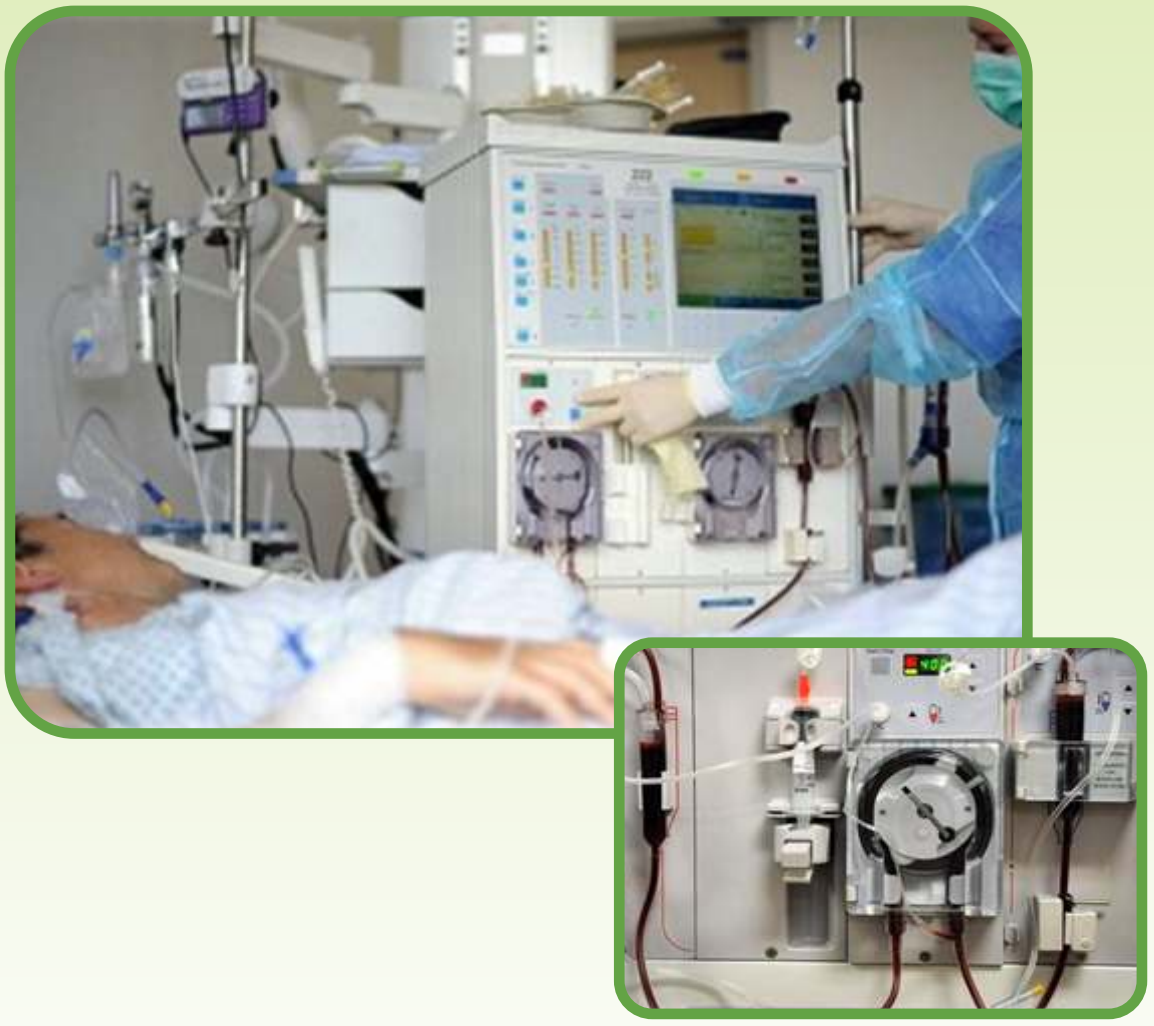
सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

NATIONAL DIALYSIS PROGRAM
UNDER
NATIONAL HEALTH MISSION



Ministry of Health & Family Welfare
Government of India

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NATIONAL DIALYSIS PROGRAM
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जगत प्रकाश नड्डा
Jagat Prakash Nadda

स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India

MESSAGE

Health remains a key priority within social sectors and Government of India provides key focus on social and rural sectors as evident in the Union Budget, 2016-2017. The burden of Non-Communicable Diseases (NCDs) has been alarmingly increasing and was flagged in the special UN convention for Health. All member countries were urged to provide adequate importance to various programs for preventive and curative aspects of the NCDs. End stage renal disease is a result of several NCDs. While our efforts would continue towards prevention and management of NCDs in initial stages, providing access to dialysis care to treat End Stage Renal Disease would be our key priority. At present, lack of dialysis services particularly in Tier 2 and Tier 3 cities and prohibitive cost of dialysis services act as major barrier to access and utilise hemodialysis services.

2. I am happy to state that within a month of budget announcement, Union Ministry of Health & Family Welfare has put in place program guidelines for implementing the National Dialysis Program in district hospitals on PPP mode. While strengthening the district hospitals, this program would provide a great relief to ESRD patients, as dialysis is a life time requirement for such patients. We hope to roll out this initiative in the current financial year in a large number of district hospitals and save lives, besides averting financial catastrophe.

(Jagat Prakash Nadda)

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सचिव
B.P. SHARMA
Secretary

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

MESSAGE

In the Budget speech 2016-2017, the Union Finance Minister announced the launch of a National Dialysis Program under Public Private Partnership at District Hospitals. Every year about 2.2 Lakh new patients of End Stage Renal Disease (ESRD) get added in India resulting in additional demand for 3.4 Crore dialysis every year. High cost of Dialysis care leads to financial catastrophe for practically all families with such patients. With substantial gain in quality of life and extension of progression free survival for patients, families continue to stretch financially to make large out of pocket spends. It has been felt that both in terms of provision of this important life saving procedure close to the community and also for reducing impoverishment on account of out of pocket expenditure for patients, a Dialysis program is required.

Ministry of Health & Family Welfare with technical support from National Health Systems Resource Centre has prepared a brief program introduction along with model tender documents. I urge all States/UTs to incorporate this important program under the National Health Mission.

(B.P. SHARMA)

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सत्यमेव जयते

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निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI-110011

FORWEORD

Strengthening of District Hospitals has been a key priority under the National Health Mission so that people can receive affordable multi-speciality care close to their place of stay. Providing dialysis services in district hospitals would be an important step in this direction. End Stage Renal Disease continues to be a result of existing and emerging burden of non-communicable disease. Providing for renal transplant facilities for ESRD patients depends upon availability of infrastructure and robust organ donation system coupled with adequate availability of trained qualified manpower. Within the limited choices, dialysis practically remains the first and in majority of cases, the only choice for ESRD patients.

To gain from available capacity of private sector existing in dialysis care segment and their capability to install and operate dialysis care system in quick time, and compliment the emerging strengths of public sector such as availability of drugs and diagnostics, it has been proposed that Dialysis program be undertaken in Public Private Partnership. The envisaged program will also boost the district hospitals strengthening mandate of the NHM.

To facilitate quick and easy roll out, the MOHFW with the support of NHSRC and inputs from experts and state governments, has prepared a small document of National Dialysis Programme including the draft model tender document for guidance of the states/ UTs. I request states/UTs to roll out the programme under the NHM on priority and adopt the tender document with suitable modifications, as appropriate to suit their context.

(C.K. Mishra)

New Delhi
5th April, 2016

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन
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सत्यमेव जयते

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निर्माण भवन, नई दिल्ली - 110011
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Ministry of Health & Family Welfare
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FORWEORD

Hon'ble Prime Minister, in his address after the presentation by Secretaries' Group on Health and Education, desired that a mechanism should be worked out to provide improved access to dialysis services. Accordingly, the Ministry started working on it in the right earnest with support from the National Health Systems Resource Centre. Relevant models on Dialysis services being practiced under PPP mode were studied. These included models of West Bengal, Kerala, Karnataka, Mumbai and Delhi NCR. Further, a consultation with experts in this field including from AIIMS & PGIMER as well as private service providers was held in the Ministry of Health & Family Welfare to discuss the modalities of envisaged program. Draft RFP and Service Level Agreement for the Dialysis in the PPP mode in the district hospitals were shared with the states for their inputs and have been finalized after incorporating their suggestions. The Ministry is also working simultaneously to strengthen the screening and timely intervention for the NCDs such as diabetes and hypertension, so that end stage kidney disease is prevented to the extent possible.

The model tender document to support dialysis services was prepared to facilitate states in undertaking contractual agreements to implement the services without delay. It is suggested that the states include National Dialysis Programme proposal in their main/ supplementary Program Implementation Plan for 16-17. We look forward to your feedback on the document as well as sharing your learning while using them for implementing the services.

(Manoj Jhalani)

Inputs from Following Experts are Gratefully Acknowledged

Shri C K Mishra, AS & MD (NHM), MOHFW
Shri Manoj Jhalani, Joint Secretary (Policy), MOHFW
Dr. Sanjiv Kumar, Executive Director, NHSRC
Dr. Jitendar Sharma
Mr. Prabhat
Mr. Mohammad Ameel
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Mr. Ajai Basil
Dr. Yogita Kumar
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Shri Gautam Guha, Financial Expert
Shri Debashis Ghosh, Deputy Manager (Procurement), WBMSCL

Contents

SECTION - I

INTRODUCTION

Dialysis Program under the National Health Mission

Rationale: Every year about 2.2 Lakh new patients of End Stage Renal Disease (ESRD) get added in India resulting in additional demand for 3.4 Crore dialysis every year. With approximately 4950 dialysis centres, largely in the private sector in India, the demand is less than half met with existing infrastructure. Since every Dialysis has an additional expenditure tag of about Rs.2000, it results in a monthly expenditure for patients to the tune of Rs.3-4 Lakhs annually. Besides, most families have to undertake frequent trips, and often over long distances to access dialysis services incurring heavy travel costs and loss of wages for the patient and family members accompanying the patient. This therefore leads to financial catastrophe for practically all families with such patients. With substantial gain in quality of life and extension of progression free survival for patients, families continue to stretch financially to make large out of pocket spends. It has been felt that both in terms of provision of this important life saving procedure and also for reducing impoverishment on account of out of pocket expenditure for patients, a Dialysis program is required.

Hon'ble Prime Minister, in his address after the presentation by Secretaries Group on Health and Education, desired that a mechanism should be worked out to provide improved access to dialysis services. Accordingly, MoHFW with support from the National Health Systems Resource Centre (NHSRC) studied relevant models on Dialysis services being practiced under PPP mode. These included models of West Bengal, Kerala, Karnataka, Mumbai and Delhi NCR. Further, a consultation with experts in this field, experts from AIIMS & PGIMER as well as private service providers was held in the Ministry of Health & Family Welfare on the 16th Feb 2016 to discuss the modalities of envisaged program. Draft RFP and Service Level Agreement for the Dialysis in the PPP mode in the district hospitals were prepared and were shared with the states and valuable feedback was received. The Dialysis Program under Public Private Partnership was formally announced in the Union Budget 2016-17 by the Hon'ble Finance Minister.

Solution Strategy:

There are two main types of dialysis, which are hemodialysis and peritoneal dialysis.

a) Hemodialysis (HD, commonly known as blood dialysis): In HD, the blood is filtered through a machine that acts like an artificial kidney and is returned back into the body. HD needs to be performed in a designated dialysis centre. It is usually needed about 3 times per week, with each episode taking about 3-4 hours.

b) Peritoneal dialysis (PD, commonly known as water dialysis): In PD, the blood is cleaned without being removed from the body. The abdomen sac (lining) acts as a natural filter. A solution

(mainly made up of salts and sugars) is injected into the abdomen that encourages filtration such that the waste is transferred from the blood to the solution. There are 2 types of PD - continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis (APD). CAPD needs to be done 3 to 5 times every day, but does not require a machine. APD uses an automated cycler machine to perform 3 to 5 exchanges during the night while the patient is asleep.

Close medical supervision is not required for most PD cases, thus making it a feasible option for patients who may want to undergo dialysis in the home setting. Each treatment option has its advantages and disadvantages, which vary with the condition of the patient and presence of underlying diseases. It is therefore important for every patient with ESRD to discuss various treatment options in detail with his doctor before starting treatment.

The majority of patients in India receive renal replacement therapy in hemodialysis center. The number of patients on Hemodialysis and the number of hospital based and free standing units is steadily growing. A dialysis unit delivers patient care, and has specific requirements of treated water, electricity, medical gases and waste disposal. It additionally requires accommodating all the workers involved in patient care, allow emergency procedures, permit adequate hygiene and maintenance of specialized equipment. The design and layout of a unit must take into account all the above features in order to function smoothly and prevent development of complications. Proper planning of a dialysis unit is therefore essential.

Public Private Partnership for Hemodialysis services:

Based on consultation with experts and discussion with some of the states implementing the Dialysis program in the PPP mode, the following was considered as the ideal and cost -effective approach.

(i) It is desirable to roll out dialysis services in the states, beginning with the District Hospitals in a PPP mode. Direct provisioning by the state governments would be time consuming and likely to be costly and risky.

(ii) Service Provider should provide medical human resource, dialysis machine along with RO water plant infrastructure, dialyzer and consumables.

(ii) Payer Government should provide space in District Hospitals, Drugs, Power and water supply and pay for the cost of dialysis for the poor patients.

Financing the program:

Depending on the fiscal space with the states and resource envelope of NHM, the modalities of extent of coverage among patients of various economic groups would be worked out. Currently, under NHM 100 % of the service procedure fees for patients from below poverty line (BPL) economic group is proposed to be covered. However, non BPL patients would have the benefit of accessing the services close to the community at the district hospitals at same rates as paid by the Government for the BPL patient.

While there exist health schemes such as Rashtriya Swasthya Bima Yojana (RSBY) funded by Govt. of India which cover hemodialysis procedure, it is evident that due to high cost and recurring sessions required over the life time, the total cost for providing dialysis cannot be adequately covered. However, for BPL families registered under RSBY, the cost of dialysis care shall be catered through RSBY funding upto its maximum coverage. The additional resources required would be provided to the state under the National Health Mission.

Conclusion:

While dialysis services shall reduce a substantial cost to families and benefit the patient population, the evidence from a cost effectiveness perspective does not favor hemodialysis compared to renal transplant or peritoneal dialysis care. However renal transplant requires adequate super specialty hospitals with necessary skill sets, seemless donor registries, and expenditure incurred on post transplant care which may be unaffordable for families. Hence states/UTs are advised that while hemodialysis program may be rolled out, sufficient importance on developing renal transplant infrastructure, donor registry and training for peritoneal dialysis should be provided. While the requirement of such consultation has been inbuilt into the RFP part of this document, expert consultation and assessment of patient condition for initiating hemodialysis is critical to safety of patient and success of the program.

DEPARTMENT OF HEALTH & FAMILY WELFARE GOVERNEMNT OF

(Insert name of the State).....

TENDER ENQUIRY DOCUMENT FOR Provision of Dialysis Facility at District Hospitals

SECTION - II

NOTICE INVITING TENDERS (NIT)

<Insert the name of the Procuring Authority (Department/Directorate/Agency/Institution)>

Address:……..

……

URL: www……

Email:……

Telephone Phone: ……

Tender Enquiry No. PHFW/ / / Dated: / /

NOTICE INVITING TENDERS

1. <insert the designation and office of the tender invitinga uthority and the department/ agency>invites sealed tenders from eligible service providers for supply of services as given in **Section-IV**of this document for the period from……..to…….

2. Schedule of Events

Sl. No.	Description	Schedule
1	Date of sale of Tender Enquiry Documents	
2	Place of Sale/website download of Tender Enquiry Document	
3	Cost of the Tender Enquiry Document	
4	Pre-tender Meeting (Date & Time)	
5	Pre-Tender Meeting Venue	
6	Closing Date and Time of Receipt of Tender	
7	Time, Date and Venue of Opening of Technical Tender/ Bid	
8	Time, Date and Venue of Opening of Financial Tender/ Bid	

3. Interested bidders may obtain further information about this requirement from the above office selling the documents. Tender Enquiry Documents may be purchased on payment of non-refundable fee of <insert tender cost in Rs.> per set in the form of account payee Demand Draft, drawn on a scheduled bank in India, in favour of "<insert the designation and office of the tender inviting authority" payable at <insert the place>.

4. If requested, the Tender Enquiry Documents will be mailed by Registered Post/Speed Post to the interested bidders, for which extra expenditure per set will be Rs 100.00 for domestic post. The bidder is to add the applicable postage cost in non-refundable fee mentioned in Para 3 above. The purchaser will not be responsible for late receipt/ non- receipt of tender document by the vendor.

5. Bidder may also download the tender enquiry documents (a complete set of document is available on website) from the web site www……...com or www……..nic. in and submit its tender by using the downloaded document, along with the required non-refundable fee as mentioned in Para 3 above. The tender paper will be rejected if the bidder changes any clause or Annexure of the bid document downloaded from the website.

6. All prospective bidders may attend the Pre Tender meeting. The venue, date and time are indicated in Schedule of Events as in Para 2 above.

7. Bidders shall ensure that their tenders, complete in all respects, are dropped in the Tender Box located at (place to be inserted) on or before the closing date and time indicated in the Para 2 above, failing which the tenders will be treated as late tender and rejected. The tenders sent by post/ courier must reach the above said address on or before the closing date & time indicated in Para 2 above, failing which the tenders will be treated as late tender and rejected.

8. In the event of any of the above mentioned dates being declared as a holiday /closed day for the purchase organisation, the tenders will be sold/received/opened on the next working day at the appointedtime.

9. The Tender Enquiry Documents are not transferable.

10. All Tenders must be accompanied by EMD as mentioned against each item. Tenders without EMD shall berejected.

(Name & Designation of the Tender Inviting Authority)

SECTION - III

INSTRUCTIONS TO BIDDER

1. General Instructions

a) The bidder should prepare and submit its offer as per instructions given in this section.

b) The tenders shall be complete with all documents. Those submitted by fax or by email with attachments shall not be considered.

c) The tenders which are for only a portion of the components of the job /service shall not be accepted. (The tenders /bids should be for all components of the job /service.)

d) The prices quoted shall be **firm** and shall include all applicable taxes and duties. This shall be quoted in the format as per attached **Appendix 'F'** only.

e) The tenders (technical and financial) shall be submitted (with a covering letter as per **Appendix 'E'**) before the last date of submission. Late tenders / bids shall not be considered.

2. Inspection of Site and Equipment

The interested bidder may inspect the locations where the services are to be rendered during

10.00 AM TO 5.00 PM on all working days till last date of sale of tender as given in the tender schedule. The <Insert designation of the tender inviting authority >shall not be liable for any expenditure incurred in such inspection or in the preparation of the bid(s).

3. Earnest Money Deposit (EMD)

a) The tender shall be accompanied by Earnest Money Deposit (EMD) as specified in the Notice Inviting Tender (NIT) in the shape of Bank Draft / Bankers cheque from any Schedule Bank in favour of < Insert designation of the tender inviting authority > payable at <insert place>

b) It may be noted that no tendering entity is exempt from deposit of EMD. Tenders submitted without EMD shall be rejected.

c) The EMD of unsuccessful bidder will be returned to them without any interest, after conclusion of the resultant contract. The EMD of the successful bidder will be returned without any interest, after receipt of performance security as per the terms of contract.

d) EMD of a bidder may be forfeited without prejudice to other rights of the purchaser, if the bidder withdraws or amends its tender or impairs or derogates from the tender

in any respect within the period of validity of its tender or if it comes to notice that the information /documents furnished in its tender is incorrect, false, misleading or forged. In addition to the aforesaid grounds, the successful bidders' EMD will also be forfeited without prejudice to other rights of purchaser, if it fails to furnish the required performance security within the specified period.

4. Preparation of Tender

The bids shall be made in TWO SEPARATE SEALED ENVELOPES as follows:

I. The **first envelopes** shall be marked in bold letter as "**TECHNOCOMMERCIAL BID"** which shall be sent forwarding letter**("Appendix-E")** and shall include the following:

1) Receipt regarding payment of Tender Cost.

2) Bank Draft /Bankers Cheque towards **E.M.D.** DD/ Banker's cheque towards the cost of tender document to be attached in case bid document has been downloaded from website.

3) Confirmation regarding furnishing **Performance Security** in case of award of contract.

4) Original tender document duly stamped and signed in each page along with the Forwarding Letter confirming the performing the assignment as per **"Appendix E".**

5) Particulars of the bidder as per "**Appendix-D"**

6) Copy of the Income Tax Returns acknowledgement for last three financial years.

7) Copy of audited accounts statement for the last three financial years

8) Power of attorney in favour of signatory to tender documents and signatory to Manufacturer's Authorisation letter.

9) Copy of the certificate of registration of CST, VAT, EPF, ESI and Service Tax with the appropriate authority valid as on date of submission of tender documents.

10) A duly notarized declaration from the bidder in the format given in the **"Appendix-H"** to the effect that the firm has neither been declared as defaulter or black-listed by any competent authority of Government of India OR Government of any State. .

In addition to the above documents,

1) The tender of the Authorized Agent shall include the manufactures authorization letter as per perform given in "**Appendix -B"**.

2) The tender of others (i.e. those who are neither manufactures nor authorized agents) shall include a statement regarding similar services performed by them in last three years and user's certificate regarding satisfactory completion of such jobs as per proforma given in "**Appendix -C**".

II. The second envelope shall contain the financial proposal and shall be marked in bold letters

as "FINANCIAL BID". Prices shall be inclusive of all taxes & duties and quoted in the proforma enclosed at "**Appendix F**" as per scope of work / service to be rendered.

5. Tender Validity Period and renewal of contract

The tenders shall remain valid for 5 years for acceptance and the prices quoted shall remain for the duration of the contract with 3% escalation on the quoted financial bid per annum with respect to preceding year. The contract may be extended for another term based on review of performance and with mutual consent.

6. Tender Submission

The two envelopes containing both technical and the financial bid shall be put in a bigger envelope, which shall be sealed and superscripted with "TENDER NO <Insert Tender No.> due for opening on<Insert due date for Opening>

The offer shall contain no interlineations or overwriting except as necessary to correct errors, in which cases such correction must be initialed by the person or persons signing the tender. In case of discrepancy in the quoted prices, the price written in words will be taken as valid.

7. Opening of Tenders:

The technical bid will be opened at the time & date specified in the schedule. The bidders may attend the bid opening if they so desire.

SECTION - IV

EVALUATION OF TENDERS

1. Scrutiny of Tenders

The tenders will be scrutinized by the selection committee appointed by the authority to determine whether they are complete and meet the essential and important requirements, conditions and whether the bidder is eligible and qualified as per criteria laid down in the Tender Enquiry Documents. The bids, which do not meet the aforesaid requirements, are liable to be treated as non-responsive and may be ignored. The decision of the purchaser as to whether the bidder is eligible and qualified or not and weather the bid is responsive or not shall be final and binding on the bidders. Financial bids of only those bidders, who qualify on technical bid, will be considered and opened.

2. Infirmity / Non-Conformity

The purchaser may waive minor infirmity and/or non-conformity in a tender, provided it does not constitute any material deviation. The decision of the purchaser as to whether the deviation is material or not, shall be final and binding on the bidders

3. Bid Clarification

Wherever necessary, the purchaser may, at its discretion, seek clarification from the bidders seeking response by a specified date. If no response is received by this date, the purchaser shall evaluate the offer as per available information.

SECTION - V

SCOPE OF THE WORK

The Service Provider shall be responsible for operationalization of Dialysis facility at district/ sub-district hospital to the patients referred by District Hospital. Ownership status of all movable assets created from the investments made by the Service Provider shall remain with the Service Provider. This could be achieved by a mix of any of the following across several districts in the state:

I. The service provider is allotted a space (@ 120 sq. ft. per machine) by the authority and the service provide shall make complete arrangements to make the dialysis facility operational (should factor all required infrastructure, HR (trained Nephrologists, Medical officers, Nurses, technicians), supportive infrastructure, dialyzer and all other consumables etc., operational and maintenance cost for the project including consumables and facility for pediatricpatients.

II. The decision to refer a patient for dialysis in District/ hospital should originate from a qualified nephrologist in a Government hospital. In all cases, the diagnostic tests (Urea, Creatinine, Sodium, Potassium, complete bio-chemistry & hematology profile) before and after the dialysis should be done through the free diagnostic program OR governments own laboratory. Incorrect laboratory tests may lead to wrong referral for dialysis hence due precautions would be taken to refer a patient for dialysis and laboratory reports before and after the dialysis cycle should be recorded. A minimum of 4 Dialysis machines plus one dedicated machine for infective cases (Hepatitis B, Hepatitis C, HIV etc)

III. The service provider arranges for a space at its own cost in proximity to the hospital within 3 kilometers of the hospital premises in district where government cannot provide space for the facility and then makes complete arrangements as detailed above

IV. The facilities such as observation rooms, recovery rooms among other should be provided.

V. Provide dashboard for monitoring of service delivery with due diligence to patient privacy for administrative Staff. Treating Nephrologist should have complete access to the dashboard.

VI. SMS based appointment system for all patients enrolled for services.

The obligations of the service provider/firm under this service contract shall include all service activities and commitments. The details of various services required at different locations and type of facilities is given in **Appendix 'A'**. The Service Provider shall not be entitled to levy any charge on the patients. The services shall be provided completely cashless to all patients referred by district/sub-district hospitals.

SECTION - VI

ELIGIBILITY CRITERIA

1. The Bidder shall be a sole provider or a group of providers (maximum3) coming together as Consortium to implement the Project, represented by a lead partner. The bidder cannot be an individual or group of individuals. A bidder cannot bid as a sole provider as well as a partner in a consortium. No bidder can place more than one bid in any form in the state. In support of this, the bidder's letter shall be submitted as per proforma in **Appendix 'B'.** The Service provider should be registered as a legal entity.

2. The Bidder shall have a minimum of three years of experience in carrying out similar type of assignment / service in private or public sector. In support of this, a statement regarding assignments of similar nature successfully completed during last three years should be submitted as per proforma in **Appendix 'C'**. Users' certificate regarding satisfactory completion of assignments should also be submitted. The assignment of Govt. Depts. / Semi Govt. Depts. should be specifically brought out. (The decision of the Purchaser as to whether the assignment is similar or not and whether the bidders possess adequate experience or not, shall be final and binding on the bidders.)

3. Operated & managed dialysis facilities, having at least a total of 50 Hemodialysis machines.

4. The above experience could be demonstrated by the single bidder or the lead member of the consortium. In case of consortium bidding, aggregate financial turnover of only those members of consortium would be considered who qualify the technical eligibility independently.

5. The facilities should have operational Hemodialysis facility for at least 3 years prior to the submission date

6. The Bidders are not presently blacklisted/ Debarred by the Purchaser or by any State Govt. or its organizations by Govt. of India or its organizations.

7. The bidder shall declare all ongoing litigations it is involved in with any government agency/state/central department

8. The principal bidder/lead partner shall have an average turnover of **Rs 10.00 Crores per annum** in last three financial years

9. In case of audited financials not being available for the last completed financial year, CA certified provisional financials should be provided

10. The principal bidder/lead partner shall be legally responsible and shall represent all consortium members, if any, in all legal matters

SECTION - VII

TERMS AND CONDITIONS

1. Signing of Contract

The purchaser shall issue the Notice for Award of Contract to the successful bidder within the bid validity period. And the successful bidder will be required to sign and submit the contract unconditionally within15days of receipt of such communication.

2. Modification to Contract

The contract when executed by the parties shall constitute the entire contract between the parties in connection with the jobs / services and shall be binding upon the parties. Modification, if any, to the contract shall be in writing and with the consent of the parties.

3. Performance Security

a) The successful bidder shall furnish a performance security in the shape of a Bank Guarantee issued by a Nationalised Bank in favour of Tender Inviting Authority for an amount equal to 5% of the total contract value. The Bank guarantee shall be as per proforma at **"Appendix: G"** and remain valid for a period, which is six months beyond the date of expiry of the contract. This shall be submitted within 15 days (minimum) of receiving of Notice for Award of Contract, failing which the EMD may be forfeited and the contract may be cancelled.

b) If the firm / contractor violate any of the terms and conditions of contract, the Performance Security shall be liable for forfeiture, wholly or partly, as decided by the Purchaser and the contract may also be cancelled.

c) The Purchaser will release the Performance Security without any interest to the firm / contractor on successful completion of contractual obligations.

4. Compliance of Minimum Wages Act and other statutory requirements

The bidder shall comply with all the provisions of Minimum Wages Act and other applicable labour laws. The bidder shall also comply with all other statutory provision including but not limited to provisions regarding medical education and eligibility criteria of human resources used by the bidder for providing the services, biomedical waste management, bio-safety, occupational and environmental safety.

Legal liability of the services provided by the bidder shall remain with the service provider but in case of any death the certificate shall be issued by the government doctor. The Service provider shall maintain confidentiality of medical records and shall make adequate arrangement for cyber security.

5. Income Tax Deduction at Source

Income tax deduction at source shall be made at the prescribed rates from the bidder's bills. The deducted amount will be reflected in the requisite Form, which will be issued at the end of the financial year.

6. Periodicity of Payment

The payment will be made on weekly basis not extending beyond 12 noon of the last bank working day of the week through ECS for all invoices raised. The purchaser shall give standing instructions to the bank for implementation of this requirement. The bidder will raise its invoice on completion of services during this period duly accompanied by evidences of services provided. The payment will be subject to TDS as per Income Tax Rules and other statutory deductions as per applicable laws.

7. Damages for Mishap/Injury

The purchaser shall not be responsible for damages of any kind or for any mishap/ injury/accident caused to any personnel/property of the bidder while performing duty in the purchaser's / consignee's premises. All liabilities, legal or monetary, arising in that eventuality shall be borne by firm/ contractor.

8. Termination of Contract:

The purchase may terminate the contract, if the successful bidder withdraws its tender after its acceptance or fails to submit the required Performance Securities for the initial contract and or fails to fulfill any other contractual obligations. In that event, the purchaser will have the right to purchase the services from next eligible bidder and the extra expenditure on this account shall be recoverable from the defaulter. The earnest money and the performance security deposited by the defaulter shall also be recovered to pay the balance amount of extra expenditure incurred by the purchaser.

9. Arbitration

a) If dispute or difference of any kind shall arise between the purchaser and the firm/ contractor in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.

b) b) If the parties fail to resolve their dispute or difference by such mutual consultations within thirty days of commencement of consultations, then either the purchaser or the firm/contractor may give notice to the other party of its intention to commence arbitration, as hereinafter provided. The applicable arbitration procedure will be as per the Arbitration and Conciliation Act, 1996 of India. In that event, the dispute or difference shall be referred to the sole arbitration of an officer to be appointed by the <insert tender issuing authority> as the arbitrator. If the arbitrator to whom the matter is initially referred is transferred or vacates his office or is unable to act for any reason, he / she shall be replaced by another person appointed by <insert tender issuing

authority> to act as Arbitrator. Such person shall be entitled to proceed with the matter from the stage at which it was left by his predecessor. The award of the provision that the Arbitrator shall give reasoned award in case the amount of claim in reference exceeds Rupees One Lac (Rs.1,00,000/-)

c) Work under the contract shall, notwithstanding the existence of any such dispute or difference, continue during arbitration proceedings and no payment due or payable by the Purchaser or the firm / contractor shall be withheld on account of such proceedings unless such payments are the direct subject of the arbitration.

d) Reference to arbitration shall be a condition precedent to any other action at law.

e) Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued.

10. Applicable Law and Jurisdiction of Court:

The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force. The Court located at the place of issue of contract shall have jurisdiction to decide any dispute arising out of in respect of the contract. It is specifically agreed that no other Court shall have jurisdiction in the matter.

11. Other Terms & Conditions

a) The Project will be awarded for a period of 5 years and the Service Provider will be obliged to establish, manage and operate the Project in accordance with the provisions of a Contract Agreement and terms and conditions therein. It could be cancelled at any time after providing an opportunity of hearing by the Authority, in case the contractor does not follow the rules, regulations and terms and condition of the contract.

b) The Authority may provide the required space, for establishing the Project. A lease agreement shall be enforced for the full term of the contract at value and terms declared by the authority. A Possession Certificate in plain paper shall be issued while handing over the above mentioned space. In case the authority is unable to provide the space; the service provider may carry these services at its owned/rented/leased space or partner with an already existing Dialysis facility near the hospital. In any of these cases refurbished Dialysis machine is not allowed.

c) New Installation & continuation: The service provider shall commission the Dialysis facility within 90 days of the signing of the contract by both parties. In case of continuation of the service provider for the subsequent contract period, this time period shall not be valid.

d) Technology Up gradation: The machine shall be suitably upgraded by the service provider under following conditions:

(i) Review by a board appointed by Authority upon assessing the need for a technology up gradation. Such reviews should not be made in less than one year.

(ii) Upon declaration of any national or international guideline accepted by the Government prohibiting the use of earlier (currently installed) technology

(iii) After completion of 2 contract periods each not less than 5 years, the entire Equipment machinery shall be replaced.

e) List of tests & their associated cost may be furnished as per **Appendix F**

f) One Dialysis facility would be installed for every district/sub-district hospital; for districts having population less than 7.5 Lakhs, one facility may be installed for every 2 or more districts or as per state's discretion. The list provided by state is attached as appendix A.

g) All the pre-requisites such as civil, electrical, air-conditioning, computer or any other changes in the site for installation of machine will be executed by the service provider at its own cost, with due permission of the Authority (permission required only if the space is provide by the administration). The district hospital administration will not be responsible for any loss/ damage to the machine/ property due to natural hazard and licensee will take adequate insurance cover at his own risk & liability for all damages arising out due to any unprecedented reasons. The service provider shall provide round the clock security services for the Dialysis facility at its own cost for the entire period of contract. The contract and terms thereof shall be governed by indemnification clause.

h) All expenses on account of man power, electricity, water and other maintenance of premises and the machine, security or any other expenses incurred in the day to day running of the machine shall be borne by the provider.

i) The service provider shall provide for storage of soft copy and hard copy of all records at the District/Sub-district Hospital at its own cost. In case of change of service provider for any reason, the stored data must be transferred to the new provider for continuation of storage.

j) Service Provider shall ensure best quality of tests and protocols and shall submit a half yearly report of clinical audit done by a third party or as nominated by the authority. Service provider to provide the Kt/v and standardised Kt/V report for each patient to the committee.

k) Annual review of performance and observance of terms & conditions shall be carried out by a committee which shall include CMO & Head of department of Nephrology of the Govt. Teaching hospital along with other members nominated by the authority. The report of this annual review shall form the basis for extension of the contract annually within the contract period.

l) The service provider will have to maintain an uptime of 90% with maximum 7 days of downtime at a stretch of any single dialysis machine of the facility. In case the service provider fails to do so, the provider shall pay a sum equivalent to cost

of a single dialysis multiplied by total number of dialysis done per day during the given month, for each day of shutdown beyond 7 days. If shut down extends beyond 30 days due to technical and/or administrative reasons on the part of service provider, the contract may be cancelled. Contractor shall make alternative arrangements for provision of dialysis (including free transportation of patients) in case the machine is out of order/ broken down for period greater than 24 hours. The rates at which the Authority has engaged the service provider shall not change in any case.

m) State authority shall make payment to the service provider for its services on weekly basis through ECS for all invoices raised for the previous week. The payment should be made latest by Saturday 12 Noon every week to the service provider.

n) A no-fee receipt shall be provided by the service provider to every patient. A copy of all such receipts shall be submitted on a weekly basis by the service provider to the District Hospital Authority. This will form the basis of weekly payment by purchasing authority to the service provider for the said services. All receipts shall be subjected to a third party annual audit and the audit report submitted as part of annual work report of the service provider for that facility.

o) The following records shall be maintained on a daily basis by the service provider:

p) Daily patients register including outside as well as for patients referred by District Hospital to be separately maintained.

q) Log book for record of any breakdown/shut down of the machine/facility.

r) The service provider shall not sell or transfer any proprietary right or entrust to any other third party for running the facility. The service provider may however refer the test to another center in case of breakdown/shutdown ensuring all other conditions pertaining such as services, reports, records, patient transport and safety of processes and procedures in the referred center.

s) The provider shall take a third party insurance policy to cover the patients sent by the District Hospital against any mishap during patient transport, inside the dialysis facility and for consequences arising due to reporting error. Conforming to the provision of the consumer protection act shall be the sole and absolute responsibility/liabilityoftheserviceprovider.

t) After closure of the contract agreement between the service provider and the authority, the service provider shall vacate the space occupied, if provided bythe authority, within a period of 60days.

u) Availability of Space, Electricity, water, shall be provided by the authority.

v) The service provider shall provide a resuscitation facilities with crash cart for providing lifesaving support if required by patients within the dialysis facility.

w) Provider shall arrange for appropriate and adequate signage and IEC (Information-education- communication) activities for facility as decided by the authority.

x) The provider shall abide by all the guidelines issued by the Authority and statutory bodies. In case of violation the contract could be terminated after providing an opportunity of hearing to the contractor, at one month's notice. Dispute resolution shall be as per arbitration clause given in the contract.

y) The Authority shall receive Bids pursuant to this RFP in accordance with the terms set forth herein as modified, altered, amended and clarified from time to time by the Authority, and all Bids shall be prepared and submitted in accordance with such terms on or before the date specified in Clause for submission of Bids.

z) The Service provider shall be obligated to provide 24X7(round the clock) dialysis services, if required to meet the work load ensuring that no patient has a wait time of more than 24 hours from the scheduled dialysis session.

Further, the increase in dialysis units shall be according to space availability and in case of space constraint the service provider shall create a facility within 3 Km of district hospital to meet patient load.

<Insert name and address of the tender inviting authority>

APPENDIX - A

LOCATION OF FACILITY AND FACILITY WISE DESCRIPTION OF SERVICES REQUIRED

Name of District/ Sub-District Hospital & bed strength	No. of Dialysis Machines required	Land/space to be provided by the corresponding District Hospital (Yes/No)
Total		

APPENDIX -B

BIDDER'S AUTHORISATION LETTER

(To be submitted by authorized agent)

To

<Name, Address and Designation of the Tender Inviting Authority>

Ref. Your TE document No.----------, dated----------

Dear Sirs,

We,…….. are the suppliers of ---------- ---------- (name of services(s) and hereby conform that;

1. Messrs ---------- (name and address of the agent) is our authorized agents for ----------
2. Messrs ---------- (name and address of the agent) have fully trained and experienced service personnel to provide the said services.
3.

Yours faithfully,

_____

_____

[Signature with date, name and designation]

For and on behalf of Messrs _____

[Name & Address of the Manufacturers]

Note:

1. **This letter of authorization should be on the letterhead of the manufacturing firm and should be signed by a top executive of the manufacturing firm.**
2. **Original letter shall be attached to the tender.**

APPENDIX - C

ASSIGNMENT OF SIMILAR NATURE SUCCESSFULLY COMPLETED DURING LAST THREE YEARS

1. Attach users' certificates (in original) regarding satisfactory completion of assignments.

Sr.No	Assignment contract No &date	Description of work services provided	Contract price of assignment	Date of commencement	Date of completion	Was assignment satisfactorily completed	Address of organization with Phone No. where assignment done
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Note: Attach extra sheet for above Performa if required.

Signature……

Name ……..

APPENDIX -D

PARTICULARS OF THE BIDDER'S COMPANY

(To be submitted by all bidders)

1. Name :

2. Registered Address

3. Phone/Fax/Mail id

4. Type of Organisation :Prop./Partnership/Company/ Consortium/Trust/ Not for Profit Organization

5. Address of Service centres in the region:

(a) Total No. of services personnel at the existing centres:

(b) Total No. of locations where organization currently has centres:

6. Number of service personnel:

Name	Qualification	Experience (Similar Service)
		(use extra sheet if necessary)

7. Whether the bidder has NABL/NABH/ISO or any other accreditation?

(If yes/ whether documents attached with techno commercial bid).

8. Registration. Nos.

(a) EPF

(b) ESI

(c) Sales Tax

(d) VAT

(e) Service Tax

(f) PAN No.

(g) Audited Accounts Statement for past three financial years

(h) Copy of Income Tax Return for past three financial years

(i) Experience certificate of Bidder regarding existing Dialysis services

9. Brief write-up about the firm / company. (use extra sheet if necessary)

Signature of Bidders

Date: Name

Place: Office Seal

APPENDIX -E

Forwarding Letter for Technical Bid

(To be submitted by all bidders in their letterhead)

Date:…….

To

<Name, Designation and Address of Tender Inviting Authority>

Sub: Tender for supply of services under Tender No….

Sir,

We are submitting, herewithour tender for providing Dialysis services for……. Number of districts in the state

We are enclosing Receipt No…….. or Bank Draft/Bankers Cheque No……., Dated……(amount……)toward stender cost/fee (if documents have been downloaded from website) and Bank Draft / Bankers Cheque No……. Dated…… (Amount……) towards Earnest Money Deposit (EMD), drawn on…… Bank in favour of <Tender Inviting Authority>.

We agree to accept all the terms and condition stipulated in your tender enquiry. We also agree to submit Performance Security as per ClauseNo.3 of Section VI of Tender Enquiry document.

4. We agree to keep our offer valid for the period for the period stipulated in your tender enquiry.

Enclosures:

1.

2.

3.

4.

5.

Signature of the Bidder……

Seal of the Bidder……

APPENDIX -F

FINANCIAL BID

1. Name of the Bidder:……..
2. **The Quote is for per session cost of Hemodialysis and factors all the infrastructure, HR (trained &qualified Nephrologist, medical officers, Nurses, technicians, supportive infrastructure, dialyzer and all other consumables etc.), operational and maintenance cost for theproject.**
3. The bidder is expected to deliver the services for a minimum period of five years
4. 4. The bidder has to deposit 5 % of the contract value as performance security in form of Irrevocable Bank Guarantee with validity through the duration of the contract.

The cost per Hemodialyis session Rs……/- (in words Rs……)

The prices shall be firm and inclusive of all taxes and duties presently in force.

Signature……

Name……..

APPENDIX -G

Proforma For Bank Guarantee

To

< Name, Designation and Office Address of Tender Inviting Authority>

WHEREAS……..(Name and address of the Service Provider) (Hereinafter called " the Service provider" has undertaken, in pursuance of contract No…….. dated …….. (Herein after "the contract") to provided Dialysis services.

AND WHEREAS it has been stipulated by you in the said contract that the service provider shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligations in accordance with the contract;

AND WHEREAS we have agreed to give such a bank guarantee on behalf of the service provider;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the service provider, up to a total of…….. (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the service provider to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforeside, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the service provider before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the service provider shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid up to 6 months after the contract termination date …….. (indicate date)

……

(Signature with date of the authorized officer of the Bank)

……

Name and designation of the officer

……..

Seal, name & address of the Bank and address of the Branch

APPENDIX -H

Declaration By Bidder

I / We …… agree that we shall keep our price valid for a period of one year from the date of approval. I / We will abide by all the terms & conditions set forth in the tender documents No. **……../**

I/We do hereby declare I/We have not been de- recognized/ black listed by any State Govt. / Union Territory / Govt. of India / Govt. Organisation / Govt. Health Institutions.

Signature of the bidder:

Date :

Name & Address of the Firm:

Affidavit before Executive Magistrate / Notary Public in Rs.100.00 stamp paper.

APPENDIX -I

Records for Procedure

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
    l. 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 weakly treatments
    e. Outcomes
    f. Staff/patient's hepatitis status
3. Staff and patient vaccination and antibody titer status as applicable
    a. Hepatitis B (double dose) – 0, 1,2,6 months
    b. Influenza – annually
    c. Pneumococcal – every 5 years
4. Water treatment
    a. Bacteriological
    b. Endotoxin
    c. Chemical
5. Facility and equipment maintenance schedule
    a. Preventive maintenance
    b. Corrective measures

APPENDIX -J

Equipment List

Emergency equipment: The following equipment should be provided for by the service provider:

S. No	Name of Equipment
1	Resuscitation equipment including Laryngoscope, endotracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag-Adult &Paediatric (neonatal ifindicated)
2	Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasalprongs
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
10	Dialyzer reprocessing unit
11	ACT machine
12	Cardiac monitors
13	Vein finder
14	All required consumables for adult and pediatric patients

APPENDIX -K

Records for Procedure

It is recommended to have the following minimum standards and staffing pattern for the Dialysis unit.

Sl .No	Staff Ratio
1	Qualified Nephrologist / MD Medicine with one year dialysis training from recognized center performing one visit every fortnight and clinical review for all patients
2	Medical Officers (on duty) – One doctor (MBBS) per shift for a maximum of 10 machines. 3 Dialysis technicians/ nurses: One technician for every 3 machines and one dedicated for dialysis machine for patients with blood borne infections per shift
3	Dietician (optional)
4	sweepers 1 for every five machine per shift
5.	Hospital attendant 1 for every five machines per shift

APPENDIX -L

Hemodialyis Machine & associated Systems

A. HD machine: Mandatory

1. Blood pump to achieve a unidirectional flow up to 400ml/min
2. Heparin pump
3. Arterial line and venous line pressure monitors
4. Functional air bubble detector
5. Mixing proportion of unit with bicarbonate dialysis facility, rate of
6. Dialysate delivery from 300 to 500 ml/min or more.
7. Conductivity meter
8. Functional blood leak detector
9. Dialysate temperature regulator that has a range of temperature 35 to 390C
10. Volumetric UF control
11. Safety devices functioning alarms, venous blood camp
12. Dialysate filter
13. The HD machine should be FDA approved or European CE marked.

B. HD machine: Optional

1. On line blood volume monitor
2. On line urea clearance
3. Sodium profiling of dialysate
4. Single needle dialysis facility
5. Hemodiafiltration
6. Optical detector

C. Monitoring and Evaluation of HD machine

1. Conductivity of the final dialysate being delivered to the dialyzer should be checked before every treatment. According to manufacturers' instructions, the conductivity should be checked with an independent reference meter which is known to be properly calibrated. Conductivity must be within the manufacturer's stated specifics. The frequency of checking

with independent reference meter should be as per manufacturer's guideline and also every time the machine is calibrated and repaired.

2. When used, the pH of bicarbonate dialysate should also be confirmed before each treatment. If the pH is below 6.5 or above 7.5, dialysis should not be started, even when conductivity within limits acceptable. The pH can be checked with a similar pH meter.

3. Temperature should also be within the manufacturer's specifications. Temperature may be checked with an independent reference meter or with a reference thermometer.

4. Absence of residual germicide should be verified on all delivery systems connected to a single water treatment "loop" before dialysis begins. Such testing must be performed with an assay known to detect the minimum standard level.

5. A test of proper functioning of the air/foam detector should be performed before dialysis is initiated. This test should be a direct test of function of the alarm, causing interruption of the blood pump an actuation of the blood line clamp, either by introducing air into the venous level detector or by removing the tubing so that air is sensed by the detector as recommended by the device manufacturer.

6. The blood detector must be checked for proper armed status according to the method recommended by the manufacturer.

7. The user should perform applicable tests of the UF control system as prescribed by the manufacturer.

8. All other alarms must be tested according to the manufacturer's instructions for use before every treatment including low and high conductivity alarm, low and high temperature alarm, dialysate pressure alarm, water pressure alarm, etc. Documentation of that testing should be performed. If the particular delivery system is equipped with a "self-alarm check" mode, it is important that the user understand that, most often, it is a check of the electronic circuitry, and not a confirmation of some of the vital functions of specific alarms.

9. Observation of dialysate flow should be made while the machine is in a "dialyzing" mode. Absence of dialysate flow should be confirmed when the machine is in "bypass" mode actuated by both manual setting of the machine to bypass or via any of the alarm functions that will cause the machine to enter a bypass mode.

10. The automatic "self-test" should be performed if this facility is available prior to each HD treatment to confirm proper performance of operative and protective functions of the machine and should never be bypassed.

Recommendation for once monthly evaluation and monitoring: (D)

11. Periodic (Monthly) Microbiological monitoring: water for production of dialysate and actual dialysate proportioned and exiting the dialyzer should be monitored for bacterial levels on no less than a monthly basis. Microbiological monitoring is performed to establish ongoing validation of proper disinfection protocols. The sampling should be done at the termination of dialysis at the point where dialysate exits the dialyzer. Results for total

microbial counts shall not exceed 2,000 colony forming units per ml.

12. Assessing trends: Pertinent information, i.e., bacterial levels, conductivity and pH readings, etc., should be logged on a chart across a page so that readings can be examined and compared over an extended period of time. This tool makes it possible to compare current readings to those taken during the past several days/weeks/months.

D. Dialyzer (filter) specifications:

The hollow fiber dialyzer forms the central component of dialysis deliver system, where in actual process of transfer of solutes and water occurs across a semi-permeable membrane. A large array of dialyzers is available for clinical use with several permutations and combinations based on biocompatibility, flux and surface area of the dialyzer. Most often a single type of dialyzer may be sufficient in most patients in a dialysis unit. However, some patients may have specific needs and may require change in the dialyzer specifications. Hence, dialyzers with specifications other than that generally used in the dialysis unit may also be routinely stocked or should be made available at a short notice when the need arises.

E. Recommendations for dialyzer use in HD:

1. Biocompatible, synthetic (e.g., polysulfone, polyacrilonitrile, polymethylmethacrylate) or modified cellulose membrane (e.g., cellulose acetate) should be preferred over unmodified
2. cellulose membranes (e.g., cuphraphan). Cupraphane membranes should only be used when patient is intolerant to other biocompatible membranes..
3. Either low flux or high flux biocompatible membrane may be used for regular HD.
4. An allergic reaction to a specific dialyzer is rarely encountered in some patients. In such situation, the particular dialyzer should be avoided and this should be specifically written in bold letters on the dialysis folder of the patient to prevent its inadvertent use.
5. Dialyzer may be use for NOT more than 10 times or till the bundle volume is >70% of original capacity and in such cases reused only for the same patient after due sterilization using dialyzer reprocessing unit. Dialyzer should not be reused for sero positive cases on isolated machine.
6. Blood line, Transducer Protectors, IV sets, Catheters any other disposables should not be should NOT be reused .

F. Dialysis fluid specifications:

Dialysate, or dialysis fluid, is a non-sterile aqueous solution with an electrolyte composition near that of normal extracellular fluid. Its electrolyte composition is designed to correct the metabolic imbalance that occurs as a result of azotemia. Dialysate concentrates are manufactured commercially in liquid or powder form. The chemicals present in the dialysate have access, via the dialyzer, to the bloodstream of patients undergoing dialysis. Hence, the proper concentration of all of these chemicals as well as the quality of the concentrate and

the water used to dilute the concentrate is critical. The following is to be ensured:

1. Electrolyte content of dialysate includes sodium, potassium, chloride, magnesium, calcium, glucose (optional), and bicarbonate as a buffer. The concentration of HD solutions should be such that after dilution to the stated volume the final concentrations of the ions expressed as mmol/L are usually in the following ranges: Sodium 135-145, 40 Potassium 0-4, Calcium 1.0-2.0, Magnesium 0.25-1.0, bicarbonate (32-40, Chloride 95-110. 42; Sodium concentration may be adjusted to levels outside the range of 135-140 mmol/L by HD machines with variable sodium capabilities only when prescribed by physician in charge.

2. Commercially produced concentrates are classified as medical devices and should be approved for clinical use by appropriate authority. The dialysate should contain bicarbonate as the buffer 3. The final diluted dialysate should be analyzed every 6 months, with every new batch of dialysate and after each major servicing/repair of dialysis machine.

4. Water used to prepare the dialysate must have a bacteriological colony count of less than 200 CFU/ml. Bacteriological analysis of the dialysate shall be carried out at least 2 monthly, preferably every 15 days. The colony count in dialysate samples collected at the termination of dialysis a) in a single pass system or b) in a re-circulating single pass system at the periphery of the re-circulating chamber containing the dialyzer shall be less than 2000 colony-forming units/ml. Dialysate containing glucose at 100- 200 mg/dl concentration should be used.

G. Recommendations for storing and mixing dialysis concentrate:

1. Store and dispense dialysate concentrates as though they were drugs. Ensure that all personnel in the facility are aware of the types of dialysate concentrates available, even if currently only one type is being used.

2. Develop a policy, management, and storage system that will effectively control the mixing and dispensing of all concentrates. Storing concentrates according to type, composition, and proportioning ratios should reduce the risk of mismatching concentrates. Prohibit access to storage areas and allow only authorized, specially trained personnel to mix and dispense concentrates.

3. Double-check and record concentrate formulas on the patient's record. Consider a procedure for countersigning patient and storage records. Do not dispense concentrates from large containers into smaller ones without a "keyed" dispensing system. Whenever possible, purchase concentrates in single-treatment (2½-4 gallon) containers (optional).

4. Always dispose of concentrates remaining from the previous treatment. Do not pour remaining concentrate into another container or use in the next treatment. Replace empty or partially full containers with full ones. Whenever possible, standardize equipment so that only one bicarbonate concentrate system is used.

H. Water Treatment System:

1. Dual water treatment system is mandatory.

2. Each water treatment system includes reverse osmosis membranes.
3. The water treatment system components are arranged and maintained so that bacterial and chemical contaminant level in the product water does not exceed the standards for Hemodialyis water quality.
4. Proper function of water treatment system is continuously monitored during patient treatment and be guarded by audible or visual alarm that can be heard or seen in the dialysis treatment area in case performance of the water treatment system drops below specific parameters.
5. Written logs of the operation of the water treatment system for each treatment day are in place.
6. Procedure guidelines for Disinfection of Reverse Osmosis Machine and Loop as recommended by the manufacturer are in place.
7. No Hemodialyis procedure is performed during disinfection of the water treatment system and the loop.
8. Microbiological testing of the treated water from the water treatment system and the loop is done regularly and preferably monthly.
9. For dialysis unit performing HDF, testing of treated water for endotoxin at regular interval is needed.
10. Written record and results of microbiological and chemical testing of water are in place and reviewed. Corrective action is recorded if indicated.

I. Reuse of Haemodialyzers and related devices

1. Procedure guidelines for dialyzer reprocessing are in place.
2. Testing for presence of disinfectant in the reprocessed dialyzer before rinsing and absence of disinfectant after rinsing are performed and documented.
3. Each dialyzer is clearly labeled and identified to be re-used by the same patient.
4. Routine disinfection of active and backup dialysis machines are performed according to defined protocol. i.e HD Machine shall be disinfected after every dialysis session with 20 minutes of Citric Acid, to avoid cross contamination. Also end of the day 1hour of Citric and thermal dis-infection shall be done to all HD machines. The same shall be documented

J. Other Activities for patient care

1. Blood chemistry and haematocrit (or hemoglobin) of each dialysis patients are checked at regular interval (preferably every month) to ensure patient's well being and viral markers be tested every 3 months (HIV/HBsAg/HCV)iPTH and vitamin-D should be done every 6 monthly.

2. Contingency plan or procedures are available in case of equipment failure, power outages, or fire so that the patient healthy or safety can be ensured.
3. Drill for CPR and emergency conditions outlined are performed regularly.
4. Routine disinfection of active and backup dialysis machines are performed according to defined protocol. Documentation of absence of residual disinfectants is required for machines using chemical disinfectant.
5. Samples of dialysate from machines chosen at random are cultured monthly. Microbial count shall not exceed 200 colony forming units per millilitre (cfu/ml) for HD and shall not exceed 10 –1 cfu/ml for online HDF before IV infusion into the patient's circulation. Periodic testing of inorganic contaminant is performed.
6. Repair, maintenance and microbiological testing results of the hemodialysis machine are recorded with corrective actions where indicated.
7. All staff including janitorial staff is educated with clear instruction on handling blood spillage on equipment and the floor.
8. All blood stained surface shall be soaked and cleaned with 1:100 sodium hypochlorite if the surface is compatible with this type of chemical treatment.
9. All new dialysis patients or patients who return to the dialysis unit after treatment from high- or unknown-risk areas are tested for HbsAg and Anti-HCV etc.
10. HBsAg/HCV-positive patient should be treated in a segregated area with designated Hemodialyis machines.
11. Carrier of HCV receives hemodialysis using designated machines.
12. Patient with unknown viral status is dialyzed using designated hemodialysis machines until the status is known.

CONTRACT FORMAT

Contract Form For Providing Dialysis Facilities

……..

……..

(Address of the Tender Inviting Authority/Office issuing the contract)

CM Contract No._____ dated_____

This is in continuation to this office's Notification for Award of contract No …….. dated .

Name & address of the Service Provider: …….....

Reference: (i) Tender Enquiry Document No ……. Dated ……and subsequent Amendment No ……, dated …….. (if any), issued by the Tender Inviting Authority (ii) Service provider's Tender No ……. Dated ……and subsequent communication(s) No ……..

Dated ……. (if any), exchanged between the supplier and the purchaser in connection with this tender.

THIS AGREEMENT made the ……. Day of …….. 2011 between (name of tender inviting authority) (hereinafter called the ***Procurer***) of one part and ……. (name of service provider) (Hereinafter called the ***Service Provider***) of the other part:

WHEREAS the Procurer is desirous that certain services should be provided by the Service Provider, viz, (brief description of services) and the Procurer has accepted a tender submitted by the Service Provider for the Services for the sum of …… (Contract price in words and figures) (Hereinafter called the Contract Price),

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. The following documents shall be deemed to form part of and be read and constructed as integral part of this Agreement, viz.:

   (i) Terms and Conditions;

   (ii) Location and Description of Equipment;

   (iii) Job Description;

   (iv) Manufacturer's Authorisation Form (if applicable to this tender);

   (v) Purchaser's Notification of Award.

2. In consideration of the payments to be made by the Procurer the Service Provider hereby covenants to provide the Dialysis Services for the specified facilities in conformity in all respects with the provisions of the Contract.

3. The Procurer hereby covenants to pay the Service Provider in consideration of the services , the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed in the Contract.

4. The bank guarantee valid till _____ [(fill the date)] for an amount of Rs. _____ [(fill amount) equivalent to 10% (minimum) of the cost of the contract value] shall be furnished in the prescribed format given in the TE document, within a period of 15 (fifteen) days of issue of Notice for Award of Contract failing which the EMD shall be forfeited.

5. Payment terms: The payment will be made against the bills raised to the Procurer by the Provider on weekly basis after satisfactory completion of said period, duly certified by the designated official. The payment will be made in Indian Rupees.

6. Paying authority: _____ (name of the Procurer i.e. Office, Authority)

_____

(Signature, name and address of authorised official)

For and on behalf of_____

_____

Received and accepted this contract

(Signature, name and address of the supplier's executive duly authorised to sign on behalf of the Provider)

For and on behalf of _____

(Name and address of the Provider)

(Seal of the provider)

Date: _____

Place: _____

Ministry of Health & Family Welfare
Government of India

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