Contract Agreement for Providing Dialysis Facilities

Mission Director, National Health Mission, State Health & Family Welfare Society, Tripura, SIHFW Building, 1st Floor, Palace Compound, Agartala, West Tripura – 799001


This is in continuation to this office’s Notice for Award of Contract (AOC) of Contract No.F.3 (5-3127)-FWPM/SHFWS/2016-17 dated 16th December 2016.

Eskag Sanjeevani Pvt. Ltd.
P-48, Kshirod Vidyavinod Avenue
Baghbazar, Landmark: Girish Manch
Kolkata-700 003, West Bengal
E-mail: eskag_sanjeevani@yahoo.co.in
Tel: 033 40251800

Reference: (i) Tender Enquiry Document No.F.3 (5-3127)-FWPM/SHFWS/2016-17 dated 22nd September 2016 & Corrigendum vide even No. dated 7th October 2016 issued by the Tender Inviting Authority (ii) Service Provider’s bid submitted on 24th October 2016.

THIS AGREEMENT made the 19th day of January 2017 between State Health & Family Welfare Society, Tripura (hereinafter called the Procurer) of one part and Eskag Sanjeevani Pvt. Ltd. (Hereinafter called the Service Provider) of the other part:

Page 1 of 15
NO. 53/19

DATE 18-10-12

STAMP VALUE

PURCHASED BY:

R. K. G. S. S. S. E.

CONSIGNMENT

AW. ADVOCATE

SUMEN Deb

STAMP VENDOR, AGARTALA
WHEREAS the Procurer is desirous that certain services should be provided by the Service Provider, viz. Providing Dialysis Facilities and the Procurer has accepted a tender submitted by the Service Provider for the Services at a rate of Rs.1,107/- (Rupees one thousand one hundred and seven) only per Hemodialysis session (Hereinafter called the Contract Price).

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

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

1. Terms and Conditions:

1.1 Modification to Contract:
The contract when executed 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. Services shall be valid for a period of 5 (five) years from the date of approval by the Authority and it could be cancelled at any time after providing an opportunity of hearing by the Authority, in case the Service Provider does not follow the rules, regulations and terms and condition of the contract and or RFP. However, based on performance can be extended to another term of 5 (five) years.

1.2 Performance Security
1.2.1 The projected target to provide services for one year is 13,550 nos. of hemodialysis session and so the total contract value is for Rs.150.00 Lakh. Therefore, the successful bidder shall furnish a performance security in the shape of a Bank Guarantee issued by a Nationalised Bank in favour of State Health & Family Welfare Society, Tripura for an amount equal to 5% of the total contract value which is Rs.7,50,000.00 (Rupees Seven lakh fifty thousand) only as per prescribed proforma 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.

1.2.2 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.

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

1.3 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.

1.4 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.

1.5 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.
1.6 **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.

1.7 **Termination of Contract**
The purchaser 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.

1.8 **Arbitration**
1.8.1 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.
1.8.2 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 Mission Director, NHM, Tripura 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 Mission Director, NHM, Tripura 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/-).
1.8.3 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.
1.8.4 Reference to arbitration shall be a condition precedent to any other action at law.
1.8.5 Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued.

1.9 **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.

1.10 **Other Terms & Conditions**
1.10.1 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.
1.10.2 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.

1.10.3 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.

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

1.10.4.1 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.

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

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

1.11 One Dialysis facility would be installed for every State/ District Hospital as per Section-2 detailed below. The numbers of Dialysis Facilities may be increased as decided by the State Government at the same rate of contract to extend the services at other District Hospitals in future.

1.12 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.

1.13 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.

1.14 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.

1.15 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.

1.16 Annual review of performance and observance of terms & conditions shall be carried out by a committee which shall include CMO & Head of Department of Medicine 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.

1.17 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.

1.18 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.
A no-fee receipt shall be provided by the service provider to every Below Poverty Line (BPL) patient. A copy of all such receipts along with a copy of BPL Ration Card of the patient countersigned by the Medical Superintendent of the Hospital shall be submitted on a weekly basis by the service provider to the District Hospital Authority. The Medical Superintendent of District Hospital shall countersign all the receipts. The Service Provider shall submit the countersigned copies of (i) No-fee receipt & (ii) BPL Card for every patient and submit it to the Mission Director, NHM, State Health & Family Welfare Society, Tripura by 10:00 AM on every Saturday. 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.

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

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

1.20.2 Daily patients register for Above Poverty Line (APL) including outside as well as for patients referred by District Hospital to be separately maintained.

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

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 procedure 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.

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/liability of the service provider.

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

Electricity, water, medical gases and all other required amenities including waiting area for patient & patient attendant shall be the responsibility of the service provider.

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

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

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.

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.

2. Location & Description of Equipments:-

<table>
<thead>
<tr>
<th>Name of District Hospital &amp; bed strength</th>
<th>No. of Dialysis Machines</th>
<th>Description of Equipments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indira Gandhi Memorial Hospital, Agartala (510 bedded)</td>
<td>4+1=5</td>
<td>Details of Hemodialysis Machine &amp; Associated Systems at Annexure-A.</td>
</tr>
<tr>
<td>Gomati DH, Udaipur (150 bedded)</td>
<td>4+1=5</td>
<td></td>
</tr>
<tr>
<td>North Tripura DH, Dharmanagar (100 bedded)</td>
<td>4+1=5</td>
<td></td>
</tr>
<tr>
<td>Dhalai District Hospital, Kulai (150 bedded)</td>
<td>4+1=5</td>
<td></td>
</tr>
<tr>
<td>South Tripura District Hospital, Santirbazar (100 bedded)</td>
<td>4+1=5</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td></td>
</tr>
</tbody>
</table>
3. Job Description

3.1 The Service Provider shall be responsible for operationalization of Dialysis facility at (i) Indira Gandhi Memorial Hospital, Agartala, (ii) Gomati District Hospital, Udaipur (iii) North Tripura District Hospital, Dharmanagar, (iv) Dhalai District Hospital, Kulai and (v) South Tripura District Hospital, Santirbazar 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 the districts in the state:

3.1.1 The service provider is allotted a space (@ 120 sq. ft. per machine) by the authority, also authority shall be responsible for Erythropoietin and Injectable Iron and the service provider 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 pediatric patients.

3.1.2 The decision to refer a patient for dialysis in District hospital should originate from a qualified Nephrologist/ Consultant/ Physician in a Government hospital along with requisite sessions required. Surgery for Fistula / Graft placement Haemodialysis for Dialysis shall be responsibility of the Authority. In all cases, the diagnostic tests (Urea, Creatinine, Sodium, Potassium, complete bio-chemistry & hematology profile and quarterly Viral Markers) before and after the dialysis should be done by the service provider. 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) in each District Hospital.

3.1.3 The facilities such as observation rooms, recovery rooms, toilets etc., if available, at District Hospitals may be utilized by the service provider.

3.1.4 Provide dashboard for monitoring of service delivery with due diligence to patient privacy for administrative Staff. Treating Nephrologist/ Consultant/ Physician & the ‘Procurer’ should have complete access to the dashboard.

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

3.1.6 Central Venous line / Jugular vascular access required for acute Dialysis treatment shall be the responsibility of the service provider.

3.1.7 In case of any cross contamination the service provider is liable to provide free Dialysis services for life to the concerned patients. In case of more than 5 (five) cases in one calendar year authority may terminate the contract.

3.2 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 under Section-2 above. The Service Provider shall not be entitled to levy any charge on the BPL patients. The services shall be provided completely cashless to all BPL patients referred by district/sub-district hospitals after obtaining countersignature of District Hospital Authority on copy of BPL Card. For APL patients the service provider shall charge at a rate of contract price.

3.3 A list of APL patients availing hemodialysis at each hospital shall be submitted after countersigning by Medical Superintendent of the District Hospital every week along with the no-fee receipt bill for BPL patients. Records for Procedure to be maintained, list of Emergency equipments to be provided and minimum standards & staffing pattern for each Dialysis unit, at Annexure-B, C & D.

4. Purchaser's Notification of Award at Annexure-E.

II. 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.

III. The Procuer 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.

IV. The Bank Guarantee valid till 29th June 2022 for an amount of Rs.7,50,000/- (Rupees Seven lakh fifty thousand) only equivalent to 5% (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.

V. Payment terms: The payment will be made against the bills raised to the Procuer 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.

VI. Paying Authority: Mission Director, NHM, State Health & Family Welfare Society, Tripura

(Dr. Shailesh K. Yadav, IAS)
Mission Director, NHM
State Health & Family Welfare Society, Tripura
For and on behalf of Department of Health & Family Welfare, Govt. of Tripura

Received and accepted this contract
(Signature, name and address of the supplier’s executive duly authorized to sign on behalf of the Provider)
For and on behalf of: Eskag Sanjeevani Pvt. Ltd.
P-48, Kshirod Vidyavinod Avenue
Baghbazar, Landmark: Girish Manch
Kolkata-700 003, West Bengal
E-mail: eskag_sanjeevani@yahoo.co.in
Tel: 033 40251800

Date: 11 January 2017

Place: Agartala, Tripura
Annexure-A

Hemodialysis 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.

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, polyacrylonitrile, polymethylmethacrylate) or modified cellulose membrane (e.g., cellulose acetate) should be preferred over unmodified

2. Cellulose membranes (e.g., cuprophane). Cuprophane 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.

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 used 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.

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 Hemodialysis 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 Hemodialysis 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 1 hour of Citric and thermal disinfection shall be done to all HD machines. The same shall be documented

Other Activities for patient care

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)PTH 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 health 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 milliliter (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 Hemodialysis 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.

(Handwritten signatures by Dr. Shalinee K. Yadav, IAS, Mission Director, National Health Mission, Govt. of Tripura.)

DR. SWAPAN DEY
VICE-PRESIDENT
ESKAG SANJEEVANI PVT. LTD
Records for Procedure

Each 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 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
List of Emergency Equipments

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

<table>
<thead>
<tr>
<th>Sl.</th>
<th>Name of Equipments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Resuscitation equipment including Laryngoscope, end tracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag Adult &amp; Paediatric (neonatal if indicated)</td>
</tr>
<tr>
<td>2.</td>
<td>Oxygen cylinders with flow meter/tubing/catheter/face mask/nasal prongs</td>
</tr>
<tr>
<td>3.</td>
<td>Suction Apparatus</td>
</tr>
<tr>
<td>4.</td>
<td>Defibrillator with accessories</td>
</tr>
<tr>
<td>5.</td>
<td>Equipment for dressing/bandaging/suturing</td>
</tr>
<tr>
<td>6.</td>
<td>Basic diagnostic equipment- Blood Pressure Apparatus, Stethoscope, weighing machine, thermometer</td>
</tr>
<tr>
<td>7.</td>
<td>ECG Machine</td>
</tr>
<tr>
<td>8.</td>
<td>Pulse Oxymeter</td>
</tr>
<tr>
<td>9.</td>
<td>Nebulizer with accessories</td>
</tr>
<tr>
<td>10.</td>
<td>Dialyzer reprocessing Unit</td>
</tr>
<tr>
<td>11.</td>
<td>ACT machine</td>
</tr>
<tr>
<td>12.</td>
<td>Cardiac monitors</td>
</tr>
<tr>
<td>13.</td>
<td>Vein finder</td>
</tr>
<tr>
<td>14.</td>
<td>All required consumables for adult and pediatric patients</td>
</tr>
</tbody>
</table>

\[\text{(Dr. Shailaesh K. Yadav, IAS)}
\text{Mission Director,}
\text{National Health Mission,}
\text{Govt. of Tripura.}
\]

\[\text{DR. SWAPAN DEY}
\text{VICE-PRESIDENT}
\text{ESKAG SANJEEVANI PVT. LTD.}\]
## Minimum standards and staffing pattern for the Dialysis unit

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Staff Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Qualified Nephrologist / MD Medicine with one year dialysis training from recognized center performing one visit every fortnight and clinical review for all patients.</td>
</tr>
<tr>
<td>2</td>
<td>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</td>
</tr>
<tr>
<td>3</td>
<td>Dietician (optional)</td>
</tr>
<tr>
<td>4</td>
<td>Sweepers 1 for every five machines per shift</td>
</tr>
<tr>
<td>5</td>
<td>Hospital attendant 1 for every five machines per shift</td>
</tr>
</tbody>
</table>

---

(Dr. Sibi Bhattacharya, IAS)  
Mission Director,  
National Health Mission,  
Govt. of Tripura.

---

DR. SWAPAN DEY  
VICE-PRESIDENT  
ESKAG SANJEVANI PVT. LTD
To
Dr. Swapan Dey
Vice President
Eskag Sanjeevani Pvt. Ltd.
P-48, Kshirod Vidyavinod Avenue
Baghbazar, Landmark: Girish Manch
Kolkata-700 003
E-mail: eskag_sanjeevani@yahoo.co.in

Sub: - Notice for Award of Contract (AOC) for implementation of ‘Pradhan Mantri National Dialysis Program’ under National Health Mission, Department of H&FW, Govt. of Tripura.

Ref: - RFP No. F.3 (5-3127)-FWPM/SHFWS/2016-17 dated 22nd September 2016 & Corrigendum vide even No. dated 7th October 2016.

Sir,

With reference to the subject cited above, it is hereby informed that the Technical & Financial Evaluation Committee constituted w.r.t. the above Request for Proposal (RFP) has selected Eskag Sanjeevani Pvt. Ltd. as L1 on the basis of the technical and financial proposals submitted for the bidding process.

2. It is to further inform that the Supply / Work Advisory Board (SAB / WAB) in its meeting held on 06/12/2016 recommended acceptance of the rate quoted by Eskag Sanjeevani Pvt. Ltd. as per details shown below:-

<table>
<thead>
<tr>
<th>Item</th>
<th>Rate quoted per Hemodialysis session (inclusive of all taxes and duties presently in force)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation of ‘Pradhan Mantri National Dialysis Program’ under National Health Mission</td>
<td>Rs.1,107.00</td>
</tr>
<tr>
<td></td>
<td>(Rupees one thousand one hundred and seven) only</td>
</tr>
</tbody>
</table>

3. It is, therefore, requested for execution of Contract Agreement and submission of Performance Security in the shape of a Bank Guarantee issued by a Nationalised Bank in favour of State Health & Family Welfare Society, Tripura for an amount equal to 5% of the total contract value and remain valid for a period, which is six months beyond the date of expiry of the contract as per terms & conditions of the RFP document 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.


Enclo: A stated

Yours faithfully

(Dr. Shailash K. Yadav, IAS)
Mission Director, NHM
Govt. of Tripura

Cont...P/2
Copy for information to:-
1. The Director, Health Services, Govt. of Tripura, Agartala.
2. The Director, Family Welfare & P.M., Govt. of Tripura, Agartala.
3. The State Finance Manager, NHM, Tripura, Agartala.

Copy forwarded to:-
1. PS to the Hon’ble Minister, H&FW, Govt. of Tripura, Agartala.
2. PS to the Principal Secretary, H&FW, Govt. of Tripura, Agartala.
3. PS to the Joint Secretary, Govt. of India, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi – 110011.
4. The Director, RRC-NESS (Branch Office of NHSRC), Ministry of Health & Family Welfare, Govt. of India, Assam Medical Council Bhawan, Guwahati, Khanapara-781022.
5. Dr. Jitendar Kumar Sharma, Sr. Consultant & Director (HCT Division), National Health Systems Resource Centre, NIHFW Campus, Baba Gangnath Marg, Munirka New Delhi 110067.

(Dr. Shalish K. Yadav, IAS)
Mission Director, NHM
Govt. of Tripura