

# **ROTARY CLUB OF MUMBAI KANDIVALI WEST GLOBAL GRANT PROJECT**

**DIALYSIS CENTRE** 

# **Table of Contents**

Chapter 1 -	Introduction
1.1. Proj	ect idea1
1.1.1.	Basis for selection of this project1
1.1.2.	Why Dialysis?
1.1.3.	Why NGO and Private Participation (NPP) for this project?
1.1.4.	Objectives of the project
1.2. App	broach & Methodology, studies, surveys including data collection, analysis
Chapter 2 -	Sector Profile
2.1. Indu	stry Overview
2.1.1.	Brief Introduction
2.1.2.	Leading manufacturers of Dialysis Equipments
2.2. Key	v Issues
Chapter 3 -	Market Assessment
3.1. Indu	stry Outlook7
Chapter 4 -	Project
4.1. Des	cription of the Project
4.2. Con	nponents of the project
4.3. Inte	raction with stakeholders
4.4. Bes	t case studies for similar projects in Kandivali10
Chapter 5 -	Project Financials
5.1. Cos	t Estimation 11
5.1.1.	Running cost
Chapter 6 -	Statutory and Legal Framework
Chapter 7 -	Indicative Environmental & Social Impacts
7.1. Env	ironmental Impacts
7.2. Soc	ial Impacts
7.3. Mit	igation Measures
Chapter 8 -	Operating Framework
8.1. Proj	ect Structure at a Glance
8.2. Risł	cs & Mitigation
Chapter 9 -	Way Ahead

# **Executive Summary**

Dialysis is essential for patients suffering from "*End Stage Renal Disease (ESRD)*" and it is observed from preliminary studies that the prevalence of Chronic Kidney Disease (CKD) the precursor to ESRD is 0.8% in India. The major contributing causes to CKD are diabetes and high blood pressure among others; these diseases are increasing at an alarming rate across the country. Hypertension is observed in 20-40 percent adults in urban areas and 12-17 percent adults in rural areas, the number suffering hypertension is expected to be 213.5 million in 2025. India is the world capital for diabetes cases with projected number to be 57.2 million in 2025.

The cost of supporting the treatment of patients undergoing dialysis and suffering from ESRD is very high in the order of Rs.10,000 to Rs.20,000 per month. The World Bank reviewed and proposed revisions in May 2014, to its poverty calculation methodology and purchasing power parity basis for measuring poverty worldwide, including India. According to this revised methodology, the world had 872.3 million people below the new poverty line, of which 179.6 million people lived in India. In other words, India with 17.5% of total world's population, had 20.6% share of world's poorest in 2011, it is impossible to support such high treatment costs. Cost of per session of dialysis is anywhere between Rs.1000 to Rs.2000 in the private set up, low cost dialysis centers in the country provide dialysis between Rs.150 to Rs.600, but these centers are run by NGOs and supported by philanthropists. The dialysis set up by NGO and government is very limited. This results in non-availability of service for suffering patients.

The objective of this project is to establish dialysis centers to provide nephrology support and dialysis for patients who require the same. The centers will be located in Kandivali West, Mumbai, India, the emergency medical, laboratory and ambulatory support will be provided by Atlantis Hospital, Kandivli West. The center will be operated by qualified dialysis technicians and supported by trained nurses and shall operate two shifts every day, six days a week. The government will reimburse the partner at an agreed rate with the partner (Government runs a special Orange Ration Card program wherein the total cost of such people is reimbursed by the government). Further, the center would provide the dialysis for other section of the society at a very subsidized rate of Rs.800/- per cycle.

The proposed project will be based on a Tri-Party agreement between *Sai Vilayatrai Sai Jiwatsingh Sai Vishindas Charitable Trust( 1st Party), Rotary Club of Mumbai Kandivali West -RCMKW (2nd party) and Atlantis Hospital (3rd party),* wherein the 1st Party will provide with space for installing 5 (Five) new machines along with their existing 4 (Four) machines, 2nd Party will provide funds for purchase of 5 (Five) new machines plus basic infrastructure required for the center and 3rd Party would be responsible for the day to day running of the center (including doctors, nurses and other manpower) and adhering to the laws and regulations that govern the process.

This project shall be verified for its success and ability to meet the specified objectives at the end of every year. Upon successful achievement of the objectives, the project may be replicated at other place in the locality following the same model or modifying it as per the requirement.

# **Chapter 1 - Introduction**

# 1.1. Project idea

### 1.1.1. Basis for selection of this project

The public healthcare service follows the national pattern and consists of different levels of public healthcare institutions, starting from the bottom of the pyramid of healthcare facilities and going to the top, an integrated; step up referral system with a network of sub-centers, primary health centers, community health centers, taluka hospitals, district hospitals, and medical college hospitals. Patients are provided advanced level of curative, surgical, and diagnostic services as they move up the hierarchy.

The Government of Maharashtra in its commitment to improve the health and wellbeing of the people has provided extensive resources to the primary and secondary level public health facilities, however wide gaps exist between the desired and the actual level of services provided to the people at tertiary level, one of them is the provision of dialysis service.

Dialysis is the essential requirement for patients suffering from advanced chronic kidney disease and kidney failure when renal replacement is not possible. A nephrologist prescribes dialysis after detailed analysis and examination of the patient; Haemo dialysis and Peritoneal Dialysis are the two ways by which dialysis is provided to patients. Haemo dialysis is more popular as it involved lesser capital cost and is done under supervision in a center. Peritoneal dialysis can is self-administered at home, but it involves high initial investment and operation cost.

Private dialysis centers are operated either attached with a hospital/clinic or as a standalone center similar to a diagnostic center. The cost of dialysis in a private center ranges from Rs.2000 to Rs.3000 per sitting depending on the location, type of dialysis, consumables used, reuse of consumables and funding received by the dialysis center from support organizations.

Patients prescribed with dialysis need to undergo the process until they undergo renal replacement and the frequency of dialysis varies from once a week to once a day depending on the severity of the renal failure. Patients undergoing haemodialysis at private facilities spend between Rs.10,000 to Rs.20,000 every month for the process; additionally patients undergoing haemodialysis have to take special food and additional medicines to support the system. The trauma of the disease coupled with the high expenditure of treatment drains the patients emotionally and economically, hence RCMKW decided to step in and provide cost effective and viable alternative.

As the Government's centers are few it is difficult for patients relying on them. Hence, RCMKW intends to provide dialysis services locally, which would help people in the local surrounding to take the benefit of the facility.

### 1.1.2. Why Dialysis?

The human kidney performs the following functions:

- 1. Removes the waste and water from the blood stream
  - a. Excess salt, and other chemicals are filtered by the blood to maintain the appropriate balance required for the body, these chemicals and salts are along with the excess water is removed from the body in the form of urine by the kidneys. Excess water in the body results in high blood pressure and swelling of body parts leading to failure.
- 2. Balancing the chemical composition of the body
  - a. By balancing the fluid levels in the body the kidneys assist in maintaining the chemical composition of the body. Chemical imbalance in the system disrupts the normal metabolism resulting in multiple diseases.
- 3. Assist in producing Red Blood Cells (RBC)
  - a. Kidneys produce Erythropoietin; this hormone simulates the production of RBC cells in the body. RBC cells act as oxygen carriers in the blood stream, reduction of RBC count results in anemia and ultimately weakening of the body.
- 4. Assist in maintaining the blood pressure
  - a. The kidneys release hormones such as renin and angiotensin, these hormones regulate the salt and fluid content of the body and assist in contracting and relaxing the blood vessels that manage the blood pressure. Failure of kidneys increases blood pressure, resulting in contraction of blood pressure leading to high blood pressure, which strains the heart.
- 5. Assist bone development
  - a. Kidneys produce a hormone called Calcitriol, this maintains the correct level of calcium and phosphate in the blood and bones, failure of kidneys causes reduces calcitriol production and leads to renal bone disease

Kidney failure or failure of kidney function is broadly classified as,

- 1. Acute kidney failure
  - a. The kidney suddenly stops working, in most cases this is temporary and is caused because of injury, accident or poisoning
- 2. Chronic kidney failure
  - a. Gradual loss of kidney functions is called as chronic kidney failure and this may lead to permanent kidney failure. The causes of CKD is still unknown, but the following have been identified as leading causes,
    - i. Diabetes Mellitus
    - ii. High Blood pressure
    - iii. Glomerular Disease

Disease

iv. Inherited and Congenital Kidney

- v. Polycystic Kidney Disease
- vi. Renovascular Disease
- vii. Chronic Pyelonephritis
- viii. Kidney Stones
- ix. Analgesic nephropathy and drugs

Patients who suffer from acute kidney failure are provided drug relief and temporary dialysis till normal operation of the kidney starts, but when patients reach the peak of chronic kidney failure the only option for cure/survival is to replace the kidney from a suitable donor, but with a paucity of replacement kidney, the only other option is to opt for dialysis till replacement kidney is available.

Dialysis is done in two ways,

1. Peritoneal Dialysis

A special fluid is infused in the peritoneal cavity in the stomach, which is surrounded, by arteries and veins. The wastes in the blood are transferred through the semi permeable peritoneal membrane. PD is done in two ways

- a. Continuous Cyclic PD The patient is connected with the PD machine overnight and the dialysis happens during the sleeping hours
- b. Continuous Ambulatory PD The patient is infused with the fluid every and after a 3-6 hour period it is drained. The number of cycles may vary depending upon the intensity of the disease and the ability of the person to carry fluid.
- 2. Haemo Dialysis

During haemodialysis the blood is removed from the body, is cleaned using a dialyzer, and is returned to the body. An Arteriovenous Fistula is surgically attached to the body for removing and injecting blood into the system. Haemodialysis is done in the following ways,

- a. Home Haemodialysis
  - i. Under medical supervision haemodialysis can be done at home either in the mornings or nocturnal
- b. In center Haemodialysis
  - i. Under medical supervision haemodialysis is done at a center either during waking hours or nocturnal

In center waking hour haemodialysis is the most commonly found and preferred option because it offers comparatively lower cost of procedure for the patient, but this method has the following restrictions,

- i. Patient has to travel to the haemodialysis center for every procedure
- ii. The dialysis timetable has to be strictly followed
- iii. The dialysis schedule restricts the ability to travel elsewhere
- iv. Full time work schedule is affected
- v. Special diet for the dialysis patient has to be strictly followed
- vi. Support medications need to be taken regularly

#### **1.1.3.** Why NGO and Private Participation (NPP) for this project?

This planned strategy of having NPP is most suitable for this project which intends to bring the dialysis service affordable and at the door step of patients requiring the service:

- 1. The operation is a service delivery excellence intensive model, and several private dialysis centers pioneer this across the country, a NPP contract would bring in both the private sector efficiency and bring down the cost of service delivery
- 2. Standalone dialysis center has been established as a viable business in the country and leading healthcare organizations are entering the fray across the country
- 3. There is a human resource constraint to operate the center, besides this current staff is inadequately trained
- 4. Delay in reporting of problems in the hard & soft healthcare infrastructure lead to bigger and un-reparable problems.

### **1.1.4.** Objectives of the project

NPPs combine the varied skills and resources of partners in innovative ways and allow for the sharing of benefits, risks, and responsibilities. Therefore, the society looks increasingly to NPP as a model to:

- 1. Provide Dialysis service by tapping the expertise of the private sector
- 2. Utilize the ability of renowned NGO to mobilize capital to speed up the delivery of infrastructure and services
- 3. Reduce the travel time of patients by providing dialysis service at the local level
- 4. Enable efficient use of Dialysis service by improving the identification of long-term risks and their allocation, while maintaining affordable tariffs
- 5. Provide higher quality of services
- 6. Access best practices
- 7. Enable regular maintenance and upgrades

# 1.2. Approach & Methodology, studies, surveys including data collection, analysis

A primary research was carried out to,

- Study and understand the operations of the selected place in the locality and identify their needs
- Assess the availability of Dialysis for the local population with the public and private facilities
- Assess the business environment in terms of market dynamics, pricing competition, regulations
- A detailed sensitivity analysis on the base case projections with respect to the key drivers affecting revenue, streams of business and capital cost.

Based on the sensitivity analysis, the ideal pricing structure for the Dialysis service has been proposed.

#### Secondary research

We supplemented the primary survey with secondary research focused on similar NPP models across the country, operating models of dialysis centers and pricing of services

# **Chapter 2 - Sector Profile**

### 2.1. Industry Overview

### **2.1.1. Brief Introduction**

The first dialysis center in India was established at CMC Vellore in 1961 and soon KEM Mumbai, AIIMS New Delhi, PGI Chandigarh started dialysis in the same decade. In the last four decades dialysis have been established in multiple formats viz.

- 1. Nephrologist owned dialysis centers
- 2. In hospital dialysis centers
- 3. Dialysis centers by charitable organizations
- 4. Standalone dialysis centers

Hospital run dialysis centers were popular till a few years before because of the following reasons,

- 1. Availability of nephrologist and in house on duty doctors
- 2. Availability of trained manpower and support system
- 3. Dependability on the hospital brand for delivery of service

Dialysis centers operated by charitable organizations are very popular in Mumbai, which has the highest number of dialysis centers in the country. The success of these centers in providing low cost services is owed to,

- 1. Low or no cost incurred for the building for dialysis centers
- 2. Nephrologists/Doctors associated with the institutions provide the service for free or for minimal fee
- 3. Machines are procured with the assistance of philanthropists
- 4. Dialyzers are reused, reducing the variable cost per dialysis

Standalone dialysis centers by Nephrologists are also found across the country, the advantages and disadvantages of such a unit are,

- 1. The nephrologist owns the building or rents at a lower rate
- 2. Scale up of number of units is difficult hence the capacity is limited
- 3. Service delivery would be of high quality owing to the focused care
- 1. Renkare Fortis
  - a. Fortis has ventured in the dialysis service through its subsidiary Renkare. It offers dialysis through six centers in New Delhi and plans to expand to 50 locations across the country in the next two years
- 2. Apex Kidney Care Mumbai
  - a. Apex Kidney Care Mumbai has eight centers across the country and intends to expand it to 50+ centers.

### 2.1.2. Leading manufacturers of Dialysis Equipments

The global market for dialysis is highly consolidated with majority of the market being held by a few major players, BBraun (Germany), Fresenius (Germany), Baxter International (USA), and DaVita (USA). The other players in the dialysis equipment industry include NIKKISO (Japan), NIPRO (Japan), Gambro (Sweden) etc. Indian dialysis market is also dominated by the aforementioned MNCs.

### 2.2. Key Issues

The key issues in setting up Dialysis centers are,

- 1. High cost of capital equipments
- Limited availability of trained clinical and para clinical manpower Nephrologists are in short across the country and there is a huge shortage for dialysis technicians, most hospitals/centers train nurses and BSc Biology/Zoology graduates as dialysis technicians
- 3. Short life of dialysis equipment seven years in the normal operation life of a dialysis machine
- 4. Requires rigorous infrastructure set up
- 5. Regular maintenance of equipment's as the running time of machines is high
- 6. High cost of associated employee salary
- 7. Power supply, procurement of supplies adds to cost

# **Chapter 3 - Market Assessment**

# 3.1. Industry Outlook

The exact number of persons requiring dialysis in the country is still not known authoritatively. The Indian Society of Nephrology has established a Chronic Kidney Disease (CKD) registry and this is expected to provide useful epidemiological data in future.

In the prevention study done in Chennai, the prevalence at the community level is 8600 per million population (pmp) in the study group and 13900 pmp in the control group. The second study based in Delhi revealed a prevalence of CKD (serum creatinine more than 1.8 mg %) at 7852 pmp. The third study from Bhopal revealed an incidence of 151 pmp suffering from end stage renal disease (ESRD).<sup>1</sup>

AIIMS, New Delhi conducted two studies, the first study covering a population of 4712 subjects in New Delhi who participated in a blood biochemistry test. Mean age was  $42.38\pm12.54$  years, 56.16% were male. Thirty-seven were found to have chronic renal failure (prevalence rate of 0.78%). If these data are applied to India's 1 billion population there are ~7.85 million CRF patients in India. Aetiologically, diabetes (41%), hypertension (22%), chronic glomerular nephritis (16%), chronic interstitial disease (5.4%), ischaemic nephropathy (5.4%), obstructive uropathy (2.7%), miscellaneous (2.7%) and unknown cause (5.4%) constituted the spectrum.

In the second study by AIIMS 48 centers were distributed all over India. Data were based on prospective investigations conducted over a period of one month (33 hospitals) to three months (15 hospitals) comprising 4145 CKD patients. It showed the following aetiological pattern: diabetes (29.7%), chronic glomerulonephritis (19.3%), hypertension (14%), chronic interstitial disease and vesico-ureteral reflux (12.6%), obstruction and calculus (9.3%), ADPKD and Alport Syndrome (8.4%), undiagnosed (6.2%). This study shows that the prevalence of CRF in India is ~0.8%. If we combine the two, diabetes has emerged as the most frequent cause (30–40%) followed by hypertension (14–22%), CGN (16–20%), CIN (5.4–12.7%), heredofamilial disease (8.4%), obstruction including calculus (2.9%). The two studies, which are different in some ways, perhaps explain the wide range in incidence, suggesting regional influences.

Based on the above surveys following assumption is considered for arriving at the requirement.

- 1. CRF prevalence rate 0.8% of the population
- 2. Population dependant on Government System for Dialysis 50%
- 3. Population dependant on charitable organisation for Rajiv Gandhi scheme & concessional dialysis 20 %.
- 4. Dialysis requirement per patient one/TWO per week
- 5. Annual population growth rate 1.87% (Average annual growth rate in the past 10 years)
- 6. Number of cycles per machine per day 3
- 7. Operating efficiency of the dialysis machine 95% (95% of the time the machine is up and running during working hours)

	2017	2018	2019	2020	2021	2022
Mumbai Population(in million)	23.50	23.93	24.387	25.307	25.780	26.263
Kandivali Population (in	1.00	1.01	1.04	1.06	1.08	1.10
million)						
PERSON Requiring Dialysis	8,000	8,149	8,301	8,456	8,614	8,775
in KANDIVALI						
NEEDY PERSON Requiring	4,000	4,074	4,150	4,228	4,307	4,387
Dialysis in Kandivali						
Person requiring Dialysis at	1,600	1,629	1,660	1,691	1,722	1,755
charitable organization						

Ī	2017	2018	2019	2020	2021	2022
Number of Cycles required per	2	2	2	2	2	2
patient per week						
Total Cycles required per	3,200	3,258	3,320	3,382	3,444	3,510
WEEK						
No of M/c required assuming 3						
cycles per m/c per day	177	181	184	187	191	195
No of M/c assuming operating						
efficiency	186	190	193	196	210	205

It is found that the Kandivali requires 180 plus dialysis machines immediately. This assumption does not include the requirements of seropositive patients who need to be provided with separate dialysis machine to avoid cross infection. Though these numbers look exaggerated, it should be noted that there is no standardized study on the number of people requiring dialysis.

The below table gives the distribution of dialysis machines among government hospitals and existing dialysis center in & around Kandivali.

Dial	Dialysis Machine at various places in and around Kandivali				
Sl.No.	District	No of Machines			
1	Shatabdi hospital	8			
2	Hitwardhak Mandal	13			
3	Kambar Darbar	6			
4	Billa Dialysis Center	10			

It is observed that center have the maximum load and the average utilization of the machine varies from 2.5 to 3 cycles per machine per day. It should be noted that utilization of dialysis service also depends on,

- 1. Availability of nephrologist
- 2. Uptime of the dialysis machine
- 3. Routine availability of consumables
- 4. Availability of trained manpower
- 5. Availability of advanced diagnostic support to assess and advice dialysis

# **Chapter 4 - Project**

# 4.1. Description of the Project

RCMKW is planning to provide dialysis services at Sai Vilayatrai Sai Jiwatsingh Sai Vishindas Charitable Trust of Kandivali (Dialysis Centre).

- 1. The dialysis centers will be located in the Dialysis center with existing machine in operation. The center will start with additional five-dialysis machines and have the building infrastructure to expand to 10 machines. We have provided scenario analysis for five plus four machine center.
- 2. The partner shall employ one nephrologist who will consult all patients. Adequate manpower shall be employed by the partner for operating the dialysis center as agreed.
- 3. The center shall demarcate one machine out of five for Sero positive cases, this is an average and can be altered based on the local profile of the patients.
- 4. The lab tests required will be provided by private partner and the ambulance requirement also will be from the private partner and 108 services.
- 5. The private partner shall provide entertainment facilities during the dialysis period. The patients shall bear the cost of special food required for dialysis patients.
- 6. The private partner shall provide the service for all patients requiring dialysis, the patient has to be advised dialysis by the nephrologist associated with the center and it should be approved by the committee created for this purpose.
- 7. The private partner shall collect the minimum charges prescribed by the committee for availing dialysis services from the beneficiaries. The private partner shall seek reimbursement from government for the number of cases served under Rajiv Gandhi scheme.

### 4.2. Components of the project

For setting up of a dialysis center, the requirements are as follows,

- 1. Space for dialysis unit 2000 sqft to 3000sqft of built up space for running 5-10 dialysis machines including supportive services.
- 2. Haemodialysis Dialysis machines
- 3. RO plant
- 4. Cot, Mattresses and Dialysis Chairs
- 5. Para monitors, Ancillary equipment's and crash cart
- 6. Consumables

#### Services/ Items to be provided by the partners

#### **General Provisions**

Administrative responsibilities, required space, adequate raw water, required electrical power required for running the project by the 1<sup>st</sup> Party.

#### Professional and other support services

Required investigations, other supportive and emergency services, treatment of complications, medicines and services for complications shall be ensured by the 3<sup>rd</sup> party.

#### Infrastructure Works

The 1<sup>st</sup> party shall execute the work of modifying the existing civil and electrical infrastructure to facilitate and establish Haemodialysis Plants.

#### Haemodialysis Machines

 $2^{nd}$  party shall provide, install, the Haemodialysis units at the hospital. It will also be responsible for comprehensive maintenance and standby machine in case of breakdown of machine to ensure uninterrupted service.

#### **RO** Plant

2<sup>nd</sup> party shall provide, install and run fully automated compatible RO water plant of required capacity.

#### Cot, Mattresses and Dialysis Chairs

2<sup>nd</sup> party shall provide, install and maintain cots, mattresses and Dialysis Chair as per the WHO guidelines/ Indian Society of Nephrology guidelines

#### Para monitors

The 2<sup>nd</sup> party shall provide, install and maintain Para monitors of approved specification as per following ratio:

- 1. 1 Para monitors for 5 machines
- 2. 2 Para monitors for 10 machines

#### Ancillary equipments

The 3<sup>rd</sup> party shall provide and maintain all ancillary equipments like the Weighing scale, BP apparatus, Stethoscopes, Ph meter, TDS meter etc. required for proper operation of the system.

The 1<sup>st</sup> party shall provide the backup power requirements for 90 minutes to the machines to have uninterrupted dialysis.

The 1<sup>st</sup> party shall provide facilities for the disposable, equipments and patient belongings as per the standard requirements of Haemodialysis procedure.

The 1<sup>st</sup> party shall arrange for proper Biomedical Wastes collection as per Maharashtra State Pollution Control Board norms and shall provide all the necessary infrastructure supports that are required. Disposal of the BMW shall be done by the 3<sup>rd</sup> party.

### 4.3. Interaction with stakeholders

All the participants welcomed the idea of operating dialysis center and concurred to the fact that there is a dearth of dialysis service in the Kandivali. Both the private players offering dialysis have plans in pipeline to expand their existing capacity for dialysis.

# 4.4. Best case studies for similar projects in Kandivali

#### Project Brief:

There are number of patients who require dialysis treatment on regular basis. The number of dialysis machines is inadequate in government hospitals. There is always a long waiting status for the patients in government hospitals. The dialysis procedure in private hospitals is very costly and is difficult for poor patients to continue treatment in private hospitals.

It was felt that a fully equipped Nephrology Centers be created in Kandivli to meet the demand of patients requiring dialysis procedure continuously.

# **Chapter 5 - Project Financials**

# 5.1. Cost Estimation

#	Category*	Description	Supplier	Cost in local currency	Cost in USD
1	Equipment	DIAMAX- Hemodialysis Machine	Nipro Medical (India) Pvt. Ltd.	2,900,000	45,313
2	R O Plant Modification			100,000	1,563
3	Air Conditioner			50,000	781
4	Beds for patient			100,000	1,563
5	Electrical Fittings			200,000	3,125
6	Renovation & Painting			500,000	7,813
7	Working Capital for 12 months			240,000	3,750
Tota	l budget:	4,090,000	63,906		

The Haemodialysis equipments include the core dialysis equipments required for delivering the service.

### 5.1.1. Running cost

The model assumes the following manpower requirement for the taluka centers,

Cost of Dialysis (per cycle)

Sr. No.	Description	Cost INR
1	Consumables	329
2	Doctors cost	151
3.	Staff Salaries	159
4.	Miscellaneous	138
	Total Rs.	776

# **Chapter 6 - Statutory and Legal Framework**

The Dialysis unit where RCMKW is planning to install the additional machines already has all the required statutory and legal clearances for running of a dialysis center.

The service provider/partner running the dialysis center shall be responsible for procurement and management of all statutory and legal requirements from time to time.

# **Chapter 7 - Indicative Environmental & Social Impacts**

# 7.1. Environmental Impacts

The dialysis procedure does not produce harmful radiations or noise, but body fluid wastes are generated during the procedure, which needs to be collected, stored, and disposed safely. Stringent bio medical waste disposal processes is developed and implemented by the private partner.

# 7.2. Social Impacts

- The project will enable provision of dialysis service at local level, this penetration cuts down the overall cost of treatment
- Improved availability of tertiary medical treatment
- The low cost availability of the service will reduce the cost of service at a private center
- Increased awareness among the public which will indirectly lead to lowering of hypertension, diabetes cases
- Society will get the best of public and private services at one place i.e. private sectors quality and efficiency at public rates thus reducing their economic cost of availing the healthcare services.
- Enhanced patient satisfaction and diminished strain
- Employment generation for the trained manpower required for operating the center
- Streamlined operation and efficient work culture of private partner will impact the public healthcare functioning in the long run

### 7.3. Mitigation Measures

Dialysis equipment's and process will be operated under strict trained manpower supervision, the following safety measures are/will be taken into account,

- 1. Dialysis machines and associated equipment's must be located and designed as per the manufacturer's specific layout guidelines.
- 2. New machines will be purchased instead of refurbished one.
- 3. Machine will be always under Comprehensive Maintenance Contract (CMC) for regular maintenance.
- 4. Proper Bio Medical Waste (BMW) collection, storage and disposal norms are developed and adhered to.

# **Chapter 8 - Operating Framework**

# 8.1. Project Structure at a Glance

Sl No	Parameter	Description
1	NPP Model	NGO, Public and Private.
2	Concession Component	1. Right to operate dialysis center at Sai Vilayatrai Sai Jiwatsingh Sai Vishindas Charitable Trust.
		2. Building and utilities provision at the center.
		3. Can serve private patients at concessional rates.
3	Government Support	1. Rajiv Gandhi scheme.
4	Project Benefits	1. Provision of dialysis service at local level
		2. Economic benefits to the needy patients
		3. Easy accessibility and availability for patients
		4. Availability of service so far not available
		5. Private sector efficiency in operation and maintenance
5	Operation and Maintenance	1. Operation of the dialysis center for providing hemodialysis service
		2. Ensure 95% machine uptime
		3. Operates on one shifts from 8AM to 8 PM.
		4. Service provider will address all maintenance related issues.
		5. Provide requisite reports as agreed.
6	User Charges Involved	1. The dialysis center is free to serve private patients at the price arrived by project partners.
7	Inventory Management	1. Procure and manage all consumables and inventory required
		2. Maintain optimum inventory and ensure nil stock out.
8	Revenue Management	1. The dialysis center will be reimbursed for all the eligible cases at an agreed rate by the Government every month.

### 8.2. Risks & Mitigation

In NPP arrangements, risks are inherent in the project due to the varied pursuits and value systems of the two sectors involved in the contract. The private sector is predisposed to prioritizing shareholder return and taking measured risks, whereas regulations and authorities, political opinion and the achievement of societal goals influence the public sector. Additional problems arise because public taxpayers may not welcome the idea of NPPs due to a perceived lack of transparency in the private sector. Full disclosure may also be an issue for the private sector who has an interest in protecting proprietary information to ensure their competitiveness.

Following are the perceived risks involved in developing a dialysis center.

1. Market risk arising from

- a. Insufficient demand
- b. Impractical user levies

- 2. Finance risk arising from
  - a. Inflation

3.

- b. Change in interest rates
- c. Increase in taxes
- Operation and maintenance risks arising from
  - a. Technology risk
  - b. Manpower risk
- 4. Legal risks arising from
  - a. Changes in law

The emphasis is on optimal allocation of risk or risk transfer. This can "incentivize" partners to ensure that objectives of the agreement are met. Risk transfer has the opportunity to be extremely beneficial to the public sector but if not appropriately managed insufficient risk is transferred to the private sector.

SI	Category	Risk	Risk	Mitigation Strategy
No			Incurred by	
1.1	2 Implementation Risk	Delay in project clearance	Partner	1. The dialysis center is already operational under the banner of Kambar Darbar Charitable institute.
1.2		Renovation cost/time overrun	Partner	<ol> <li>Building will be provided by the partner.</li> <li>Renovation required is very basic and we do not anticipate any over runs due to the same.</li> </ol>
1.3		Non availability of Medical and technical personnel to operate the center	Partner	1. The partner will provide a list of manpower already under employment
2.1	Market Risk	Insufficient demand	Partner	<ol> <li>Project partner can anytime get in touch with government hospital in the vicinity to obtain the list of waiting patient with them incase their own list is not able to utilize the capacity of the center.</li> <li>Partners are free to service patients referred from private institutions, but shall not levy charges more than what is agreed for all patients.</li> </ol>
2.2	.2	Impractical user levies	Partner	1. The service will be priced at sustainable rate compared to private/ government institutes, it shall be lower than the prevailing market rate at the time of fixing the rate.

#### **Risk Mitigation Strategies**

SI No	Category	Risk	Risk Incurred by	Mitigation Strategy
3.1	Einenee Disk	Inflation risk	Partner	The partner shall charge what is required to sustain the center.
3.2	Finance Kisk	Exchange rate fluctuation	Partner	The partner has to bear the exchange rate fluctuation during the procurement process
4.1		Technology obsolescence	Partner	<ol> <li>The initial contract is for a period of five years, beyond which if the parties agree to continue the contract the dialysis machines should be replaced to meet the latest technology specification at that point of time</li> </ol>
4.2	Operation and Maintenance	Man power retention	Partner	<ol> <li>The private partner shall employ manpower as agreed.</li> <li>The private partner shall frame effective human resource policies for the training and retaining manpower at the center, there shall be defined plans for replacement of trained manpower.</li> <li>The center shall not be deficit of the number of employees agreed for not more than one week at a stretch</li> <li>Should employees go on leave, fall sick or leave the organisation the private partner has to ensure the replacement within a week</li> <li>The private partner shall adequately train its manpower annually</li> <li>All new recruits by the private partner shall be trained by the private partner for a period agreed</li> </ol>
4.3		Utilities	Private	1. Kambar Darbar Charitable Institute shall provide the electrical and water (already in place for the existing set up)
4.4	.4	Process adequacy and Quality of Service	Private	<ol> <li>The private partner shall maintain detailed books of records of,         <ol> <li>Medical records</li> <li>Consumables – in stock, out of stock, consumption pattern – as per the existing government guidelines</li> <li>All expenditure involved in the day to day operation of the hospital as per the agreed tri-party agreement.</li> <li>Maintain and display quality indicators as per the machine standards</li> </ol> </li> <li>The dialysis unit shall maintain and adhere to detailed Standard Operating Procedures for,         <ol> <li>Service delivery</li> </ol> </li> </ol>

SI No	Category	Risk	Risk Incurred by	Mitigation Strategy
				<ul> <li>b. Patient handling</li> <li>c. Documentation management</li> <li>d. Emergency and Disaster management</li> <li>e. Bio Medical waste management</li> <li>f. Ethical treatment and management of patients</li> <li>g. Cleaning and sterilisation</li> </ul>
4.5	Operation and Maintenance	Equipment Maintenance	Partner	<ol> <li>The private partner and the equipment manufacturer need to produce a defined maintenance contract document at the time of contract award.</li> <li>The cost of any maintenance of the machine has to be borne by private partner after expiry of initial CMC of 3 years.</li> <li>Insurance cost of the machine shall be borne by the private partner.</li> <li>All the partner shall maintain 95% uptime during a month</li> <li>All service issues shall be attended to within 24 hours of intimation by the equipment manufacturer</li> <li>If there is an equipment downtime period of more than 72 hours at a stretch, the private partner has to arrange for dialysis service to be provided from an alternate center at the same cost, while bearing the cost of transportation of patients</li> </ol>
5.1		Changes in Policy	Private	The partners shall be cognizant of the impact of any policy change that may adversely affect the contract (this is apart from the issues relating to taxes, inflation changes, change of interest rates, exchange rate fluctuation which have been discussed above).
5.2	Legal risk	Adherence to legal and regulatory compliances	Partner	<ol> <li>The private partner is responsible for adherence legal and regulatory compliances</li> <li>Any loss arising from inadequate compliance to legal and regulatory norms are to be borne by the private partner.</li> </ol>
5.3		Medico legal risk	Government/ Private	1. The medico legal risk is shared between the private partner and the equipment manufacturer on a case to case basis.
5.4		Employee legal risk	Private	1. The private partner is absolutely responsible for any legal risk arising out of employee disputes

# **Chapter 9 - Way Ahead**

Currently the project plan is to increase the capacity of dialysis center at Kambar darbar charitable institute.

Once implemented the success of the project can be measured in terms of the impact of service delivery, availability of universal access, assistance in treatment, benefits accrued to the society, and the feasibility of the project.