. FACILITY INFORMATION

Name of Dialysis Clinic : _____

Complete Address : _____

No. & Street	Barangay
City/Municipality	Province
Contact Number	E-mail Address:
Name of Owner/Corporation	Region
Name of Medical Director	
Latest DOH License Number (if renewal):	
Number of Dialysis Stations:	

Classification: Government Hospital-Based
 Private Non-Hospital-Based

II. TECHNICAL REQUIREMENTS

Instruction: In the appropriate box, place a check mark (√) if the hemodialysis clinic (HDC) is compliant or x mark (X) if it is not compliant.

STANDARDS AND REQUIREMENTS	COMPLIANT	REMARKS
A. PERSONNEL		
Every Hemodialysis Clinic (HDC) shall have an adequate number of qualified, trained, and competent staff to ensure efficient and effective delivery of HD services.		
HEAD OF CLINIC		
For Nephrologist		
• Specialty Board Certificate		
• Valid PRC ID and PTR		
• Notarized Contract of Employment/MOA		
For Non-nephrologist		
• Valid PRC ID and PTR		
• Notarized Contract of Employment/MOA		
• Certificate of Employment from previous Employer (<i>at least 3 months experience</i>)		
• Certificate of training (<i>in accordance to PSN guidelines</i>)		
Shall visit at least once a week (documented) AND shall handle a maximum of three (3) HDCs.		
• Attendance Logbook		
• Notarized List of HDCs handled and corresponding work schedules		

	COMPLIANT	REMARKS
PHYSICIAN ON DUTY		
Physician: HD station ratio = 1:15 (Shall attend to patients within HDF under the supervision of the Head of Clinic		
For Nephrologist		
<ul style="list-style-type: none"> • Specialty Board Certificate 		
<ul style="list-style-type: none"> • Valid PRC ID and PTR 		
<ul style="list-style-type: none"> • Notarized Contract of Employment/MOA 		
For Non-nephrologist		
<ul style="list-style-type: none"> • Valid PRC ID and PTR 		
<ul style="list-style-type: none"> • Notarized Contract of Employment/MOA 		
<ul style="list-style-type: none"> • Certificate of Employment from previous employer (<i>at least three (3) months experience</i>) 		
Shall:		
<ul style="list-style-type: none"> • Have training in ACLS 		
<ul style="list-style-type: none"> • Be present during hours of operation 		
NURSE		
(NURSE:PATIENT/STATION RATIO 1:4)		
<ul style="list-style-type: none"> • Valid PRC ID 		
<ul style="list-style-type: none"> • Notarized Contract of Employment/MOA 		
<ul style="list-style-type: none"> • Certificate of training in the nursing care of renal dialysis patients from competent training providers. 		
<ul style="list-style-type: none"> • Certificate of training in Basic Life Support (BLS) conducted by competent authorities or professional organizations 		
<ul style="list-style-type: none"> • Schedule of Duty reflecting at least one nurse per shift with an updated training in Advanced Cardiac Life Support (ACLS) conducted by competent authorities or professional organizations 		
DIALYSIS TECHNICIAN		
<ul style="list-style-type: none"> • Certificate of training as Dialysis Technician 		
<ul style="list-style-type: none"> • Notarized Contract of Employment/MOA 		
MEDICAL RECORDS OFFICER (MRO)		
<i>There shall be a designate MRO.</i>		
<ul style="list-style-type: none"> • Certificate of Training on Medical Records Management (required for dialysis facility with more than twenty dialysis stations) 		
<ul style="list-style-type: none"> • Notarized Contract of Employment reflecting duties and responsibilities as Medical Records Officer 		
ADMINISTRATIVE STAFF		
<ul style="list-style-type: none"> • Notarized Contract of Employment 		
DESIGNATED REGULATORY COMPLIANCE OFFICER		
<ul style="list-style-type: none"> • Job description, duties and responsibilities 		
<ul style="list-style-type: none"> • Appointment/Designation paper 		
<ul style="list-style-type: none"> • Compilation of pertinent laws and DOH issuances 		

	COMPLIANT	REMARKS
B. PHYSICAL FACILITIES Every HDC shall have physical facilities with adequate areas to ensure the safety of staff, patients, and their relatives.		
HDC shall conform to applicable local and national regulations for the construction, renovation, maintenance and repair of the same.		
<ul style="list-style-type: none"> • Business Permit 		
<ul style="list-style-type: none"> • Occupancy Permit (for new HDC) 		
Every HDC shall conform to the required space for the conduct of its activities depending on its workload and the services being provided.		
<ul style="list-style-type: none"> • DOH-approved PTC 		
<ul style="list-style-type: none"> • DOH-approved floor plan 		
WATER TREATMENT ROOM (12.0 square meters)		
<i>Plumbing system delivers treated water to the individual dialysis machine. Two types:</i>		
1. <i>Direct feed single-pass RO system</i>		
2. <i>Indirect feed RO system (with holding tank)</i>		
Process Flow		
- Raw water storage tank		
- Multimedia filters tank		
- Softener		
- Carbon filter tank		
- Conventional bulk filters tank		
- Reverse Osmosis tank		
- Total Dissolved Solids (TDS) meter		
<ul style="list-style-type: none"> • Water treatment monitoring logbook • Allowable TDS 0-10 mg/L (ppm) 		
Written policies and procedures for storage of water and appropriate disinfection/sterilization method		
There shall be policy on proper maintenance and monitoring of physical facilities.		
<ul style="list-style-type: none"> • Pest and vermin control • Protocol on Housekeeping • Building/Clinic Maintenance Schedule • Equipment Maintenance Schedule 		
Raw water supply shall be adequate in volume and pressure. Likewise, potability and safety of water shall be monitored/ensured.		
<ul style="list-style-type: none"> • Monthly results of microbiological water analysis from three sampling points namely: <ul style="list-style-type: none"> 1. Raw water 2. Product water 3. Point of use 		
Requirements: <ul style="list-style-type: none"> ▪ HPC < 200 CFU/mL ▪ Fecal Coliform < 1.1 MPN/100 mL 		

	COMPLIANT	REMARKS
Periodic water analysis for Chemical Test at point of use shall be done before the initial operation of HDC and six (6) months thereafter. Laboratory result of chemical analysis done by DOH-recognized water testing laboratory for dialysis water.		
Corrective measure shall be undertaken in the area of the suspected cause for results which exceed AAMI water standard limit.		
<ul style="list-style-type: none"> HDC shall stop operating until corrective actions were taken and water analysis results are within AAMI standards 		
<ul style="list-style-type: none"> Record of maintenance/corrective action done 		
<ul style="list-style-type: none"> Repeat testing of affected parameter 		
The water for HD purpose shall be treated accordingly to maintain a continuous water supply that is biologically and chemically compatible with acceptable HD techniques. Regular replacement of RO membrane shall be done.		
DIALYZER REPROCESSING AREA (for HDC that reprocesses dialyzers)		
<ul style="list-style-type: none"> dialyzer rack re processor <ul style="list-style-type: none"> if manual (specify disinfectant soln.) 		
<ul style="list-style-type: none"> sterilizing oven <ul style="list-style-type: none"> citric acid specify period of sterilization and temp. 		
SERVICE SUPPORT AREA Properly labelled:		
<ul style="list-style-type: none"> Waste holding cubicle/area 		
<ul style="list-style-type: none"> Trash bins: 		
<ul style="list-style-type: none"> Green 		
<ul style="list-style-type: none"> Black 		
<ul style="list-style-type: none"> Yellow Hard plastic/puncture-proof container for sharp objects 		
<ul style="list-style-type: none"> Soiled linen cubicle/area hamper 		
<ul style="list-style-type: none"> Janitor's closet 		
<ul style="list-style-type: none"> mops 		
<ul style="list-style-type: none"> gloves 		
<ul style="list-style-type: none"> detergents 		
<ul style="list-style-type: none"> disinfectant 		
<ul style="list-style-type: none"> cleaning implements 		
<ul style="list-style-type: none"> Emergency/Standby generator area 		
<ul style="list-style-type: none"> Generator (not less than 20 KVA) appropriate to the size of the facility 		

	COMPLIANT	REMARKS
1. <u>NON-TREATMENT AREA OR RECEPTION AREA/SECTION</u>		
BUSINESS AREA		
Reception/Information Counter		
<ul style="list-style-type: none"> • Computer equipped with internet connection 		
<ul style="list-style-type: none"> • Digital weighing scale (can weigh patients in wheel chair) 		
C. EQUIPMENT/INSTRUMENTS, SUPPLIES, AND MEDICINES Every HDC shall have available and operational equipment, instruments, materials and supplies, and medicines . (Refer to Annex A of this Assessment Tool)		

III. FACILITY OPERATIONS

	COMPLIANT	REMARKS
<p>STANDARD OPERATING PROCEDURES</p> <p><i>Note: SOPs shall be duly approved by the Head of Clinic. All pages shall bear the initials of Head of Clinic.</i></p> <p>Documented Standard Operating Procedures (SOP) for the provision of HDC services and for the operation and maintenance of the facility shall include:</p> <ul style="list-style-type: none"> - HD treatment protocol - Reprocessing of dialyzers (for HD that reprocessed) - Treatment of water for HD - Prevention of hepatitis and other infections - Management of complications - Sterilization techniques - Management of infectious wastes - Patient referral and/or transfer to another facility <p>A Memorandum of Agreement (MOA) shall be entered into with a hospital capable of blood transfusion.</p>		
<p>HEALTHCARE WASTE MANAGEMENT</p> <p>Each HDC shall establish and implement a system for proper solid waste management which shall be in accordance with the revised DOH Manual on Health Care Waste Management and with Department of Environmental and Natural Resources - Environmental Management Bureau (DENR-EMB) relevant issuances, environmental laws, particularly R.A. 9003 (Ecological Solid Waste Management Act), the Environmental Sanitation Code, and other pertinent policy guidelines and/or issuances.</p> <p>Each HDC shall establish and implement a system for proper liquid waste management which shall be in accordance with the revised DOH Manual on Health Care Waste Management and other EMB-DENR policy guidelines and/or issuances.</p> <p>There shall be procedures for the proper disposal of infectious wastes and toxic and hazardous substances and the same shall be made in accordance with R.A. 6969 and other related policy guidelines and/or issuances.</p> <p>There shall be a "No Smoking" policy and the same shall be strictly enforced.</p> <p>"No Smoking" signages (receiving area, waiting area, pantry, toilet, and water treatment room)</p>		
<p>CONTINGENCY PLAN</p> <p>There shall be a contingency plan in case of accidents and emergencies including equipment breakdown.</p>		
<p>SCHEDULE OF RETENTION AND DISPOSAL OF RECORDS</p> <p>There shall be policy and procedures on schedule of retention and disposal of records and other relevant information whether paper-based or electronic (in accordance with issuances of DOH and other authorized agencies).</p>		
<p>QUALITY IMPROVEMENT ACTIVITIES</p> <p>HDC shall have policies and procedures on Quality Assurance Program (QAP) and Continuous Quality Improvement (CQI) reviewed periodically.</p> <p>The Quality Assurance Program (QAP) shall have written plan and its implementation shall be continuous with periodic reviews.</p> <ul style="list-style-type: none"> - Client Satisfaction Survey (e.g. comments, feedback) - Corrective Actions taken - Management meetings (with minutes of meetings) 		

	COMPLIANT	REMARKS
RECORDS/FILES		
Contents of Patient's Medical Records		
Summary of face sheet with patient identification data, diagnosis, physician's name and contact number, patient's address and phone number and date of admission, family member to be contacted in case of emergency and phone number.		
Dialysis chart with properly filled out data sheet		
Standing order for hemodialysis - updated quarterly		
Physician's order - Standing order shall be updated as deemed necessary.		
Informed consent form - updated annually and as deemed necessary.		
Laboratory and x-ray reports		
Clinical and graphic patient's vital signs		
Medication record		
Dietary assessment, updates, and progress notes		
Consultations, hospitalizations		
Nurse's notes for every dialysis session		
Problem list		
Clinical abstract		
Advance Directive, if any		
Documented patient education		
Hepatitis profile		
Patient's vaccination status:		
<u>The following are required:</u>		
- Hepatitis B vaccination at 0,1, 6 months		
- Booster dose for Hepatitis B		
- Routine post-vaccination testing thirty days after the last dose; Titer Result		
<u>The following are highly recommended:</u>		
- Influenza vaccination annually		
- Pneumococcal vaccination every five (5) years		
Complications/Adverse Events Logbook shall include, but not be limited to, the following format (Refer to Annex-C of A.O. No. 0012-0001):		
-Date		
-Name of Patient		
-Age		
-Complication Noted		
-Description of Incident/Time		
-Action taken		
-Disposition		
-Time		
-Signature of Nurse on Duty		
REDCOP Patient Registry Every HDC shall register its patients to PRDR in support of REDCOP of DOH and in coordination with PSN. For initial – Look for letter of intent to participate		
- Encoding should be done using required forms from REDCOP		
- Annual Statistical Report		
- Certificate of Participation/Proof of receipt of annual statistical report by REDCOP		

	COMPLIANT	REMARKS
Administrative Records		
Every HDC shall maintain the following:		
a. Minutes of the meeting		
b. Attendance logbook		
c. 201 files of personnel Resume		
Job description		
Physical Examination		
Laboratory test results		
Certificates of training		
Record of personnel vaccination:		
1. Hepatitis B vaccination at 0,1,6 months		
2. Routine post-vaccination testing thirty days after the last dose		
2. Influenza vaccination annually		
3. Pneumococcal vaccination every five (5) years		
d. Reports of DOH inspection and monitoring		
Technical Records/Logbook		
-Records showing that the RO Systems are properly maintained and monitored by licensed and reputable companies		
- Logbook/Records on efficiency/machine hours of HD machines		
- Inventory card of each HD machine to determine the dates of manufacture		
- Date of acquisition and installation		
- Schedule of calibration of HD machine/equipment		
- Logbooks/Records of preventive and corrective maintenance of HD machine/equipment.		
TRANSFER AGREEMENT/REFERRAL SYSTEM		
Record of transfer/referral of patient to another facility		



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ANNEX A – List of Equipment, Instruments, Supplies, and Medicines

	MINIMUM REQMNT	COMPLIANT		MINIMUM REQMNT	COMPLIANT
EQUIPMENT			EQUIPMENT		
HD Machine	1		Thumb forceps		
• Presence of manufacturing date			Oxygen tank with holder (with gauge and humidifier)	1	
• Not more than 10 years or 30,000 machine hours			Portable suction device	1	
• Certificate of Warranty			Stretcher and gurney	1	
• Proof of purchase			Trolley for oxygen tank	1	
• Machine Manual					
• Calibration certificate from recognized calibration facility					
Dialysis chair(s) capable of full recline and Trendelenburg position or patient bed(s), (90cmx70cm) with guard rails or its equivalent	1		E-CART WITH BASIC EQUIPMENT/ INSTRUMENTS		
Refrigerator with non-mercurial thermometer (exclusive for medicines)	1		Airway adjuncts (oropharyngeal and nasopharyngeal airways)	1	
Fire extinguisher	1		Airway intubation kit: - Bag-valve-mask device (adult set)	1	
Foot stool	1		- Endotracheal tube (size 7.5-8)		
Floor lamp (droplight or gooseneck)	1		- Laryngoscope, adult set		
IV stands/poles	1		Calculator	1	
Mayo table with tray	1		Cardiac board	1	
Minor surgical set:	1		Cardiac / ECG leads	1	
Kelly forceps, curved, 6 inches			Defibrillator with cardiac monitor and pulse oximeter	1	
Knife handle with blade			Glucometer with strips	1	
Mayo scissors, curved, 8 inches			Nebulizer	1	
Mayo scissors, straight, 8 inches			Penlight or flashlight	1	
Metal tray cover, 8 inches x 12 inches			Stethoscope	1	
Metzenbaum scissors, 8 inches			Sphygmomanometer	1	
Mosquito forceps, curved			Thermometer	1	
Needle holder, 8 inches					
Skin retractors					
Tissue forceps, with teeth					
Tissue forceps, without teeth					

	MINIMUM REQMNT	COMPLIANT		MINIMUM REQMNT	COMPLIANT
BASIC SUPPLIES					
Adhesive plaster			Oxygen tubing		
Alcohol, 70%			Povidone-iodine antiseptic solution		
Asepto syringe, 50 ml			Protective face shields or masks		
Gloves, different sizes, sterile and clean			Standard face mask		
Hydrogen peroxide			Water-proof aprons		
IV cannula			Sterile gauze		
IV line			Sutures		
Nasal cannula			Test Strip for residual dialyser disinfectant		
Nasogastric tube					
EMERGENCY DRUGS					
Amiodarone 150mg/ampule	2 ampules		Intravenous Fluids: -D5 0.3 NaCl 500 ml/bottle	2 bottles	
Aspirin USP grade 325mg/tablet	6 tablets		-D5LR 1 L bottle	2 bottles	
Atropine Sulfate 1 mg/ml ampule	10 ampules		-D5NM 500 ml bottle	2 bottles	
B-Adrenergic agonists-salbutamol 2mg/ml	5 ampules		-D5NSS 1 L bottle	2 bottles	
Benzodiazepine [diazepam 10 mg/2 ml ampule and/or midazolam]	4 ampules		-D5W 250 ml bottle	2 bottles	
Calcium Gluconate, 10 mg/ampule	2 ampules		Lidocaine, 5% 1g/50ml	2 vials	
Caloric agent, D50W 50 ml/vial	5 vials		Mefenamic acid 500 mg/tab	4 tablets	
Clonidine 75 mg tablet	10 tablets		Nitroglycerine spray or isosorbide dinitrate 5 mg/tablet	10 tablets	
Diphenhydramine maleate, 50 mg/amp	10 ampules		Noradrenaline 2 mg/ampule	4 ampules	
Digoxin 0.5 mg./ampule	2 ampules		Paracetamol 300 mg/ampule	4 ampules	
Dobutamine 250 mg./20 ml vial	2 vials		Phenobarbital IV or tablet Grains 60mg or 30 mg	4 ampules/ 4 tablets	
Dopamine 200mg/vial	2 vials		Sodium Bicarbonate 50 mEq/ampule	4 ampules	
Epinephrine 1 mg/ml ampule	10 ampules		Terbutaline 0.5 mg/ampule	2 ampules	
Hydrocortisone IV	4 vials		Tramadol 50 mg tablet	5 tablets	



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Name of Dialysis Clinic _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

For issuance of License as Hemodialysis Clinic.

Number of Stations _____ Classification _____

Validity from _____ to _____

Issuance depends upon compliance to the recommendations given and submission of the following within _____ days from the date of inspection:

Non-Issuance : Specify _____

Inspected by:

Name	Position/Designation	Signature
_____	_____	_____
_____	_____	_____
_____	_____	_____

Received by:

Signature _____
Name _____
Position/Designation _____
Date _____



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Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

B. For Monitoring Process:

Issuance of Notice of Violation

Non-issuance of Notice of Violation

Others (Specify) _____

Monitored by:

Printed Name

Signature

Position/Designation

Received by:

Signature _____

Printed Name _____

Position/Designation _____

Date _____