

Guidelines for Dialysis Centre

**Directorate General of Health Services
Government of India**

Introduction

Table of Contents

Sr. No.	Particulars	Page No.
1.	Definition	3
2.	Scope	3
3.	Infrastructure	3
4.	Equipments	5
5.	Human Resource	5
6.	Legal/Statutory Requirements	7
7.	Record Maintenance and Reporting	7
8.	Basic process	7
9.	Annexure 1: Minimum space for hemodialysis centre	9
10.	Annexure 2: Furniture and Fixtures	10
11.	Annexure 3: Equipments	11
12.	Annexure 4: Drugs, Medical Devices and Consumables	12
13.	Annexure 5: List of Legal Requirements	14
14.	Annexure 6: Records	16
15.	Annexure 7: Patients' rights and responsibilities	17
16.	Annexure 8: Informed Consent / Consent Guidelines	18

Dialysis Centre

1. Definition

A Dialysis Centre is a clinical establishment that provides the treatment of patients with renal failure. Sometimes patients with normal renal functions also require hemodialysis like patients with some poisoning. Treatment procedures require professional supervision by staff experienced in renal pathophysiology. The Dialysis Centre may serve either or both inpatients and outpatients, depending upon the medical facility type, and may provide self-dialysis training and care for Peritoneal Dialysis in addition to hemodialysis. The Dialysis Centre administers both single-patient and multi-patient Haemodialysis systems.

Dialysis is a type of renal replacement therapy which is used to provide an artificial replacement for lost kidney functions. There are two main forms of dialysis, Hemodialysis and Peritoneal Dialysis, both of which are life support treatments; but dialysis does not treat kidney diseases. Dialysis may be used for patients who have recently lost kidney functions (acute renal failure) or for patients who have permanently lost kidney functions (chronic or end-stage renal failure).

2. Scope

The scope of services of dialysis centre may include:

1. Acute Haemodialysis
2. Chronic Haemodialysis
3. Hemofiltration and other similar modalities to adult and paediatric patients
4. Peritoneal dialysis

3. Infrastructure Requirements:

3.1	Signage
3.1.1	The Dialysis Centre shall display appropriate signage which shall be in at least two languages
Following informative signage shall be displayed:	
3.1.2	Name of the care provider with registration number
3.1.3	Registration details of the hospital as applicable
3.1.4	Availability of fee structure of the various services provided
3.1.5	Timings of the Dialysis centre and services provided
3.1.6	Important contact numbers such as Blood Banks, Fire Department, Police and Ambulance Services available in the nearby area.
3.1.7	Patients' rights & responsibilities.

Following safety signage shall be displayed:	
3.1.8	Safety Hazard and Caution signs, for e.g. hazards from electrical shock, inflammable articles, radiation etc shall be displayed at appropriate places, and as applicable under law.
3.1.9	Appropriate Fire exit signage.
3.1.10	Signage for “No Smoking” in prominent places
3.2.	Other requirements
3.2.1.	Access to the Dialysis Centre shall be comfortable for the patient and/or attendants/visitors.
3.2.2.	The Centre shall be developed and maintained to provide safe, clean and hygienic environment for patients, their attendants, staff and visitors
Dialysis Service Complex	
3.2.3.	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 6 square meters to accommodate a bed or chair, the dialysis equipment and emergency equipment if needed.
3.2.4.	Separate hemodialysis area shall be designated solely for use of Hepatitis B patients. Current understanding for Indian set-up is that for HCV infected patients also isolation is required.
3.2.5.	Nursing station shall be located in an area that allows adequate surveillance of patients on <i>hemodialysis machines</i> . It shall also be the releasing area for post-hemodialysis patients.
3.2.6.	There shall be storage area for sterile instrument/supplies and other materials.
3.2.7.	There shall be work area that contains a work counter, hand washing sink, storage cabinets.
3.2.8.	There shall be designated water treatment area and toilet facility for the staff/patients with urinal, water closet, and lavatory.
3.2.9.	There shall be a designated area for CAPD training for patient and her/his family member.
Non-Treatment Area	
3.2.10	The centre shall have reception area for information service, admitting section, cashier etc.
3.2.11	The centre shall have waiting area with sufficient seats for patients and visitors.
3.2.12	The centre shall have 24 hour provision of potable water for drinking & hand hygiene. It shall also have 24 hour supply of electricity, either through direct supply or from other sources.
3.2.13	The centre shall have provision for analysis of water used for haemodialysis purposes for bacteria at least monthly, for chemicals at least every six months and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable hemodialysis techniques.
3.2.14	All plumbing shall be installed in such a manner as to prevent back flow or cross-contamination between potable and non-potable water supplies.
3.2.14	The Dialysis centre shall be provided with effective and suitable

	ventilation to maintain comfortable room temperature.
3.2.15	The centre shall be provided with sufficient intensity of illumination to provide effective nursing care.
3.2.16	The centre shall have clean public toilet(s) separate for males and females.
3.2.17	The centre shall have appropriate internal and external communication facilities.
3.2.18	Furniture and fixtures shall be available in accordance with the activities and workload of the centre. They shall be functional and properly maintained.
	<i>The minimum space requirements shall be as per Annexure 1</i>
	<i>Indicative list of furniture and fixtures is as per Annexure 2</i>

4. Medical Equipment and Instruments:

4.1	The Centre shall have adequate medical equipment and instruments, commensurate to the scope of service and number of beds.
4.2	There shall be established system for maintenance of critical Equipment
4.3	All equipment shall be kept in good working condition through a process of periodic inspection, cleaning and maintenance. An equipment log-book shall be maintained for all the major equipment.
	<i>Indicative list of medical equipment and instruments is as given in Annexure 3.</i>

5. Drugs, Medical devices and Consumables:

5.1	The centre shall have adequate drugs and consumables commensurate to the scope of services and number of beds
5.2	Emergency drugs and consumables shall be available at all times.
5.3	Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations.
5.4	The centre shall have defined procedures for storage, inventory management and dispensing of drugs in pharmacy and patient care areas.
	<i>Indicative list of drugs, medical devices and consumables is as given in Annexure 4.</i>

6. Human Resource Requirements:

6.1.	A Qualified Nephrologist, having DM or DNB in nephrology or its equivalent degree shall be the head of the centre. In areas where there is no Qualified Nephrologist, a certified trained dialysis physician (as per local law and regulation) shall be the head of the centre.
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6.2.	The centre shall have qualified and/or trained medical staff as per the scope of service provided and the medical care shall be provided as per the requirements of professional and regulatory bodies
6.3.	The centre shall have qualified and/or trained nursing staff as per the scope of service provided and the nursing care shall be provided as per the requirements of professional and regulatory bodies
6.4.	The support/paramedical staff shall be qualified and/or trained as per the scope of services provided, and as per the requirement of the respective professional or regulatory bodies.
6.5.	For every staff (including contractual staff), there shall be personal record containing the appointment order, documentary evidence of qualification and/or training (and professional registration where applicable).
6.6.	Periodic skill enhancement/updation/refresher training shall be provided for all categories of the staff as relevant to their job profile, as prescribed by professional bodies and as per local law/regulations.

7. Support Services:

Registration/Help desk and Billing:	
7.1.	The Centre shall have a Registration/ Help-desk & Billing counter, and the scope of this shall also include provision of patient guidance in matters like services available, cost estimation, healthcare insurance etc.
CSSD / Sterilization Area	
7.2.	Provision for instrument and linen sterilization and storage of sterile items shall be made available as per the scope of services.
7.3.	Validation of Sterilization shall be done for ensuring the effectiveness of sterilization process
Linen management:	
7.4.	Soiled linen shall be collected, transported and washed separately in clean and hygienic environment.
7.5.	Where linen is contaminated, appropriate decontamination shall be carried prior to despatch for washing.
Waste Management Services:	
7.6.	Segregation, collection, transportation, storage and disposal of biomedical waste shall be as per Bio medical waste handling rules.
7.7.	Waste management guidelines shall be followed in the case of Mercury & other toxic materials as per applicable local laws.
7.8.	Segregation, collection, transportation, storage and disposal of general waste shall be as per applicable local laws
Medical Gas	
7.9.	Oxygen for medical use shall be available. In addition other gases like Nitrous oxide, Carbon dioxide etc. may be available in consonance with the scope of services and bed strength.
7.10.	Medical gases shall be stored and handled in a safe manner.
7.11.	All applicable legal requirements shall be complied with.
7.12.	Appropriate back-up and safety measures shall be in place to ensure patient

	safety at all times.
Ambulance services	
7.13.	The Centre shall have provision of transporting patients for transfer/referral/investigations etc in safe manner.
7.14.	The ambulance service shall be in-house and shall comply with the applicable local laws.
7.15.	Critical patient shall be transported under supervision of trained and qualified staff.

8. Legal/Statutory Requirements:

8.1	Every application must be accompanied with the documents confirming compliance with local regulations and law.
	<i>Indicative list is as per Annexure 5.</i>

9. Record Maintenance and reporting:

9.1	The minimum medical records to be maintained and nature of information to be provided by the Hospitals shall be as prescribed in CG 2 Annexe as per Section 12 (1) (iii) of this Act
9.2	Medical Records may be maintained in physical or digital format.
9.3	Confidentiality, security and integrity of records shall be ensured at all times
9.4	The medical records of IPD patients shall be maintained in consonance with National or local law, MCI guidelines, and court orders.
9.5	Every Hospital shall maintain health information and statistics in respect of national programmes, notifiable diseases and emergencies/disasters/epidemics and furnish the same to the district authorities in the prescribed formats and frequency.
	<i>For records a Dialysis Centre shall maintain please refer to Annexure 6</i>

10. Basic Process:

Registration / help desk and billing services	
10.1.	The hospital shall register all patients who visit the hospital except if the required services are not available in the facility, in which case the patient is guided to the appropriate nearest facility. (Please also see Emergency Services)
10.2.	Once registered, depending on the clinical need, patient is guided to appropriate service area like OPD, ER etc
10.3.	Patient shall be guided and informed regarding Patients' rights & responsibilities, cost estimates, third party services (e.g. Insurance) etc. Annexure-7
10.4.	The billing shall be as per the Hospital tariff list, which shall be available to patients in a suitable format.
10.5.	Each centre shall have a Memorandum of Agreement with one or more

	hospitals, with service capability of at least a secondary care hospital, for the provision of in-patient care especially emergencies and other hospital services. However, the patients or their relatives should be allowed to choose which hospital to patronize.
10.6.	Each patient shall undergo an initial assessment by qualified and/or trained personnel.
10.7.	In case of non-availability of beds or where clinical need warrants, the patient shall be referred to another facility along with the required clinical information or notes
10.8.	Any examination, treatment or management of female patient shall be done in the presence of an employed female attendant/female nursing staff, if conducted by male personnel inside the hospital and vice versa.
Informed Consent Procedure	
10.9.	Informed consent shall be obtained from the patient/ next of kin/ legal guardian as and when required as per the prevailing Guidelines / Rules and regulations in the language patient can understand. <i>Please refer to Annexure 8</i>
10.10.	Patient and/or families shall be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials.
10.11.	All the relevant documents pertaining to the procedures performed shall be maintained in the record, including the procedure safety checklist.
10.12.	Monitoring of patient shall be done during and after the procedures and same shall be documented.
10.13.	Staff involved in direct patient care shall receive basic training in CPR
10.14.	Patients shall be monitored after medication administration and adverse drug reaction/events if any shall be recorded and reported (please refer http://cdsco.nic.in/adr3.pdf).
10.15.	The centre shall follow standard precautions like practicing hand hygiene, use of personal protection equipment, etc to reduce the risk of healthcare associated infections.
10.16.	Regular cleaning of all areas with disinfectant shall be done as per prescribed & documented procedure.
10.17.	Housekeeping/sanitary services shall ensure appropriate hygiene and sanitation in the hospital.
10.18.	Security and safety of patients, staff, visitors and relatives shall be ensured by provision of appropriate safety installations and adoption of appropriate safety measures.
10.19.	The Hospital shall undertake all necessary measures, including demonstration of preparedness for fire and non-fire emergencies, to ensure the safety of patients, attendants, staff and visitors. (Please also see section on Infrastructure, Security and Fire)
10.20.	All applicable fire safety measures as per local law shall be adopted. This includes fire prevention, detection, mitigation, evacuation and containment measures. Periodic training of the staff and mock drills shall be conducted and the same shall be documented. This is desirable.
10.21.	A Discharge summary shall be given to all patients discharged from the centre.

ANNEXURE 1

Minimum space for hemodialysis centre shall be as follows:

S.no.	Area	Minimum requirement
Registration Area		
1.	Reception Area	30 sq mtrs
2.	Waiting Area	
	Public Utilities	
Treatment Room		
3.	Bed Space	80 sq mtrs
4.	Procedure Room	
5.	Staff Changing Room	
6.	Dirty Utility	
7.	Clean Utility/Store	
8.	Dialyzer cleaning area	
9.	Toilet	
10.	Store Room	
11.	CAPD training area	
12.	Store & Pharmacy	
Administrative Department		
13.	Accounts Office	20 sq mtrs
14.	Medical Records	
Water treatment Area		
15	RO Plant	20 sq mtrs
16	Water Pump	
Generator Area		
17.	Generator	5 sq mtrs

Annexure 2

FURNITURE AND FIXTURES

S.N	ARTICLES
1.	Examination Table
2.	Writing tables
3.	Chairs
4.	Almirah
5.	Waiting Benches
6.	Medical Beds
7.	Wheel Chair/Stretchers
8.	Medicine Trolley, Instrument Trolley
9.	Screens/curtains
10.	Foot Step
11.	Bed Side Table
12.	Stool
13.	Examination Lamp
14.	View box
15.	Fans
16.	Tube Light/ lighting fixtures
17.	Wash Basin
18.	IV Stand
19.	Colour coded bins for BMW

****this is an indicative list and the items shall be provided as per the size of the hospital and scope of service.***

Annexure 3**EQUIPMENTS****a. Emergency Equipment**

Sr No	Name of Emergency Equipment
1	Resuscitation equipment including Laryngoscope, endotracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag- Adult & Paediatric (neonatal if indicated)
2	Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs
3	Suction Apparatus
4	Defibrillator with accessories
5	Equipment for dressing/bandaging/suturing
6	Basic diagnostic equipment- Blood Pressure Apparatus, Stethoscope,, weighing machine, thermometer
7	ECG Machine
8	Pulse Oximeter
9	Nebulizer with accessories

b. The other equipment shall also be available in good working condition as per the scope of services and bed strength Indicative list given below.

Sl. No.	Equipment
Essential Equipment	
1.	Stethoscope
2.	Sphygmomanometer
3.	Examining light
4.	Oxygen unit with gauge
5.	Minor surgical instrument set
6.	Instrument table Page 3 of 5
7.	Goose neck lamp
8.	Standby rechargeable light
9.	ECG machine
10.	Suction machine
11.	Defibrillator with cardiac monitor
12.	Stretcher
13.	Wheelchair
14.	Hemodialysis Equipment
15.	Haemodialysis Set
16.	Monitor
17.	Pulse Oxymeter

ANNEXURE 4**DRUGS, MEDICAL DEVICES AND CONSUMABLES****a. List of Emergency Drugs and consumables (Essential in all hospitals)**

Sl. No.	Name of the Drug
	<i>INJECTIONS</i>
1.	INJ. DIAZEPAM 10 MG
2.	INJ. FRUSEMIDE 20 MG
3.	INJ. ONDANSETRON 8 MG/4ML
4.	INJ. RANITIDINE
5.	INJ NOR ADRENALINE 4 MG
6.	INJ. PHENYTOIN 50 MG
7.	INJ DICLOFENAC 75 MG
8.	INJ. DERIPHYLLINE
9.	INJ CHLORPHENIRAMINE MALEATE
10.	INJ. HYDROCORTISONE 100 MG
11.	INJ. ATROPINE 0.6 MG
12.	INJ. ADRENALINE 1 MG
13.	INJ. KCL
14.	STERILE WATER
15.	INJ. SODA BICARBONATE
16.	INJ. DOPAMINE
17.	INJ. NALAXONE 400 MCG
18.	INJ. LIGNOCAINE 50 ML
	<i>OTHER</i>
19.	NEB. SALBUTAMOL2.5 ML
20.	NEB. BUDESONIDE
21.	LIGNOCAINE JELLY 2%
	<i>FLUIDS</i>
22.	RL 500 ML
23.	NS 500 ML

24.	NS 250 ML
25.	NS 100 ML
26.	DNS 500 ML
27.	DEXTROSE 5% 500 ML
28.	DEXTROSE 10% 500 ML
29.	PEDIATRIC IV INFUSION SOLUTION 500 ML

b. The other drugs and consumables shall be available as per the scope of services, bed strength and patient turnover.

Annexure 5

LIST OF LEGAL REQUIREMENTS

Below is the list of legal requirements to be complied with by a hospital a applicable by the local/state health authority (all may not be applicable):

Sl.	Name of Document	Valid From	Valid Till	Send for renewal by	Remark (Expired/ valid/NA)
1.	Registration under Nursing Home Act/ Medical Establishment Act				
2.	Bio-medical Waste Management Licenses				
	Authorization of HCO by PCB				
	MOU with Vendor				
3.	NOC from Fire Department				
4.	Ambulance				
	Commercial Vehicle Permit				
	Commercial Driver License				
	Pollution Control Licenses				
5.	Building Completion Licenses				
6.	Lift licences for each lift				
7.	DG Set Approval for Commissioning				

8.	Diesel Storage Licenses				
9.	Medical Gases Licenses/ Explosives Act				
10.	Clinical Establishments Act Registration (if applicable)				
11.	MoU / agreement with outsourced human resource agencies as per labor laws				
12.	Electricity rules				
13.	Provident fund/ESI Act				
14.	Salex Tax registration				
15.	PAN				
16.	No objection certificate under Pollution Control Act (Air/Water)				
17.	Wireless operation certificate from Indian P&T				
18.	Arms Act, 1950 (if guards have weapons)				

Annexure 6

A dialysis centre shall maintain a record system to provide readily available information on:

1. Patient care
 - a. Dialysis charts
 - b. Standing order for hemodialysis – updated quarterly
 - c. Physician's order
 - d. Completed consent form
 - e. Patient's monitoring sheet
 - f. Standing order for medication
 - g. Laboratory results
 - h. Confinements with corresponding date and name of hospital
 - i. History and physical examination
 - j. Complication list
 - k. Transfer/referral slip (for patients that will be transferred or referred to another health facility)
2. Incident and accident (in logbooks)
 - a. Complications related to dialysis procedure
 - b. Complications related to vascular access
 - c. Complications related to disease process
 - d. Dialysis adequacy of patients on thrice weekly treatments
 - e. Outcomes
 - f. Staff/patient's hepatitis status
3. Staff and patient vaccination
 - a. Hepatitis B (double dose) – 0, 1,2,6 months
 - b. Influenza – annually
 - c. Pneumococcal – every 5 years
4. Water treatment
 - a. Bacteriological
 - b. Chemical
5. Facility and equipment maintenance schedule
 - a. Preventive maintenance
 - b. Corrective measures

ANNEXURE 7

Patients' rights and responsibilities:

Patients' Rights

A patient and his/her representative has the following rights with respect to the Dialysis Centre-

1. To adequate relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs;
2. Rate of services provided by the Dialysis Centre would be displayed prominently.
3. To access a copy of case papers, patient records, investigations reports and detailed bill
4. To informed consent prior to specific tests/treatment (e.g. surgery, chemotherapy)
5. To seek second opinion from an appropriate clinician of patients' choice, with records and information being provided by treating hospital
6. To confidentiality, human dignity and privacy during treatment.
7. To have ensured presence of a female person, during physical examination of a female patient by a male practitioner
8. To non-discrimination about treatment and behaviour on the basis of HIV status
9. To choose registered pharmacy or registered diagnostic centre/laboratory with qualified personnel from which to avail service
10. To choose alternative treatment if options are available
11. To seek redressal in case of grievance related to services provided by the establishment
12. Rate of services provided by the Dialysis Centre would be displayed prominently.

Patients' Responsibilities

- Provide health related information
- Cooperate with Doctors during examination, treatment
- Follow all instructions
- Pay hospitals agreed fees on time
- Respect dignity of doctors and other hospital staff
- Never resort to violence

Annexure 8

INFORMED CONSENT / CONSENT GUIDELINES

The informed consent shall at the least contain the following information in an understandable language and format.

Sl. No.	Content
1.	Name of the patient/ guardian (in case of minor/mentally disabled).
2.	Registration number of patient
3.	Date of admission
4.	Name & Registration number of treating doctor
5.	Name of procedure/operation/investigation/blood transfusion /anaesthesia/ potential complications
6.	Signature of patient/guardian with date and time