United Dialysis Foundation Inc. Business Plan for Dialysite Inc. (ESRD) Kidney Dialysis Center

Prepared by: Mr. Terrance Dexter Parkman CEO/Founder

This guidebook is designed to give decision makers a general overview of what is involved in setting up a kidney dialysis center. It is designed to prepare a preliminary analysis by utilizing the cost estimates and to determine a center's feasibility.

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United Dialysis Foundation Inc.

Business Proposal for Dialysite Inc.

Kidney Dialysis Center

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The United Dialysis Foundation Inc. Project supports the development of this tool.

http://www.udfhelps.org.

July 2014

Activities and Operational Information

For

UNITED DIALYSIS FOUNDATION.

Mission:

The mission of ***UNITED DIALYSIS FOUNDATION***, a major voluntary nonprofit health organization, is dedicated to preventing kidney and urinary tract disease, improving the health and well-being of individuals and families affected by kidney disease and increasing the availability of all organs for transplantation. THE ***UNITED DIALYSIS FOUNDATION*** will provide (charitable) a variety of dialysis services to patients with chronic kidney failure and end stage renal disease that will inspire and encourage individuals going through physical and mental challenges in their life. UNITED DIALYSIS FOUNDATION strives to improve patient's quality of life by innovating clinical care assistance, and by offering integrated treatment plans, personalized care teams and convenient health-management services. We are a services organization anchored and guided by the philanthropy belief to provide charitable comfort and healing to the infirmed.

Planned Activities: Beginning in the 2013 UNITED DIALYSIS FOUNDATION will work closely with local dialysis clinics and hospitals to identify and serve infirmed youth and adult by providing transportation, food, clothing, assistance with paying utility bills and many other service that may be needed. UNITED DIALYSIS FOUNDATION will seek to provide educational counseling and guidance to the infirmed and their families. We will develop and coordinate in-hospital support groups to share with affected families in order to provide a practical and educational forum of family support and guidance through the storms of physical and mental malady. All such activities will be planned and coordinated by our volunteer board of directors and assisted/supported by volunteer social services professionals. All activities and services will be provided free of charge and open to the general public of infirmed within the dialysis clinics and hospitals we intend to serve (i.e. ***WellStar Hospitals, Tanner Hospitals*** and ***DaVita out-patient clinics***).

Organization's Purpose,

UNITED DIALYSIS FOUNDATION has been launched by Terrance D. Parkman to fill a nurturing void in the ESRD healthcare system community. UNITED DIALYSIS FOUNDATION see a longing need to offer individuals a peace filled outlet, an escape from a stressful environment. We are reaching out to those who are dealing with an illness themselves or caring for an infirmed loved one. Our desire is to supply a Charitable solution for these people to decrease their stress, make them laugh, offer them a peaceful outlet they can access any time of day or night. We will give them a source of hope and love.

Vision:

UNITED DIALYSIS FOUNDATION will be a premier niche organization/support group providing holistic alternatives to individuals. And enhance the lives of everyone with, at risk of or affected by kidney disease. Within 3-5 years, with appropriate funding, UNITED DIALYSIS FOUNDATION plans to establish and administer an ESRD clinic designed in creating programs for patients and teammates that realized the goodwill and awareness must spread to our families, local communities through out the nation.

Objectives:

UNITED DIALYSIS FOUNDATION is being established to provide a vehicle to inspire and encourage individuals going through a difficult time in life by providing charitable therapeutic support and services. UNITED DIALYSIS FOUNDATION will offer continuous comfort by healing the mind and body through laughter and education.

Founder's Story

In February of 2005, the purpose of dialysis was introduced to Terrance D. Parkman. His educational development came from The Georgia Medical Institute – DeKalb campus (Corinthian Schools Inc.) where Terrance D. Parkman graduated from the Dialysis Technician Program. The idea to be a Servant Leader (the philanthropy belief style) was given to Terrance D. Parkman through the word of God. UNITED DIALYSIS FOUNDATION is a combination of his life trials and tribulations. In 2010, his aunt at 57 years old was rushed to a Douglas County hospital in Douglassville, GA with kidney disease. For unknown reason, she became comatose while in ICU and died a few days later. The level of care and compassion Terrance experienced during his aunt's stay and then after death lead Terrance to a desire to "give back" one day to families dealing with life and death health issues. He noticed throughout their support he might not have been able to cope with such a lost.

NOTE: All of the program activities are and will be either Charitable, Religious or Educational and 100% of the organization's efforts are dedicated to such activities.

Program Staffing

All activities are and will be conducted and coordinated by members of our board of directors and supplemented by community volunteer board of directors and assisted/supported by volunteer social services professionals.

Administrative Staffing

In the short-term all administrative and clerical functions in support of programming objectives will be handled by our volunteer board of directors. No one will receive compensation.

Location

Initially, all activities will be conducted at local dialysis clinics and local hospitals. Eventually we will expand the services to other mainstream dialysis clinics and hospitals. For the short-term we will conduct some administrative activities from the home offices of the board members and seek the use of donated space support from the dialysis clinics and hospitals we intend to serve. No fees or rents will be charged for our space activities.

Timetable

All activities will commence in the Fall of 2013

Publicity

All program activities will be publicized to the general public through public service announcements (PSA) made through the print and electronic media. The relationship with will also be used to publicize all programed activities and opportunities.

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INTRODUCTION

In 2014 the need for hemodialysis (also commonly referred to as End Stage Renal Disease or also referred to as Kidney Dialysis) treatment is studiedly increasing drastically in our more rural communities over the past few years, as the “Ageing population others refer to the Baby Boomers” continues to populate the region. There is an increasing need for more treatment centers and better health care provisions for those in need of medical assistance in our community. As business leaders and philanthropist in our own community it is our obligation to consider and explore the options of adding a kidney dialysis treatment center that will help those less fortunate or just unable to obtain those services that are obtainable. Most important, the expectation of the kidney dialysis center over a (3 year or more) time line, will not only provide clinical services to the community but also will support itself in a relatively short period of time and will provide a cost effective service to the local hospitals and the community that it services.

Note that most rural hospitals are currently attempting to cut cost, and are becoming more cost effective or “profit generating” medical provider services and institutions who attempts to fill the wants and needs of the community as well as the financial administrational needs that helps keep the facility (hospital) stable and more functional. As community leaders and philanthropist, we all need to take a serious look at the potential market for dialysis patients: the most criteria for success for a center. It will take the participation of an entire community to successfully impact this need for hemodialysis treatment and the building of a dialysis center in our community now.

Hemodialysis centers provide medical treatment for end-stage renal disease (ESRD) caused primarily by the chronic diseases of diabetes and/or hypertension (high blood pressure). The need for hemodialysis centers is increasing as people live longer and more people develop the disease that lead to kidney (renal) failure. Also, improvements in dialysis technologies, care,

and related drugs enables dialysis patients to live longer on dialysis.

Hemodialysis centers provide their patients with needed services that are easily accessible with minimal travel time. Preferably a family member or a friend drives the hemodialysis patient to and from the treatment facility especially if the facility is a significant distance from the patient's residence. However it is not uncommon for the patient to transport his/herself because treatments are so frequent. This is very dangerous. If the patient is driven, the driver waits at the dialysis center while the patient receives treatment (approximately 4-5 hours) then drives the patient home. In instances of bad weather, the travel to and from the dialysis center may take more time and be more stressful to both the patient and/or the driver. For the patient who needs hemodialysis yet does not live within easy commuting distance of the hemodialysis center, the only option may be to move to a community that has a hemodialysis center. This means the patient may incur additional expense in relocation and may no longer have a social support system available to him/her in the local community.

The United Dialysis Foundation Inc. has developed and created a business plan that will help our local business leaders and the many philanthropist that are within our community today with determining the need for a dialysis center locally in our community. The information will provide to the decision makers the information needed to determine whether a hemodialysis center is economically feasible for the community. The information provided is a starting point for community leaders to use in determining whether their community can support this medical service. As a whole, we must all support the idea of: "humanity helping each another", and "the greatest gift is to giving" motto/concept.

OBJECIVES

This document has been developed to assist individuals, community leaders and local philanthropist to consider the development of a new hemodialysis center. The overall objective of this document is to provide a method to estimate the economic viability of a hemodialysis center. More specifically, the objectives are to:

1. Review nation studies regarding costs, capacity, utilization, and participant characteristics;

2. Present capital and operating costs, and revenue associated with a hemodialysis center;

3. Demonstrate the methodology for estimating the economic viability of at hemodialysis center through a case study;

4. Summarize results; and

5. Provide worksheets for estimating the economic viability of a hemodialysis center for the community.

OVERVIEW OF CURRENT HEMODIALYSIS PROGRAMS

National and Regional Data Sets

The End Stage Renal Disease (ESRD) Program was established in 1972 by federal legislation to extended Medicare coverage to all individuals with end state renal disease (ESRD) regardless of age who require either dialysis or transplantation to sustain life. This legislation and subsequent regulations established health and safety standards applicable to providers of ESRD services. It also established ESRD Network Coordination Councils to serve as liaisons between the federal government and the providers of ESRD services.

In 1978, the ESRD Network Coordinating Councils (ESRD Networks) became an oversight system uniting hemodialysis providers with common goals to 1) provide immediate assess to treatment, 2) treat patients with quality care, 3) help patients maintain a quality of life, and 4) enable each person to live as a functioning member of society. The ESRD Networks monitor quality of care indicators and maintain timely and complete date on the ESRD program to ensure the most efficient use of Medicare dollars for dialysis treatment and kidney transplantation.

The United States has been divided in eighteen ESRD Networks. Figure 1 from the United States Renal Data System 2013 Annual Report displays the location of the eighteen networks. Each network is required to participate in data collection, quality improvement, and the assessment of patient satisfaction. Data provided from the ESRD Networks is based upon all dialysis patients who are receiving hemodialysis in Medicare-approved facilities. Patients whose expenses are covered by insurance are included in the network reports if the facility voluntarily reports the data. In addition, there are a limited number of hemodialysis centers that provide services that are not Medicare approved. These facilities usually are located in the prison system or in the Veterans Administration system.

The ESRD Networks also serve as clearinghouses for federal agencies, renal related organizations, patients and their families. Each ESRD Network provides information on the Medicare-approved hemodialysis and transplant center functioning in their region, the number of stations for each hemodialysis center, ownership of the center, whether the facility is for-profit or non-profit, and contact information. Each network also has a list of Medicare patients receiving hemodialysis identified by zip for each county in each state. Multi-year trends of patients for each county in a specific state are also available from each ESRD Network. Information for each network can be obtained by assessing the web site for the ESRD Networks: www.esrdnetworks.org.

The United States Renal Data System (USRDS) is a national data system funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Center for Medicare and Medicaid Services (CMS), formerly HCFA. The USRDS collects, analyzes, and distributes information about end- stage renal disease (ESRD) from the ESRD Networks. The USRDS 2013 Annual Report is one of the sources of information used in the preparation of this guidebook. Data can be obtained directly form the USRDS through the Renal Data Extraction and Referencing Service (RenDER) on the website: www.usrds.org. data available through the USRDS generally have a time lag of 3 years.

According to the USRDS Annual Report 2013, expenditures for the ESRD program continue to grow. **Table 1** provides data on Medicare expenditures for all dialysis patients between 2008 and 2011. Home health care expenditures had rose 8.1 from $25.1 billion to $30.7 billion total costs for Medicare ESRD Program Expenditures for all Hemodialysis and Peritoneal Dialysis Patients.

Table 2 lists the total expenditures for ESRD program since 2011. It also provides information on the number of current ESRD patients (prevalence), new patients to the ESRD

program in the past year (incidence), and deaths. In 2011 the total number of ESRD patients in the United States was reported to be one in 10 American adults, more than 20 million, have some level of CKD (Chronic Kidney Disease) with mortality rates rising due to age, reaching 273 per 1,000 patient years at risk for ESRD patients age 65 and older, and 314 for dialysis patients of the same age. The total Medicare expenditure for 2011 was $30.7 billion, which rose 8.1 percent which includes Medicare risk patients and organ acquisition costs are excluded. Because the USRDS Coordination Center now receives up-to-date data on Part D use in the ESRD population, these numbers include the new Medicare Part D prescription drug benefit, added in 2006. Medicare coverage for patients, regardless of age or income, begins ninety days after the initiation of hemodialysis treatments. Patients receiving peritoneal dialysis receive Medicare benefits from the beginning of the treatment program.

Table 3 presents per member per month Medicare expenditures for diabetic and non-diabetic patients receiving hemodialysis. Medicare expenditures for all ESRD patients vary based upon whether the patient has diabetes and on the number of years the patient has received dialysis. In general, expenditures decrease after the first year of dialysis, irrespective of the type of dialysis treatment. Expenditures for diabetic patients receiving dialysis consistently run higher than for non-diabetic patients, irrespective for the years on dialysis.

Table 1. Medicare ESRD Program Expenditures for all Hemodialysis and Peritoneal Dialysis Patients: United States, Period Prevalent Patients.

	Percent Distribution		Average Annual Percent Change	
Treatment group	2008	2009	2010	2011
Total expenditures (Billions)	25.1	27.0	28.8	30.7
Inpatient	8.8	9.7	10.4	11.6
Outpatient	4.3	4.5	4.8	10.7
Physical/supplier	4.7	5.1	5.5	5.8
Home health	.60	.65	.69	.61
Skilled nursing	.84	.90	1.0	1.2
Hospice	.10	.97	.12	.15

Source: United States Renal Data System Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

*Note: data taken from HCFA Research Report on End-Stage Renal Disease and methods differ from those used throughout USRDS Annual Report 2013 so direct comparisons to other data should not be made.

Table 2. Patients, Deaths, and Total Medicare Expenditures, ESRD Only: Prevalent and Incident Patients, 2011, United States.

	Prevalent	New Patients	Deaths	Total Medicare Expenditures ($ billion)
2011	1,744,720	615,899	234,793	30.7

Source: United States Renal Data System Annual Report 2013

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Table 3. Per Member Per Year (PMPY) and Per Member Per Month (PMPM) Medicare Expenditures, by Patient Year and Month and Diabetic Status: Dialysis Dollars, Prevalent United States ESRD Patients

	Per Member Per Year/Per Month Medicare $			
	Diabetic	Diabetic	Non- Diabetic	Non- Diabetic
Year	PMPY	PMPM	PMPY	PMPM
2008	86,686	7223.83	75,139	6261.58
2009	87,945	7329.50	76,574	6381.16
2010	91,222	7601.83	78,616	6551.33
2011	93,915	7826.25	80,316	6693.00

Source: United States Renal Data System Annual Report 2013

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Facilities

Hemodialysis facilities are either *hospital-based or freestanding*. A hospital-based hemodialysis center usually is located in a hospital that provides the full spectrum of renal services including vascular assess, pre-ESRD care, hemodialysis, acute dialysis, and peritoneal dialysis. A freestanding hemodialysis unit is not based in a hospital facility. Hemodialysis centers can be either for-profit or non-profit. Hemodialysis centers can be either chain-affiliated of independent. A chain-affiliated unit is one of a group of freestanding hemodialysis units that are owned by a common party and located in a single state or more that on state. A hemodialysis center must have an arrangement of affiliation agreement with a hospital-based hemodialysis center for the provision of inpatient care and other hospital services. The center must have documentation from this hospital-based hemodialysis center that patients from the hemodialysis center will be accepted and treated in emergencies.

Date in Table 4 presents information on the growth of hemodialysis center by facility type for every other year beginning between 2010 and 2013. The greatest increase in hemodialysis centers between 2010 and 2013 occurred in non-hospital based (freestanding) for-profit hemodialysis centers. The majority of hemodialysis patients (75%) received their treatments in freestanding for-profit centers.

Participant Characteristics

Table 5 presents information on prevalent (current) patients alive in 2011. Approximately 50% of all hemodialysis patients alive in 2011 were between the ages of 45 to 65 years and 55.5% was male. Whites represented the largest percentage of prevalent hemodialysis patients (56.0%) yet blacks had the highest rate of hemodialysis treatment per million populations at 148,509. Approximately 90% of all hemodialysis patients were non-Hispanic. However, the rate per million for non-Hispanics is greater than the rate for Hispanics, 6,141.6 per million and 2,069.7 per million, respectively. African Americans and Hispanics has a higher rate of end-stage

renal disease because of the higher incidence of conditions that lead to ESRD, including hypertension, diabetes, and drug abuse.

Table 4. End-of-Year Dialysis Centers by Facility Type 2011.

Facility type	# of Facilities	Patient Count
Fresenius	1824	132,744
DaVita	1729	126,763
Dialysis Clinic Inc.	213	13,195
Small Dialysis Organizations (defined as 20-199 dialysis units)	660	49,102
Independent units	686	56,336
Hospital-Based units	410	36,034
All	5522	414,177

Source: United States Renal Data System Annual Report 2013

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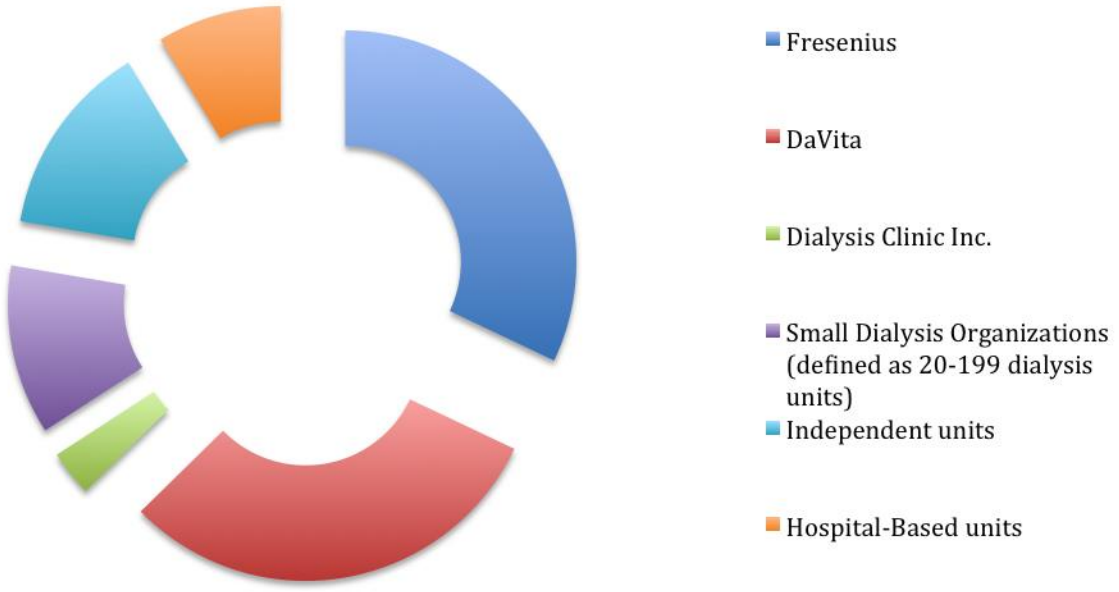
Table 4. End-of-Year Dialysis Centers by # of Facilities and Patient Count 2011



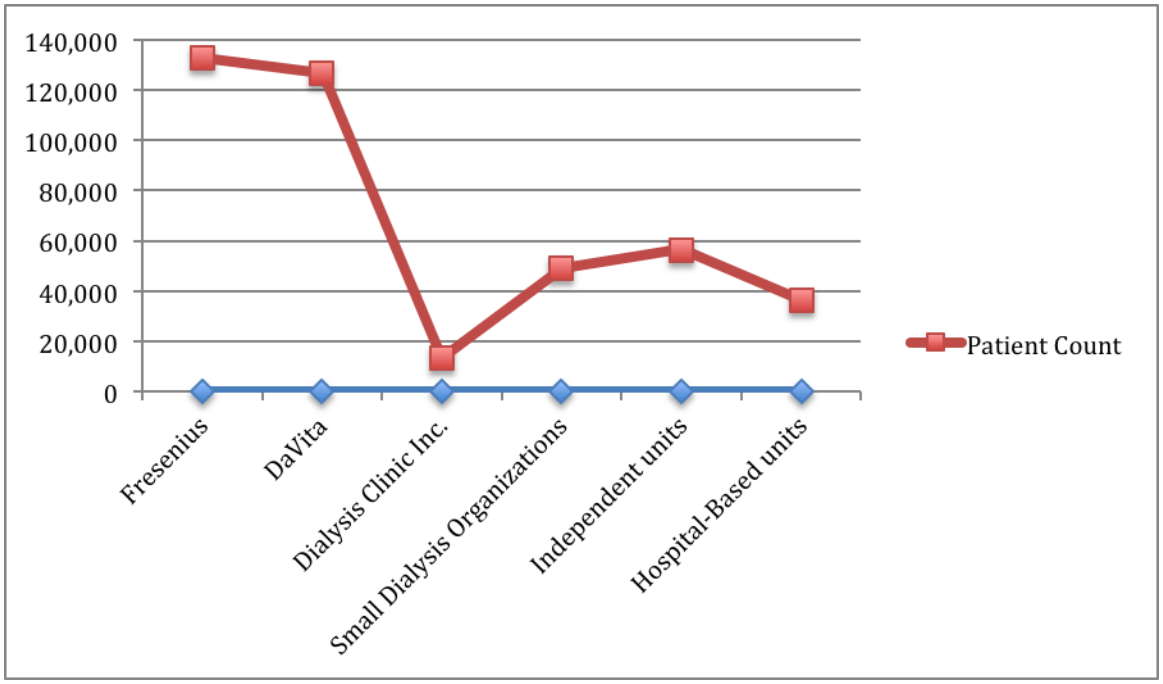


Table 5. Prevalent (Current) Counts and Rates: Hemodialysis Treatment for U.S.; Patients Alive on December 31, 2011; Rates Adjusted for Age, Gender, and Race.

Age Group	Number	Rate Per million
0-19	1,464	16.9
20-44	50,166	481.2
45-64	162,388	2133.6
65-74	89,725	4546.1
75+	84,171	5331.3
TOTAL	387,914	12494.1
Male	213,942	1509.2
Female	171,047	988.6
TOTAL	384,989	2497.8
White	213,942	805.5
Black	148,509	4352.9
Native American	5883	1986.2
Asian	387,914	1390.6
TOTAL	387,914	8535.2
Hispanic	62,818	2069.7
Non-Hispanic	132,509	6141.6
TOTAL	195,327	8211.3

Source: United States Renal Data System Annual Report 2013

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Table 6 presents counts and rates for new hemodialysis patients (incident) for 2011, adjusted for age, gender, and race. The data are presented by age, gender, race, and ethnicity. The average annual in new hemodialysis patients in 2011, was 7.8%. In 2011, males constituted 40.8% of the total population of new hemodialysis patients. Whites represented 24.9% of the total number of new hemodialysis patients in 2011 yet had the lowest rate of hemodialysis as new patients (788.0 per million population). In 2011, blacks had the highest rate of hemodialysis as new patients at 881.1 patients per million population. Hispanics has a higher rate of hemodialysis in 2011, 480.7 per million population, when compared to non-Hispanic at 307.3 per million.

Table 6. Incident (New) Counts and Rates: Hemodialysis Treatment, U.S. for 2011; Rates Adjusted for Age, Gender, and Race.

Age Group	Number	Rate Per million
0-19	680	7.9
20-44	11,025	105.6
45-64	38,859	508.6
65-74	24,480	1209.9
75+	26,639	1633.1
TOTAL	91,763	3465.1
Group-Gender	Number	Rate Per million
Male	58,197	408.8
Female	43,486	252.0
TOTAL	101,683	660.8
Age Group	Number	Rate Per million
White	66,413	249 .3
Black	29,443	881.2
Native American	1199	407.9
Asian	4628	338.8
TOTAL	101,683	1877.2
Hispanic	14,282	480.7
Non-Hispanic	87,401	307.3
TOTAL	101,683	788.0

Source: United States Renal Data System Annual Report 2013

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RENAL DIALYSIS TREATMENTS

Peritoneal dialysis and hemodialysis are the two renal dialysis methods used to treat ESRD. The nephrologist must determine whether the patient receives hemodialysis or peritoneal dialysis. The decision is made jointly between patient and physician and depends greatly on patient condition, patient capacity, and available resources among other circumstances.

Peritoneal Dialysis

In peritoneal dialysis, the dialysis fluid is placed in the patient's abdomen or peritoneal cavity. The peritoneal membrane acts as a filter to draw waste products and fluid from the blood into the dialysis fluid. After four to six hours the fluid is drained out of the abdomen, discarded, and new dialysis fluid is put into the abdomen. The draining and replacement process takes about 45 minutes. During the time the fluid is in the abdomen, the patient can resume normal activity.

There are three types of peritoneal dialysis. One type is called continuous ambulatory peritoneal dialysis (CAPD). With CAPD, most people change the dialysis solution four times a day, seven days a week –upon waking up, at bedtime, and two more times during the day. The other two types of peritoneal dialysis are called intermittent peritoneal dialysis (IPD) and continuous cycling peritoneal dialysis (CCPD). Both these types require the use of an automatic machine to control each cycle. With IPD, peritoneal dialysis is done several times a week for a total of approximately 36 to 40 hours. Sessions may last up to 24 hours. For CCPD, the patient is dialyzed by an automatic machine every night for 10-12 hours. Both IPD and CCPD may require the support of a second person to monitor the machine and the process.

Not all patients are good candidates for peritoneal dialysis. Approximately 00.0% of ESRD patients in the United States receive on of the three types of peritoneal dialysis. All three types of peritoneal dialysis can be done at home after the patient and family receive training on the procedure at a hemodialysis center. Supplies for peritoneal dialysis can be ordered from a hemodialysis center. The patient on peritoneal dialysis still goes to hemodialysis center once a month for evaluation.

Hemodialysis

Hemodialysis utilizes an artificial kidney machine with a special filter to remove waste products and fluid from the blood. The machine is connected to the patient through a fistula or shunt, usually in the forearm, or a permanent catheter in the arm or chest. The permanent catheter is more cost effective and better for the patient. A needle is used to assess the patient's blood. The blood is pumped from the patient's access site through the special filter or dialyzer that is washed with dialysate and then returned to the patient through a second needle placed near the first one in the forearm. The process usually lasts 4-5 hours and is repeated three times a week. The focus of this information is on hemodialysis centers.

Table 7 presents the percentages of patients receiving the different types of dialysis from 2008-2011. These data are taken form the annual report provided by the United Sates Renal Data System on end-stage renal disease patients in the United States. In 2011, in-center hemodialysis was the method utilized by a majority (91.3%) who required treatment for their chronic renal (kidney) failure. The trend is for more patients to use the hemodialysis method. In 2010, 90.8percent used hemodialysis and it increased to 91.3 percent in 2011. Also, in 2011, approximately 1% of ESRD patients received hemodialysis in their home. Hemodialysis is associated with the best outcome because there are more long-term options for therapy and

Table 7. Percentage of End-Stage Renal Disease Patients by Dialysis Type: U.S. 2011.

Hemodialysis (%)	93.0	92.0	91.7	92.6	92.2	91.0	90.8	91.3
Peritoneal Dialysis (%)								
CAPD	3.9	4.6	4.8	4.1	4.5	4.3	4.8	4.3
CCPD	2.6	3.4	3.5	3.3	3.3	4.8	4.5	4.4
Other PD	0.0	*	*	*	*	*	*	0.1
Uncertain Dialysis	0.0	*	*	*	*	*	*	0.0

*Totals do not add up to 100 due to rounding

Source: United States Renal Data System Annual Report 2013

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access types for hemodialysis patients than for peritoneal dialysis patients. Most hemodialysis patients travel to a hemodialysis center for treatment. As of 2011, there were approximately 0,000 hospital-based and non-hospital-based hemodialysis centers in the United States (**see Table 4**).

In a hemodialysis center, each patient receives treatment at a dialysis station that consists of the dialysis machine and dialysis chair. It takes approximately 4 hours for the patient's hemodialysis to be completed. Upon completing the hemodialysis session, it takes an additional 45 minutes or so to set the dialysis machine up for the next patient so that hemodialysis sessions are scheduled at approximately 5-hour intervals. Some hemodialysis centers operate three days a week, on Monday, Wednesday, and Friday, while others have a six-day hemodialysis week. Most hemodialysis centers begin to dialysis day at 5AM. It is possible to dialyze three patients at one station in one day, depending upon the number of hemodialysis stations, the number of sessions held daily and the number of hemodialysis days per week. For example, one hemodialysis center could have six stations and dialyze twelve patients daily (2 patients per stations daily or 2 shifts) while another center with six stations could dialyze eighteen patients daily (3 patients per station daily or 3 shifts).

Patients receiving hemodialysis also require regular treatment with medications such as calcium, phosphorus, iron, and nutritional supplements to treat the chronic problems of anemia and hypocalcaemia. The various drugs have distinct reimbursement rates that vary by payer. These treatments may be administered during the hemodialysis process or independently, based upon the type of medication. Patients receiving hemodialysis also are encouraged to receive immunization against flu, pneumonia, and hepatitis B.

Licensing and Regulations

Federal legislation authorizing the "Condition of Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services" is under section 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act. The rules and regulations can be found in the Federal Register: 41 FR 22511, June 3, 1776; designated at 42 FR 52826, September 30, 1977. Each hemodialysis center must conform to these federal rules and regulations in order to participate in the Medicare reimbursement program. These rules and regulations should also be available from each state health department. Some states may also have their own licensing laws regarding hemodialysis centers.

A new hemodialysis center requesting approval as a Medicare provider must first apply to their state health department for an on-site survey to make certain the center is in compliance with the law. The survey will look at the governing body, staffing and credentials, physical plant, water treatment, and other areas covered by the rules and regulations. If the center passes the survey, the state health department sends a recommendation for approval for Medicare to the Center for Medicare and Medicaid (CMS). CMS then assigns the center a unique provider number that enables the center to bill Medicare for hemodialysis treatments.

Some states may have a "certificate of need" (CON) process. Contact your state health department to determine your state requirements as to CON. The ESRD Network for the state examines the patient population within a certain geographic area surrounding a proposed center to determine whether there is a need for the center. If there is no demonstrated need for the center, the state will not recommend the center to CMS for a Medicare provider number.

Once the hemodialysis center has received Medicare approval from CMS, the ESRDS Network covering that center is authorized to conduct to conduct an on-site review as they deem

necessary using standards of care as outlined in the rules and regulations. In most instances, these on-site reviews are initiated in response to specific complaints and/or grievances of for data validation. The Center for Medicare and Medicaid Services (CMS) works with the ESRD networks and the renal community to determine the areas of focus for quality improvement activities.

The National Kidney Foundation has developed a set of guidelines entitled, “Kidney Disease Outcomes Quality Initiative” (K/DOQI) to improve clinical outcomes for people with all stage of kidney disease. These guidelines were released in the American Journal of Kidney Diseases. The quality improvement activities known as the National Clinical Performance Measures (CPM) are based upon the K/DOQI. Each year the DMS identifies categories of care to assess, the targeted ESRD patient population to study, and the clinical performance measures to be collected. A random sample of adult ESRD hemodialysis patients is identified. Clinical performance data for the identified quality indicators is collected on these patients from the networks. Results of the analysis are published in the End Stage Renal Disease (ESRD) Network Program Annual Report Summary. Goals to improve clinical outcomes are developed and implemented by each network based upon this evaluation process. The additional, some ESRD networks collect additional data to identify quality of care for their centers.

Management and Joint Venture Options

A hemodialysis center can enter into a management contract or joint venture arrangement with many of the regional or national corporations involved in the business of providing hemodialysis services. The management contract could provide the center with 1) consultation services from a clinical nutritionist and a social worker; 2) in-service training programs for staff; 3) computer programs for clinical documentation of services, billing and collections, and laboratory work; 40 purchasing or leasing capacity for equipment; 5) purchasing capacity for expendable supplies; and 6) quality assurance procedures for documentation to the

Center for Medicare and Medicaid Services. Purchasing equipment and supplies as part of a corporate group would enable the center to obtain these items at less cost. Corporate groups also have the capacity of doing their own market feasibility study. Under a joint venture arrangement, the corporate partner also shares in development expenses, capital expenditures, start-up and ongoing working capital requirements, and operating expenses.

METHODOLOGY FOR ESTIMATING THE ECONOMIC VIABILITY OF A HEMODIALYSIS CENTER

Estimating patient participation

Estimating potential patient participation in a hemodialysis center requires defining the service are for the center, identifying the population of the service area, and calculating the prevalence and incidence rates.

There are two methods that can be used to identify the number of hemodialysis patients for a medical service area. If the medical service area is a county or counties, or can be identified by zip code, the total number of prevalent patients can be obtained from the USRDS year but has a three-year lag. The second method that can be used to identify hemodialysis patients for a center utilizes a predictive model. This predictive model can utilize more recent data when available and can also serve to estimate patients for alternative service areas.

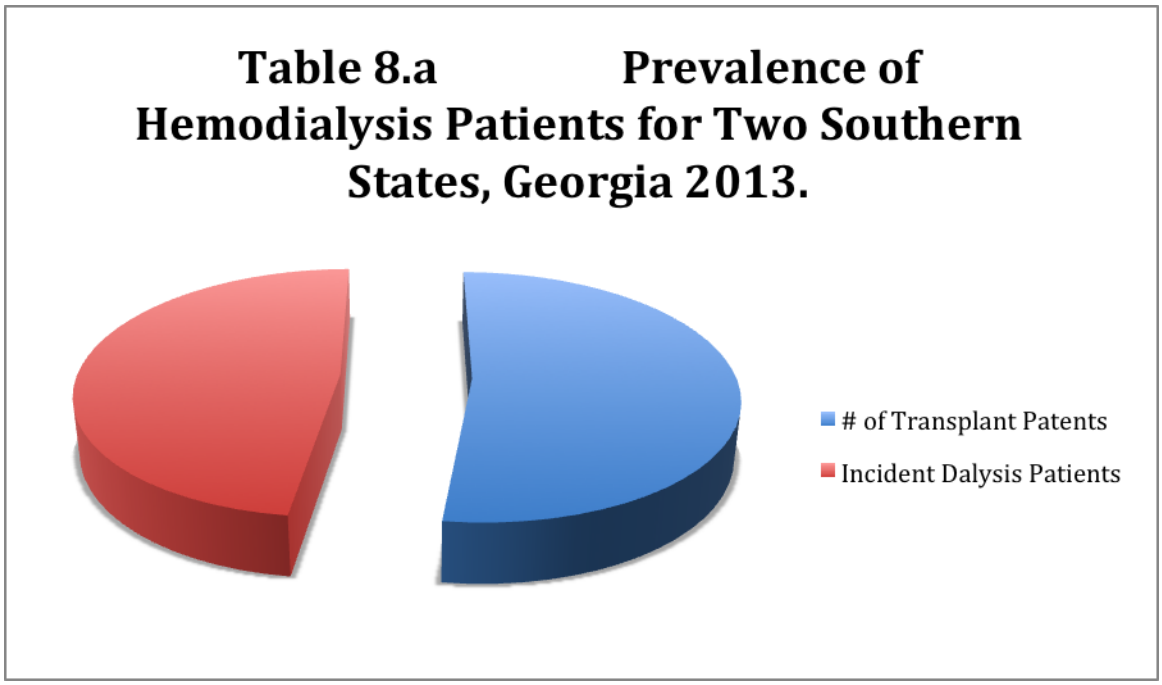
The following tables will illustrate the predictive model to estimate the number of patients for a service area using the prevalence data to derive patient participant coefficients for two southern states. This procedure will provide conservative estimates, as new patient growth is greater than the dialysis patient death rate. (see Table 2). Using the prevalence data available by state, prevalence coefficients can be developed for any state. The hemodialysis prevalence data for Georgia and Texas are presented in Table 10.a. Data in this table were obtained from the USRDS Annual Report through RenDER. The data for all races of Georgia indicates there are 17,673 total and 3995 patients in the age group 65-74. To derive prevalence coefficients, the population of the state by age and race is needed. These data are available from the U.S. Census Bureau (www.census.gov) and are presented for the sample southern states in Table 9. By dividing the number of prevalent patients by the corresponding population numbers, a utilization coefficient is derived. The division is multiplied by 100,000 population. The

hemodialysis coefficients by races, age, and total population are presented in Table 10. The mathematical formula for calculating the coefficient for all races 20-44 years of age is (435/1,222,334,) X 100,000 + 35.6. this is interpreted as 35.6 hemodialysis patients for every 100,000 people between the ages of 20-44. Thus, for prediction purposes, the number of projected hemodialysis patients could be estimated by simply multiplying these coefficients times a service area's population by age or race. The coefficient allows for prediction of patients by three methods. These include:

1. Population by race
2. Population by age
3. Total population

Table 8.a Prevalence of Hemodialysis Patients for Two Southern States, Georgia 2013.

General Population	# of Dialysis Patients	#of Transplant Patients	ESRD Prevalence per million	# of Incident Dialysis Patients	Incidence Dialysis per million
9,992,167	17,673	4,144	2,184	3,805	381

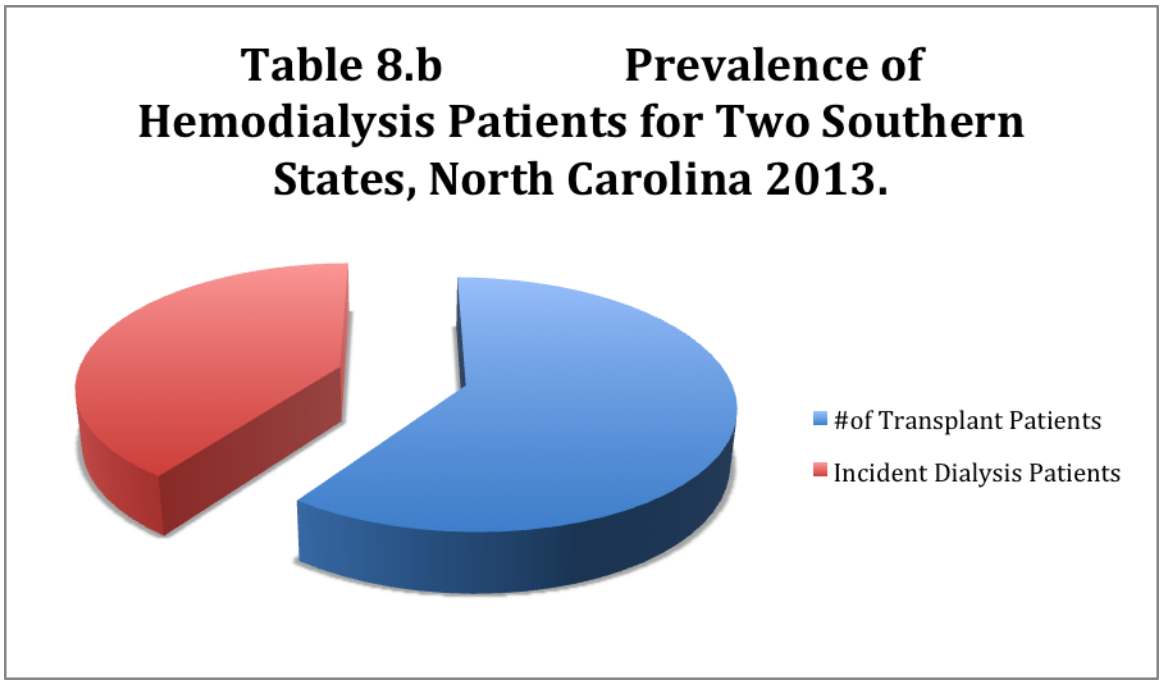


Source: Network 6 ESRD Prevalence and Incidence Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

Table 8.b Prevalence of Hemodialysis Patients for Two Southern States, North Carolina 2013.

General Population	# of Dialysis Patients	#of Transplant Patients	ESRD Prevalence per million	Incident Dialysis Patients	Incidence Dialysis per million
9,848,060	15,389	5,092	2,080	3,404	346



Source: Network 6 ESRD Prevalence and Incidence Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

Table 9.a Population of Two Southern States, 2013.

Age Group	Number
Georgia	
Population:	9,992,167
0-18	3,157,524
19-64	5,635,582
65+	1,199,060
Male	4,886,170
Female	5,102,997
White	6,245,104
Black	3,137,540
Native American	49,960
Asian	369,710
Hispanic	919,279
Non-Hispanic	9,992

Source: United States Census Bureau Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

Table 9.b Population of Two Southern States, 2013.

Age Group	Number
North Carolina	
Population:	9,848,060
0-18	2,895,329
19-64	5,544,457
65+	1,408,272
Male	4,796,005
Female	5,052,054
White	7,061,059
Black	2,166,573
Native American	157,567
Asian	256,049
Hispanic	876,477
Non-Hispanic	9,848

Source: United States Census Bureau Annual Report 2013

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Table 10.a Estimated Hemodialysis Prevalence Coefficients for Two Southern States, 2013.

Age Group	Number
Georgia	
Population:	9,992,167
0-19	53
20-44	1687
45-64	9242
65-74	3995
75+	2676
Male	9,503
Female	8,170
White	5,271
Black	12,114
Native American	7
Asian and other	281
Hispanic or Latino	444

Source: United States Renal Data System Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

Table 10.b Estimated Hemodialysis Prevalence Coefficients for Two Southern States, 2013.

Age Group	Number
North Carolina	
Population:	9,848,060
0-19	168
20-44	2264
45-64	6785
65-74	3734
75+	2541
Male	8544
Female	6845
White	5447
Black	9559
Native American	170
Asian and other	213
Hispanic or Latino	575

Source: United States Renal Data System Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

The method used will depend upon the data that are available for the service area. A case study illustration the procedure to estimate hemodialysis patients is presented later in the application section.

Estimating the financial performance for a hemodialysis center requires information on the number of patients covered by Medicare and by third-party payers and the expected reimbursement per treatment for dialysis and drugs. To determine revenue, the financial performance is offset by the costs of providing dialysis per patient per treatment, facility and equipment costs, and annual operating costs. All ESRD patients are entitled to coverage of the medical care through Medicare regardless of age or income if eligible for Medicare coverage. The process of applying for Medicare takes about three months. Therefore, the center will not be reimbursed for the first three months of treatment while the application is being processed.

If the patient has insurance through employment, that third-party payer will be billed by the center for treatment for 33 months, after which they are eligible for Medicare. These patients are considered Medicare secondary payer patients. Reimbursement by a third-party may differ between insurance companies. In the event the patient does not have insurance, the hemodialysis center bills the patient and, if the patient is unable to pay, absorbs the cost of treatment for the first three months while the patient waits for Medicare authorization. Some patients may pay out of pocket for their hemodialysis treatments.

Since services for new patients are often reimbursed differently by payee source, an estimate of the number of incidence patients is required to estimate revenue. The incidence of hemodialysis patients for the two southern states in presented in Table 11. The incidence coefficients are derived in the same manner as the prevalence hemodialysis coefficients. Again,

these are presented by age, race, and total population and indicate the number of new patients (incidence) per 100,000 population in each age and race category.

Table 11.a Estimated Hemodialysis Prevalence Coefficients for Two Southern States, 2013.

Age Group	Number
Georgia	
Population:	9,992,167
0-19	24
20-44	539
45-64	1597
65-74	936
75+	699
Male	2087
Female	1718
White	1630
Black	2082
Native American	3
Asian and Hispanic	90

Source: United States Renal Data System Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

Table 11.b Estimated Hemodialysis Prevalence Coefficients for Two Southern States, 2013.

Age Group	Number
North Carolina	
Population:	9,848,060
0-19	58
20-44	451
45-64	1406
65-74	729
75+	616
Male	1496
Female	1908
White	1717
Black	1561
Native American	36
Asian and Hispanic	90

Source: United States Renal Data System Annual Report 2013

The interpretation and reporting of these data are the responsibility of the author (s) and in no way should be seen as an official policy or interpretation of the U.S. Government

For example, for people in Georgia between 20-44, the coefficient indicates that for every 100,000 in population there would be 9.7 new hemodialysis patients in the state per year. This will be demonstrated in more detail in the case study in the application section.

Estimation Costs

The total costs of establishing and operation a hemodialysis center consist of capital costs and annual costs. Capital costs included the acquisition and preparation of a suitable facility. Total annual costs consist of annual capital costs and operation costs. Annual capital costs include the depreciation of all capital items in the facility and required investment in capital equipment and the facility. Operating costs are the daily costs incurred in the process of providing hemodialysis. Cost estimates will vary based upon the number of stations, number of patients treated, and number of treatment days per week. Four alternates are developed to demonstrate this variation. Table 12 presents the characteristics of the four alternates.

Alternate A is designed with six stations that will serve twelve patients. The twelve patients will be dialyzed in two shifts on Monday, Wednesday, and Friday. Each dialysis day will last approximately eleven hours including 5 hours per treatment and an additional hour for morning start-up and final clean up in the evening. The total labor time will be thirty-three hours per week. Additional administrative time of approximately seven hours in planned for the registered nurse at the center. Alternate A with this configuration will provide 1,872 hemodialysis treatments per year, calculated by multiplying the number of treatments per day by the number of days per week by 52 week by 52 weeks in a year (12X3X52=1,872).

Table 12. Characteristics of Four Alternate Hemodialysis Centers.

	Patient	Stations	Treatment Schedule					
			Mon	Tue	Wed	Thurs	Fri	Sat
Alternate A	12	6	2		2		2	
Alternate B	18	6	2	1	2	1	2	1
Alternate C	20	10	2		2		2	
Alternate D	30	10	2	1	2	1	2	1

	Hours Open/Day		Labor	Admin	Tx/Year
	M W Fr	T Th Sa	Hrs/Wk		
Alternate A	11		33	7	1,872
Alternate B	11	6	51	7	2,808
Alternate C	11		33	7	3,120
Alternate D	11	6	51	7	4,680

	Maximum Capacity	
	Patients	Tx/Year
Alternate A	18	2,808
Alternate B	36	5,616
Alternate C	30	4,680
Alternate D	60	9,360

Alternate A could serve a maximum of eighteen patients in three shifts on Monday, Wednesday, and Friday for a total of 2,808 treatments per year (18X3X52=2,808).

Alternate B has the same number of stations as Alternate A (six stations) but will provide hemodialysis treatments six times a week. As designed, the center will serve eighteen patients each week. Six patients will be dialyzed on Tuesday, Thursday and Saturday in one shift. Dialysis days on Monday, Wednesday, and Friday will last approximately eleven hours each. The shorter shift on Tuesday, Thursday, and Saturday will last approximately six hours each, for a total labor time of fifty-one hours per week plus additional administrative time of approximately seven hours. Alternate B will provide 2,808 hemodialysis treatments per year (18X3X52=2,808). Alternate B could serve a maximum of thirty-six patients in a six-day dialysis week for a total of 5,616 treatments per year (36X3X52=5,616).

Alternate C is designated with ten stations that will serve twenty patients. Alternate C is similar to Alternate A in that the patients will receive hemodialysis in two shifts on Monday, Wednesday, and Friday. Each dialysis day will last approximately eleven hours with an additional seven hours of administration time. Alternate C will provide 3,120 hemodialysis treatments per year. Alternate C could serve a maximum of thirty patients with hemodialysis treatments done in three shifts on Monday, Wednesday, and Friday for a total of 4,680 treatments per year.

Alternate D is designed with ten stations and will serve thirty patients. Alternate D will offer hemodialysis six days a week. Twenty patients will be dialyzed in two shifts on Monday, Wednesday, and Friday. Each dialysis day will last approximately eleven hours. An additional ten patients will be dialyzed in one shift on Tuesday, Thursday, and Saturday in a six-hour dialysis day. An additional seven hours per week is included for administrative tasks. Alternate D will provide 4,680 hemodialysis treatments per year. Alternate D has the potential of serving up to six patients per week by dialyzing thirty patients per day in three shifts for the six-day dialysis week for a total of 9,360 treatments per year.

Comparisons can be now be made for capital operating costs. Alternate A and Alternate B both have six stations but different hemodialysis treatment schedules. Alternate A and Alternate C both provide hemodialysis treatments six days a week.

Capital Costs

Capital costs for the six-station and ten-station facilities are presented in Table 13. The major components of capital costs for a hemodialysis center include land, building and parking lot, and equipment. The building or facility must be handicapped assessable. Capital costs will be different based upon whether the decision is to build a facility, remodel and existing building or area in a building, or finish off and existing building. Capital costs presented in this information are based upon finishing off and existing building and purchasing new equipment.

The hemodialysis center needs to be of sufficient size to provide approximately 350 square feet as a minimum standard for each hemodialysis station. Hemodialysis stations are arranged in a large open room so that all patients can be observed during the hemodialysis process. Figure 3 is a sample floor plan for a 10-station facility that includes a reuse room and is approximately 3,500 square feet. Figure 4 is a floor plan for a 6-station facility that is approximately 2,800 feet, somewhat larger than the minimum size.

Table 13. Estimated Capital Costs for Four Alternate Hemodialysis Centers.

		6 Stations		10 Stations	
		Alternates A & B		Alternates C & D	
	Unit Cost	#	Cost	#	Cost
Construction (sq.ft.)			2,100		3,500
Land and parking lot (local rate)(included in construction cost)					
Building (new including permits)(based on construction cost)					
Finish existing building (including permits)	$89.25		$187,425		$312.375
Utilities hook-up	$4.66		$9,786		$16,310
Communications					
Telephone system	$1.32		$2,772		$4,620
Emergency Call system	$0.35		$735		$1,255
Security system	$0.35		$735		$1,225
TV system w/VCR	$2.86		$6,006		$10,010
BUILD OUT CONSTRUCTIONS SUBTOTAL			$207,249		$345,765
Cost/sq.ft.			$98.79		$98.79
Cost/station			$34,577		$34,577
Water Treatment					
R/O system-capacity up to 30 tx/day	$25,000	1	$25,000	1	$25,000
Drum dolly	$300	1	$300	1	$300
Central bi-carb system	$2000	1	$2000	1	$2000
WATER TREATMENT SUBTOTAL			$27,300		$27,300

Table 13. (p.2). Estimated Capital Costs for Four Alternate Hemodialysis Centers.

	Cost/station		$4,550		$4,550
Bio-medical Equipment					
Electrical analyzer/tester	$2000	1	$2000	1	$2000
Conductivity meter	$233	1	$233	1	$233
Dialysate meter	$1500	1	$1500	1	$1500
R/O tds water meter	$61	1	$61	1	$61
Water analysis test kit	$25	1	$25	1	$25
Heat block	$462	1	$462	1	$462
Portable tool chest & tools	$30	1	$30	1	$30
Parts storage cart	$238	1	$238	1	$238
Miscellaneous tools, fittings, tubing	$2,000	1	$2,000	1	$2,000
Hardness test kit	$30	1	$30	1	$30
Nex-one (for machine repair)	$2,000	1	$2,000	1	$2,000
BIO-MEDICAL EQUIPMENT SUBTOTAL			$8,549		$8,549
	Cost/station		$1425		$855
Clinical Equipment					
Dialysis machine	$16,500	7	$115,850	11	$182,050
Patient lift	$1,250	1	$1,250	1	$1,250
Wheelchair/standup scales	$2,500	1	$2,500	1	$2,500
Lab refrigerator	$150	1	$150	1	$150
Lab freezer	$275	1	$275	1	$275
Meds refrigerator (tx)	$150	1	$150	1	$150
EPO refrigerator (tx)	$150	1	$150	1	$150

Table 13. (p.3). Estimated Capital Costs for Four Alternate Hemodialysis Centers.

Ice machine	$400	1	$400	1	$400
Ambu bag	$250	1	$250	1	$250
Oxygen equipment (portable)	$693	1	$693	1	$693
Infusion pump	$1,950	1	$1,950	1	$1,950
Iv pole	$125	1	$125	1	$125
Glucometer	$88	1	$88	1	$88
Thermometer (oto-temp)	$150	2	$300	2	$300
Stethoscope	$10	4	$40	6	$60
Ultrasonic mini doppler	$545	1	$545	1	$545
Mobile BP modules	$200	3	$600	5	$1,000
Infectious waste hamper	$100	2	$200	4	$400
Emergency evacuation kit	$150	1	$150	1	$150
Misc. clinical	$1,000	1	$1,000	2	$2,000
Bed pan	$4	4	$16	6	$24
Trash can	$35	4	$140	6	$210
CLINICAL EQUIPMENT SUBTOTAL			$126,822		$194,720
Cost/station			$21,137		$19,472
Clinical Furniture/Fixtures					
Dialysis chair	$895	6	$5,370	6	$8,950
Task stool	$100	3	$300	5	$500
Privacy screen	$148	1	$148	2	$296
Chart rack	$700	1	$700	2	$1,400

Table 13. (p.4). Estimated Capital Costs for Four Alternate Hemodialysis Centers.

Wheel chair	$300	1	$300	2	$600
Computer system	$3,000	1	$3,000	1	$3,000
CLINCAL FURNITURE SUBTOTAL			$9,818		$14,746
Cost/station			$1,636		$1,475
Staff Lounge/Fixtures					
Refrigerator	$750	1	$750	1	$750
Microwave	$150	1	$150	1	$150
Coffee machine	$50	1	$50	1	$50
Toaster oven	$20	1	$20	1	$20
Locker (3/unit)	$500	2	$1,000	3	$1,500
Table	$600	1	$600	2	$1,200
Chair	$163	6	$978	10	$1,630
STAFF LOUNGE SUBTOTAL			$3,548		$5,295
Cost/station			$591		$5,300
Storage Fixtures/Equipment					
Supply cart	$425	1	$425	2	$850
Shelving	$630	1	$630	2	$1,260
Hand dolly	$138	1	$138	1	$138
Flatbed truck (hand)	$349	1	$349	1	$349
Utility cart	$134	3	$403	5	$672
Floor pallets	$58	2	$115	4	$230

Table 13. (p.5). Estimated Capital Costs for Four Alternate Hemodialysis Centers.

STORAGE SUBTOTAL			$2,060		$3,499
Cost/station			$343		$350
Business Office Fixtures					
Copier machine	$1,493	1	$1,493	1	$1,493
Facsimile	$500	1	$500	1	$500
Time clock	$300	1	$300	1	$300
Answering machine	$88	1	$88	1	$88
Desk	$550	2	$1,100	2	$1,100
Chairs	$243	4	$972	4	$972
Filing cabinets with locks	$800	2	$1,600	1	$2,400
Computer system/printer/scanner	$1,400	1	$1,400	1	$1,400
BUSINESS OFFICE SUBTOTAL			$7,452		$8,252
Cost/station			$1,242		$852
Reception/Waiting Area					
Chairs	$243	8	$1,944	12	$2,916
Side tables	$300	4	$1,200	6	$1,800
Television	$300	1	$300	1	$300
Lamps	$75	4	$300	6	$450
Artwork/plants etc.	$500	1	$500	1	$500
Clock	$25	1	$25	1	$25
Coffee machine/maker	$80	1	$80	1	$80
RECEPTION SUBTOTAL			$4,349		$6,071
Cost/station			$725		$607

Table 13. (p.6). Estimated Capital Costs for Four Alternate Hemodialysis Centers.

Signage					
Interior	$100	6	$600	10	$1,000
Exterior	$3,000	1	$3,000	1	$3,000
SIGNAGE SUBTOTAL			$3,600		$4,000
	Cost/station		$600		$400
TOTAL CAPITAL COST			**$400,957**		**$619,002**
	TOTAL Cost/station		$73,950		$69,595

See page 00 (Table 14) for estimation of Operating Costs

Space will be required to store clean materials separately form soiled and biohazard materials. The building should also include a janitor's closet, staff restroom, staff lounge, administration area, reception/waiting area, and patient/visitor restroom. Televisions may be provided for patients to watch and should be mounted on the wall or ceiling so that they may be viewed by hemodialysis patients. The hemodialysis patients can bring their own personal headsets that can be plugged into an outlet at the hemodialysis station. The construction costs to finish off an existing building, excluding land and parking lot, are estimated to be $187,425 for the 6-station facilities and $312,375 for the 10-station facilities. The construction cost per station for the center is estimated to be $34,557.

The water treatment equipment requires a separate room with adequate space to house equipment sufficient to treat water for the number of stations in the center. Plumbing will need to

be installed to bring the treated water to each dialysis station and to drain used water into the sewer system. The facility will need a storage room for water treatment chemicals and supplies needed in which dialyzers can be cleaned, sterilized, and stored. The case study in the application section does not include a reuse room for the reuse of dialyzers. The water treatment system identified in this information has the capacity to serve each of the alternates at up to 30 dialysis treatments per day, thus water treatment costs are estimated at $27,300 for each alternate. The cost per station for the six-station facilities is estimated to be $4,550. The cost per station for the ten-station facilities is estimated to be $4,500.

If it is anticipated that the center will expand in the future, it is recommended that the water treatment system purchased at the construction phase have the capacity to handle the potential future need. Increasing the size of the pump for the system identified in this information would add approximately 15% to the cost of the system and enable the center to do 40 dialysis treatments per day. If the center anticipates a larger future expansion, it would be wise to purchase the appropriate system at construction. It is much more difficult and expensive to increase the capacity of the water treatment system once the system has been installed. Similarly, if expansion is anticipated, additional plumbing can be included in the construction so that additional stations can be added in the future.

Biomedical equipment is needed to monitor the water treatment and hemodialysis process. This equipment also includes tools and other materials needed for repair of equipment. The estimated cost for biomedical equipment is 8,549 for each alternate.

Clinical equipment includes the hemodialysis machines, medical equipment to assess the patient, refrigerators for medications and specimens, and emergency equipment. It is recommended that the center have at least one additional hemodialysis machine available for emergency use in the event that a hemodialysis machine breaks down. Hemodialysis equipment can be new or remanufactured. Estimated cost for new equipment is $115,850 for Alternates A and B and $182,050 for Alternates C and D.

There are furniture and fixture requirements for each of the rooms. Clinical furniture and fixtures include the dialysis chairs, stools, privacy screen, chart rack, wheelchairs, and a computer system. The estimate cost for Alternates A and B is $9,818. Estimate cost for Alternates C and D is $14,746. Locker, tables(s) and chairs, and refrigerator, and other items are needed for the staff lounge. The cost estimate for Alternates A and B is $3,548; Alternates C and D is $5,295. The hemodialysis center needs equipment and fixtures for storing chemicals and patient treatment materials. For Alternate A and Alternate B the estimated cost is $2,060. For Alternates C and D the estimated cost is $3,499. Business office equipment and furniture such as copier machine and computer can be leased or purchased as used or remanufactured. The estimated cost to purchase this equipment for Alternates A and B is $7,452 and for Alternates C and D $8,252. The public reception area should include comfortable chairs/couches, tables, lamps, reading materials, and, if possible a television. It may be desirable to have a refreshment area designated with drink machines and a coffeemaker. A restroom should be located in this area so that visitors do not enter the hemodialysis area. For Alternates A and B, the cost is estimated to be $4,349. For Alternates C and D, the cost is estimated to be $6,071. Finally, signs identifying the hemodialysis center, interior areas of the facility, restroom, exits are estimated to cost $3,600 for Alternates A and B. The estimate, at $4,000, is higher for Alternates C and D due to the larger size of the facility.

In summary, the total estimated capital costs are $400,957 ($73,950 per station) for Alternates A and B and $610,002 ($69,595 per station) for Alternates C and D.

Operating costs include costs for labor, consultants, maintenance, supplies, medical supplies, drugs, utilities, lease (if the building is leased), communications, insurance, and medical director fees.

Federal law prescribes that, at a minimum, each hemodialysis center is to have a medical director, a chief executive officer, a licensed registered nurse, a social worker, a dietitian, and a

medical records practitioner. There are specific training and licensing requirements for each position. The medical director, who can also serve as the chief executive officer, must be board certified in internal medicine or pediatrics and have a minimum of 12 months experience or training in the care of ESRD patients. The registered nurse must have at least 12 months experience in clinical nursing and an additional 6 months of experience in the clinical care of the ESRD patient including experience with the hemodialysis process. The dietitian must be registered by the American Dietetic Association and have at least one year of experience in clinical nutrition. The social worker must have a master' degree in social work and must be licensed to practice in the state.

Whenever patients are receiving hemodialysis, one licensed health professional (physician, registered nurse, or licensed practical nurse) experienced in providing ESRD care must be on duty to supervise patient care. The Center for Medicare and Medicaid Services (CMS) requires that one registered nurse be on duty to supervise patient care for every twelve patients receiving hemodialysis. Staff to patient ratios can vary by state. CMS requires the center to have one patient care staff member for every four patients. The registered nurse can be counted as one of these staff members if he/she provides direct patient care. Adequate staffing can be accomplished through the use of extended shifts and split shifts. Estimating additional staff requirements at a hemodialysis center for training patients and families in peritoneal dialysis are beyond the scope of this information.

Table 14 presents the estimated personnel costs for the four alternates. Salaried personnel for Alternate A includes one full-time registered nurse (RN), one full-time patient care technician, one full-time chief technician, a half-time housekeeper and half-time financial manager for an annual cost of $158,184, which includes benefits. Alternate B needs one and one-half full time registered nurse in order to cover a sixty-hour workweek. In addition, the center will need patient care technicians to cover 51 hours per week, a full-time chief technician, a full-time housekeeper and full-time financial manager at an annual cost of $229,700. Personnel

Table 14. (p.2) Estimated Annual Operating Costs for Personnel for Four Alternative Hemodialysis Centers.

		Alternate C		Alternate D	
	Rate/Hr	Hrs/wk	Cost	Hrs/wk	Cost
Salaried Personnel					
Registered Nurse (RN)	$28.00	40	$58,240	60	$67,200
Chief Technician	$19.00	40	$39,520	40	$39,520
Patient Care Tech (PCT)	$15.00	66	$51,480	100	$78,000
Housekeeper	$8.00	20	$8,320	40	$16,640
Financial manager	$32.00	20	$33,280	40	$66,560
Subtotal			$190,840		$267,920
Benefits @ 35%			$72,519		$101,810
TOTAL SALARIED PERSONNEL			**$263,359**		**$369,730**
	Annual				
Contract Personnel (no benefits)					
Medical Director/Nephrologist	$42,500		$42,500		$42,500
Renal social worker	$14,750		$14,750		$14,750
Hemodialysis dietitian	$13,250		$13,250		$13,250
TOTAL CONTRACT PERSONNEL	$70,500		$70,500		$70,500
Staff Development					
Staff training/continuing education			$10,000		$14,000
TOTAL PERSONNEL COSTS			**$343,859**		**$454,230**

Benefits include: medical insurance, workers compensation, FICA, short-term disability, dental insurance, and life insurance.

requirements for Alternate C are similar to the needs for Alternate A as the center will be dialyzing patients three days a week, with the increase of a patient care technician for an additional 26 hours per week. The annual cost for Alternate C is $190,840. Alternate D provides hemodialysis services six days a week that requires 1 ½ registered nurses to cover a 60 hour work week; 2 ½ patient care technicians to cover 100 hours per week, and a full-time chief technician, housekeeper and financial manager, for annual cost of $267,920.

Staff development includes training of new employees and continuing education. This can be contracted for with the larger corporation involved in hemodialysis care if in a joint venture or a management contract. The estimated contractual amount for Alternate A and Alternate C is $10,000. The amount is higher for Alternate C and Alternate D ($14,000) due to the larger number of employees.

Contract personnel can include the medical director/nephrologist, renal social worker, and dietitian. The contracted amount for the nephrologist is dependent upon the distance the physician has to travel to see patients at the hemodialysis center and the local health care resources available, including access to a local hospital with appropriate emergency services and board-certified physicians who could handle patient emergencies. The social worker and dietitian can be contracted from a local hospital or from a large corporation involved in providing hemodialysis care. The estimated cost for the contract personnel is $70,500 for each alternate. The estimated cost for personnel total $298,794 for Alternate A, $401,486 for Alternate B, $343,859 for Alternate C and: $454,230 for Alternate D.

Table 15 presents the estimated annual operating costs, including personnel costs as calculated in Table 14. Estimates of annual operating costs in this information are based upon cost per treatment data provided by several clinical managers of regional hemodialysis centers. Actual annual treatments are calculated by multiplying the number of patients by three treatments per week by 52 weeks (or 13 treatments/month times 12 months) by 90 percent attendance rate.

Table 15. Estimated Annual Operating Costs for Four Alternative Renal Dialysis Centers.

	Alternate A	Alternate B	Alternate C	Alternate D
Personnel	$263,359	$369,730	$343,859	$454,230
Maintenance				
Housekeeping/cleaning supplies	$1,928	$5,784	$5,054	$9,641
Lawn/yard maintenance (local rate)	$300	$300	$300	$300
Physical plant maintenance	$2,003	$3,500	$3,338	$26,395
Equipment maintenance	$10,558	$15,837	$15,837	$26,395
TOTAL MAINTENANCE	$14,789	$24,926	$24,530	$41,344
MANINTENANCE COST/Treatment	$7.90	$8.88	$7.86	$8.83
Supplies				
Paper/office supplies	$3,454	$5,180	$5,756	$8,635
Advertisement/ literature	$674	$1,011	$1,123	$1,685
TOTAL SUPPLIES	$4,128	$6,191	$6,880	$10,319
SUPPLIES COST/Treatment	$2.45	$2.45	$2.45	$2.45
BIO-MEDICAL				
Dialysis supplies: including dialysate, Dialyzer, chemicals, plastics products, Disposable linens, etc.	$70,484	$105,704	$117,459	$176,188

*will need cash flow available for first 6 months until begin receiving reimbursements from Medicare.

Table 15. (p2.) Estimated Annual Operating Costs for Four Alternative Renal Dialysis Centers.

	Alternate A	Alternate B	Alternate C	Alternate D
Medications: EPO, Vitamin D	$118,068	$177,067	$196,757	$295,135
Biomedical hazardous material Disposal	$5,561	$8,339	$9,266	$13,900
TOTAL BIOMEDICAL	$194,112	$291,110	$323,482	$485,222
BIOMEDICAL COST/Treatment	$115.20	$115.20	$115.20	$115.20
Utilities				
Water	$16,135	$24,198	$26,888	$40,332
Sewer	$15,263	$22,890	$25,435	$38,152
Electricity	$6,976	$10,462	$11,625	$17,438
Natural gas/heating	$1,011	$1,516	$1,685	$2,527
TOTAL UTILITIES	$39,385	$59,065	$65,633	$98,450
UTILITIES COST/Treatment	$23.37	$23.37	$23.37	$23.37
TOTAL BUILDING (Lease)	$16,850	$25,270	$28,080	$42,120
BUILDING COST/Treatment	$10	$10	$10	$10
TOTAL BUILDING (Construction 2,100 sq.ft.)	$210,000	$210,000	$210,000	$210,000
TOTAL BUILDING (Construction 3,500 sq.ft.)	$350,000	$350,000	$350,000	$350,000
BUILDING COST/Treatment				

*will need cash flow available for first 6 months until begin receiving reimbursements from Medicare.

Table 15. (p3.) Estimated Annual Operating Costs for Four Alternative Renal Dialysis Centers.

	Alternate A	Alternate B	Alternate C	Alternate D
Communications				
Telephone	$1,533	$2,300	$2,555	$3,833
Security system	$169	$253	$281	$421
Cable/satellite	$236	$354	$393	$590
Cell phones for MD and Staff	$2,400	$2,400	$2,400	$2,400
TOTAL COMMUNICATIONS	$4,338	$5,306	$5,629	$7,244
COMMUNICATIONS COST/Treatment	$2.57	$2.10	$2.00	$1.72
TOTAL INSURANCE (fire and theft)	$1,348	$2,022	$2,246	$3,370
INSURANCE COST/Treatment	$0.80	$0.80	$0.80	$0.80
TOTAL ANNUNAL OPERATING COSTS	$466,179	$683,776	$674,356	$992,490
ANNUAL OPERATING COST/Treatment	$275	$271	$240	$23

*will need cash flow available for first 6 months until begin receiving reimbursements from Medicare.

This is the formula used also to calculate potential revenues, as demonstrated later in the case study. Alternate A will provide 1,872 annual treatments; Alternate B, 2,808 annual treatments; Alternate C, 3,120 annual treatments, and Alternate D, 4,680 annual treatments. Annual operating costs also include costs for maintenance of the facility and equipment. This includes housekeeping and supplies, yard maintenance, maintenance of the physical plant, and maintenance of the hemodialysis equipment, including the water treatment system. These services can be obtained through direct employment of workers or through contractual agreements. In particular, maintenance agreements are available for the hemodialysis and water treatment equipment. The estimated costs for maintenance for Alternate A is $14,789, Alternate B is $24,926, Alternate D is $24,530, and Alternate D is $41,344.

Supplies needed for the center include office supplies, medical documentation forms, literature advertising the center and services, and advertisements, which could include costs for telephone listings and advertisement, newspapers, and other media. Estimated costs for supplies for Alternate A is $4,128 Alternate B is $6,191, Alternate C is $6,880, and Alternate D is $10,319.

Medical costs for the hemodialysis center include cost of the hemodialysis supplies, medications, and disposal of biomedical hazardous materials. Estimated costs for medical supplies for Alternate A is $194,112, Alternate B is $291,110, Alternate C is $323,482, and Alternate D is $485,222.

Utilities include water, sewer, electricity and natural gas. The hemodialysis process utilizes a great deal of water. Sewer charges may also be high if they are linked to water utilization. If sewer is not available, arrangements need to be made to have a system that will handle the large amount of water. Estimate costs for utilities for Alternate A is $39,385, Alternate B is $59,065, Alternate C is $65,633, and Alternate D is $98,450.

Building costs are an annual expense if the building is leased or rented and are dependent upon local rates. The estimated cost to lease a building (Construction 2,100 sq.ft) $210,000 and (Construction 3,500 sq.ft) $350,000.The estimated cost to lease a building for Alternate A is $16,850; Alternate B, $25,270; Alternate C, $28,080; and Alternate D is $42,120.

Communication costs include the cost for telephone, a security system for the building, cable or satellite for the televisions, and a pager system for key employees. The pagers can be leased on a monthly or yearly basis. Estimated communication costs for Alternate A is $4,338, Alternate B is $5,306, Alternate C is $5,629, and Alternate D is $7,244. Estimated insurance costs (fire and theft) for Alternate A is $1,348, Alternate B is $2,022, Alternate C is $2,246, and Alternate D is $3,370.

In summary, the total annual operating cost for Alternate A is $466,179, Alternate B is $683,776, Alternate C is $674,356 and Alternate D is $992,490. Subsequently, the cost per treatments are $275, $271, $240 and $236, respectively.

PREDICTING THE ECONOMIC VIABILITY OF A HEMODIALYSIS CENTER

General Information

The viability of a hemodialysis center is dependent upon the cost for services and facilities and the revenue generated by the center. Revenue is dependent upon the number of treatments given and the payer mix. The payer mix will vary throughout the year as new patients begin treatment and others leave to get treatment at another facility or die. According to the USRDS Annual Report 2013, Medicare covers approximately 85% of all patients on hemodialysis. Of this group, approximately 6.2% of these patients have pending Medicare enrollment so that reimbursement is not available until the enrollment is completed. Payment by third-party payers (insurance and managed care companies) will vary depending upon the specific policy. Payment is negotiated between the hemodialysis center and the commercial payer, and usually is for 60%

to 80% of the billable costs for treatment. Self-pay will also vary depending upon the patient's ability to pay.

The turn-around time for billing and receiving reimbursement from Medicare usually takes several months. Additional revenues for the center may be generated through other charges including drugs. For example, the center may sell dialysis products to peritoneal dialysis patients who dialyze at home.

Medicare reimbursement is less than reimbursement from third-party payers so that a center with a large Medicare patient enrollment will have less revenue based on patient numbers than would a center with a smaller percentage of Medicare patients. Rural communities typically have a higher Medicare eligible population and therefore, decision makers need to know the community mix and assess the number of those that can pay for the service through private insurance. Calculating the revenue dynamics can be challenging. For example, if a center overestimated revenue by $10 per patient for 50 patients, it could result in a decrease in annual revenue of approximately $72,000.

Groups experienced in the management of hemodialysis centers suggest that it will take approximately 3 years to operate at approximately 85% capacity, which provides the ability to absorb additional patients in future years. A center should estimate the number of patients needed to function at 85% capacity in the third year and work toward marketing the center to local communities, hospital(s), and health care providers and building relationships with local nephrologist(s). Experienced managers also reported that, in most instances, a small hemodialysis center with 6 to 10 stations can breakeven with 14 to 15 patients receiving dialysis on a three-day week. A 16-station facility would need 18 to 20 patients to break even. The economic success of a hemodialysis center depends greatly on the marketing efforts of the center. Excellent clinical outcomes for the hemodialysis center will also aid in marketing. Patient satisfaction and a positive history of the center in the community will also help.

Centers estimate the capital cost per station at the low end to be between $25,000 and $35,000; medium range $50,000; and high range $70,000. The hemodialysis equipment has an expected life of seven years. Operating costs for a hemodialysis center can vary greatly based upon whether the center is part of a large corporation and/ or is hospital based. The cost per treatment depends upon several variables, including staffing, management costs, and patient mix. For budget purposes, corporate groups calculate the total number of treatments given per year as 13 treatments per month times 12 months times 90% to account for absences, no-shows, and other reasons (13 X 12 X .9). In general, the cost per treatment ranges between $200 and $300.

Because of the delay in receiving reimbursements from Medicare, a new hemodialysis center should be able to function without revenue for the first six months of operation. Corporate groups recommended that most centers should have between $350,000 and $650,000 available for this start-up period. In addition, hemodialysis centers should have a minimum two-week supply of hemodialysis-related supplies on hand to buffer against delayed deliveries.

The case study presented below will demonstrate the methodology used to predict the economic viability of a hemodialysis center.

Application: Case Study

Worksheets have been developed to estimate the number of patients, costs, and revenue for a hemodialysis center. Blank worksheets are located in the Appendix. The application of these worksheets to an example county, in a southern state is presented in this section. The decision makers in the example county are evaluating whether or not to create a hemodialysis center. The service area was assumed to be the county, the area from which there is no existing facility and therefore the highest probability that ESRD patients would use the center.

Worksheet 1 illustrates how to predict the number of patients expected for the example county. The population by age and by race for the example county has been entered onto the form. The number of patients is estimated by multiplying the number of residents per 100,000 by the prevalence rate for the state. For example, in the age group 20-44 for all residents, the multiplication of 10,072 times 35.6, divided by 100,000 yields an estimate of 3.6 (10,072 X 35.6)/100,000) = 3.6). Adding the number over all groups yields a total annual estimate of 26.5 patients by age. Race data yields, a yearly estimate of 22.1 patients. The coefficient for total population gives a weighted average estimate of 24.9 current (prevalent) patients when applied to the total population of the service area.

Estimates of new (incident) patients can be obtained by the same method and is depicted in Worksheet 2. The number of new patients or incidence is projected to be 8.5 based on the estimate by race, 9.6 based upon the estimate by age, and 8.9 based on the total population. Some of the available patients might choose another facility. Thus, for the purpose of this case study, the number of stations needed is calculated based upon 20 of the prevalent patients by age (24.9) as identified in Worksheet 1and two of the 8.9 new patients identified in Worksheet 2 as a more conservative estimate.

Worksheet 3 estimates the number of stations needed to provide the number of treatments for the 22 patients identified in Worksheet 1 and 2. The 22 patients require 3 treatments per week times 52 weeks. Treatments can be offered with either one rotation (3-day week) or two rotations (6-day week). Because the patients require treatments three times per week, the total number of stations can be derived by dividing the total number of patients expected each week by the total number of daily treatments offered from the rotation(s). Thus, in the 3-day week example (3 treatments each day on Monday, Wednesday, and Friday), the total number of stations required would be the 20 patients (A.) divided by the 3 treatments per day (E.) to equal 7.3 or (rounded) 8 stations. The 6-day example results in 6 required stations. Although the total number of expected treatments will be about 90% due to absences, no-shows, and other

causes, the total number of required stations should be based upon the maximum number of treatments possible each year.

The calculations presented in Worksheet 3illustrate that adequate facilities can have various configurations. The appropriate configuration depends on desired daily hours of operation and number of days per week. For example, both a six-station facility providing treatments twice a day, Monday through Saturday and an eight-station facility that provides three treatments per day on Monday, Wednesday and Friday would be adequate for this example. The eight-station facility is chosen for this case study.

Worksheet 4 estimates the capital costs for the case study adjusted for eight stations. Capital items identified in Table 13 are based on six and ten-station facilities. Some of the costs such as those associated with water treatment are the same for both a six and ten-station facility while others must be adjusted based on the number of stations. Capital costs for this case study are based on the six-station examples (Alternates A and B) and adjusted where appropriate. The total construction cost is $276,612 based on a 2,800 square foot facility. The water treatment equipment has a maximum capacity of 30 treatments per day, which is adequate for an 8-station facility. The estimated costs for water treatment equipment are $27,300. Bio-medical equipment costs are $8,549. Cost for clinical equipment is adjusted to reflect the increase in dialysis machines and miscellaneous clinical supplies and is estimated to be $160,922. Costs for clinical furniture are also adjusted to fit 8 stations and results in an estimate of $12,308. Furniture and fixture costs for the staff lounge total $3,548. Storage costs are estimated at $2,060 and business office costs are estimated at $7,452. Costs for the reception area and business signage are $4,349 and $3,600respectively. The total capital cost for this case study is estimated to be $506,700.

Worksheet 5 estimates personnel needed for the case study. The case study will provide 3,089 treatments per year with a three-day workweek and patients will be dialyzed in three shifts

at approximately 5 hours per shift for a total of 45 hours of dialysis treatment time (Worksheet 3). The dialysis day will last approximately 16 hours, which includes start-up time in the morning to prepare the reverse osmosis water treatment system (R/O system) and clean-up time at the end of the day to prepare for the next dialysis day. Total estimated hours of operation each week is 48 hours.

CMS requires one patient-care technician for every four patients and the registered nurse can count for one of them. A registered nurse is required to be in the center for the total time that patients are receiving dialysis or approximately 15 hours per day.
The full-time registered nurse will also have administrative responsibilities at the center. The full-time registered nurse can either have overlap coverage with another registered nurse for certain days each week to facilitate administrative time, or can work less hours during the dialysis days and return to the center for administrative responsibilities on a non-dialysis day. Thus staffing will require a full-time and a part-time registered nurse to cover the hours of dialysis. Approximately 1.2 patient care technicians will be able to provide coverage for the three-dialysis days. The chief technician will need to be on site for each dialysis session for approximately 40 hours per week.

One or both of the patient care technicians can be trained in the start-up and shut-down of the water treatment system so that the chief technician would work approximately 13 hours for each of the three dialysis days. The housekeeper can work approximately 6.5 hours per dialysis day for a 20-hour workweek. The financial manager can also work a 20-workweek. Total personnel costs for the case study is $344,577.

Worksheet 6 estimates annual operating costs for the case study, including personnel costs, based upon costs adjusted for an 8-station facility. Costs were calculated for 3,089 annual treatments based upon cost per treatment estimates for Alternate C. Maintenance was adjusted to reflect the increased need for housekeeping supplies for the larger facility. Maintenance costs are estimated to be $26,062. Supplies are estimated to be $7,568 based upon an estimated cost

of $2.45 per treatment. Medical supplies, based on an estimated cost of $115.20 per treatment, resulted in an estimated cost of $355,853. Utilities are estimated to cost $72,190 based on a per-treatment cost of $23.37. Communications are adjusted to reflect the larger treatment volume at a cost of $5,952. Insurance remained fixed at a rate of $0.80 per treatment or $2,471. Total estimated operating costs are $715,922.

Revenue can be projected based upon the estimated number of treatments given per year. Worksheet 7 estimates revenue for the case study. A patient must be identified by reimbursement schedule as revenue from Medicare patients will be different from revenue from private pay patients. For the current patients, it is estimated that twenty of the patients identified in the service area will switch to the new hemodialysis center. Medicare will cover nineteen of these patients at a payment of $233 per treatment including estimated medications. One patient will have coverage through a third-party payer and reimbursement for each treatment is estimated to be $1,023. It is estimated that two of the eight new (incident) patients will seek hemodialysis treatment at the new facility, both covered by Medicare.

The total number of treatments to be given annually is estimated to be 3,089 (G + H). Gross revenue projections are based upon the number of patient treatments multiplied by the charge per treatment and the percent of collection. Total gross revenues estimated for this example are $830,337.

As mentioned previously, Medicare reimbursement does not start for new patients for three months. For new patients awaiting enrollment in Medicare, the most conservative position is that no collections will be made from this group for the first three months of treatments. The number of new patients is multiplied by 13 treatments per month by 3 months and by an attendance factor of 90%. Thus the two new patients will require 70 treatments annually that will not be reimbursed (L). Subtracting the uncollected revenues ($16,357) for these treatments results in total annual net revenues of $813,980.

Worksheet 8 presents the comparison of annual capital and operating costs to revenue to determine profit or loss for the center selected for this case study. Capital costs assume amortization of all capital expenses. Land and/or building amortization will be over a 10-year period. In this case study, the building costs are amortized over ten years at 7 percent interest. Most hemodialysis centers amortize the dialysis machines over a 7-year period, thus the nine dialysis machines are amortized over seven years at 7 percent.

The remaining equipment in this case study is amortized over 10 years at 7 percent. The total annual capital and operating costs are summed. Profit or loss is the difference between revenue and the total annual capital and operating costs. In this case study, the center will experience a profit of $19,486 for the first year.

However, the margin of profit is small and with any major flexes or changes in demand, or any increased costs in supplies, etc., the margin could decrease very quickly. A facility should not expect to make a profit in the first 3 years of operation. At the most, a facility should hope to breakeven and build their client base up to the facility's capacity. Once the initial capacity is being utilized, the facility is designed to increase patient capacity to produce a much larger margin of profit. This expansion phase can quickly develop a profit since capital expenditures will remain constant with only the labor and supplies increasing costs.

THE INFORMATION AS A TOOL

This guidebook is designed to give decision makers a general overview of what is involved in setting up a kidney dialysis center. There are websites and resources given to guide decision makers in obtaining more detailed information including facilities available and the number of persons in dialysis for every county in the U.S.

The methodology for developing a budget is the most useful tool to decision makers. It is designed to prepare a preliminary analysis by utilizing the cost estimates and to determine a center's feasibility. If the user determines they would like to pursue the building and operating of a center, then a complete business plan should be developed before proceeding with the contractual process.

Whenever available, local cost data should be utilized to give a more accurate cost analysis. Adjustments in operational days, treatments per day, staffing patterns and number of stations will provide the flexibility needed to design an economically feasible center.

To determine costs in the future, an adjustment factor can be used. There are two different adjustment factors, construction cost index and consumer price index. The adjustment factors can be applied to the current costs in this guidebook to project the future costs.
This guidebook intends to represent the start and operation of a kidney dialysis center based on current rules, regulations, and laws at the time of this writing.

People with End Stage Renal Disease are often managing comorbid conditions for which dialysis facilities and their staff are neither trained, equipped, nor reimbursed. This may include mental health needs, diabetic care and other coexisting issues. The system of ESRD care needs to be better coordinated to support and address these needs. CMS should study the referral and payment system and look for ways to improve the overall patient-centered care.

Patients who are not eligible for Medicare prior to being diagnosed as ESRD are typically required to wait three months from diagnosis to become eligible for Medicare benefits. Patients who are not otherwise insured may find this a barrier to having an arteriovenous (AV) fistula placed and may end up dialyzing via a central venous catheter (CVC), the least expensive dialysis access type to place, but also least desirable for achieving adequate urea clearance and avoiding bloodstream infections. United Dialysis Foundation Inc. recommends that CMS waive the three-month waiting period for new Medicare patients to qualify for reimbursement for placement of a permanent AV access prior to beginning dialysis or at the start of dialysis. This would include the necessary vein mapping for proper fistula placement. Currently the eligibility waiting period is waived if the patient completes home training or receives a transplant during that period. Waiving the wait period for reimbursement for fistula placement supports CMS' Aim 1 for the ESRD program, "Better Care for the Individual through Beneficiary and Family Centered Care" by removing one of the barriers to patients beginning dialysis with an AV fistula, the preferred access for achieving adequate urea clearance. Given the additional complications and potential hospitalizations that patients encounter when dialyzing via CVC, this modification would also support CMS' Aim 3, "Reduce Costs of ESRD Care by Improving Care" United Dialysis Foundation Inc. recommends CMS study medication payment policies for ESRD Medicare Patients in support of Aim 3 to identify ways to reduce costs by improving care. Currently, CMS discontinues Medicare coverage three years post-transplant (unless qualified due to age or disability). Many people choose not to pursue a transplant due to the expense of these medications. Others lose the transplant because they are not able to pay for the medications. The cost of the medications is high, but less than returning to a regular course of dialysis. Similarly, some persons on dialysis are unable to afford basic medications. If these medications were more affordable, patients would have better outcomes on dialysis, including fewer hospitalizations.

There is a need in the ESRD system to address the treatment of patients who have been denied access to care because they have previously been involuntarily discharged. These patients may be denied access to care because they have been involuntarily discharged from

their previous dialysis facility for non-compliance, or disruptive or abusive behavior. These patients are often mentally ill, or have an underlying mental health issue that has not been addressed. Another category of involuntary discharge is those patients discharged by their physician when no other physician with privileges at the facility will accept them. Once patients are discharged, they have great difficulty finding a facility or physician willing to care for them. They often over burden local Emergency Departments and are inadequately dialyzed because of the constraints and criteria for dialyzing in an inpatient hospital setting.

A need exists for outpatient facilities to care for patients who are difficult to place, including the sub-acute dialysis patients who have special needs such as wound and tracheotomy care. Most chronic dialysis facilities are ill equipped to care for these needs and do not have trained staff or the level of staffing needed to provide this type of care.

REFERENCES

United States Renal Data System 2013 Annual Report;

www.usrds.org.

www.esrdnetwork6.org

United States Census Bureau Annual Report 2013

APPENDICES

FOOT NOTES