

**FRESENIUS MEDICAL CARE**

**Certificate of Need Application**

**Establishment of a 20 Station Dialysis Facility  
in  
Anchorage**

**April 2007**

**SECTION 1**  
**General Applicant Information**



## CERTIFICATE OF NEED APPLICATION

### APPLICANT IDENTIFICATION AND CERTIFICATION OF ACCURACY

#### 1. Applicant Identification

<b>Facility Name</b> FMC DS Cook Inlet	<b>Medicaid Provider Number</b> Not applicable
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<b>Facility Address (Street/City/State/Zip Code)</b> TBD-Three sites being considered (location information in separate section) Anchorage, AK	<b>Medicare Provider Number</b> Not applicable
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**Name and mailing address of organization that operates the facility (if different from above)**

Fresenius Medical Care  
2121 SW Broadway, Suite 111  
Portland, OR 97201

<b>Facility Administrator (Name, title, mailing address, including City/State/Zip Code)</b> Mitch Long, Area Administrator Fresenius Medical Care 3950 Laurel Street Anchorage, AK 99508	<b>Telephone</b> 907-334-0701 <b>Facsimile</b> 907-561-4223 <b>E-mail</b> Mitch.Long@fmc-na.com
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<b>Applicant (Name, title, mailing address, including City/State/Zip Code)</b> Fresenius Medical Care 2121 SW Broadway, Suite 111 Portland, OR 97201	<b>Telephone:</b> (503) 944-2602 <b>Facsimile:</b> (503) 944-2699 <b>E-mail</b> Jean.Stevens@fmc-na.com
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<b>Principal Contact Person (Name, title, physical address, mailing address, including City/State/Zip Code)</b> Jean Stevens Regional Vice President Fresenius Medical Care 2121 SW Broadway, Suite 111 Portland, OR 97201	<b>Telephone:</b> (503) 944-2602 <b>Mobile Phone</b> <b>Facsimile:</b> (503) 944-2699 <b>E-mail</b> Jean.Stevens@fmc-na.com
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#### 2. Ownership Information

**A. Type of Ownership (check applicable category)**

- |   |  |
|---|--|
| <input type="checkbox"/> For profit: individual             | <input type="checkbox"/> Not for profit: government  |
| <input type="checkbox"/> For profit: partnership            | <input type="checkbox"/> Not for profit: corporation |
| <input checked="" type="checkbox"/> For profit: corporation | <input type="checkbox"/> Other (specify): _____      |

**B. List of all Owners (Page 2 of application)**

**C. Accreditation Information (Page 2 of application)**

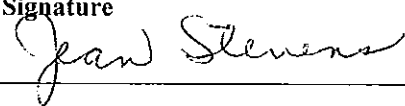
#### 3. Agreement to participate in the Uniform Statewide Reporting System

I hereby agree to participate in the uniform statewide reporting system required under AS 18.07.101 when requested to do so under 7 AAC 07.105(c).

#### 4. Certification of Accuracy by Certifying Officer of the Organization

I hereby certify that the information contained in this application, including all documents that form any part of it, is true, to the best of my knowledge and belief. I agree to provide, within 60 days from receipt of a request from the department under 7 AAC 07.050(b), any additional information needed by the department to make a decision.

<b>Name</b> Jean Stevens	<b>Title</b> Regional Vice President
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<b>Signature</b> 	<b>Date</b> April 25, 2007
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## **B. List of all Owners**

Fresenius Medical Care North America (Fresenius) is a wholly owned subsidiary of Fresenius Medical Care AG & Co. KGaA, located in Bad Homburg, Germany. Fresenius Medical Care is a publicly owned company. Information on the Co-CEOs and the current Management Board of Directors is contained below:

Co-CEO:

**Rice Powell**

**Dialysis Products, Extracorporeal Therapies and**

**Lab Group North America**

**Fresenius Medical Care North America**

Rice Powell is member of the Management Board for the Products & Hospital Group of Fresenius Medical Care in North America. He joined Fresenius Medical Care in 1997 and was appointed to the Management Board of the Company in January 2004. Mr. Powell has more than 25 years of experience in the healthcare industry. From 1978 to 1996 he held various positions within Baxter International Inc. (U.S.), Biogen Inc. (U.S.) and Ergo Sciences Inc. (U.S.).

Co-CEO:

**Mats Wahlstrom**

**Services Division North America**

**Fresenius Medical Care North America**

Mats Wahlstrom has 20 years of experience in the renal field. From 1983 to 1999 he held various positions at Gambro AB (Sweden), including President and CEO of Gambro in North America as well as CFO of the Gambro Group. In November 2002 he joined Fresenius Medical Care as President of Fresenius Medical Care's services division in North America. He became a member of the Management Board for dialysis care in North America in January 2004.

Other members of the Management Board for Fresenius Medical Care include:

**Dr. Ben Lipps**

**Chairman of the Management Board**

Dr. Lipps has been active in the field of dialysis for more than 35 years. After earning his Master's and doctoral degrees at the Massachusetts Institute of Technology in chemical engineering, Dr. Lipps led the research team that developed the first commercial Hollow Fiber Artificial Kidney at the end of the 1960s – leading directly to development of the artificial kidney – the dialyzer. Before joining the Fresenius Group in 1985, Dr. Lipps held several research management positions, among them with DOW Chemical.

**Roberto Fusté**  
**Region Asia-Pacific**

After finishing his studies in economic sciences at the University of Valencia, the Spaniard founded the company Nephrocontrol S.A. in 1983. In 1991, Nephrocontrol was acquired by the Fresenius Group, where Mr. Fusté has worked since. Before being appointed to the Management Board of Fresenius Medical Care in 1999, Mr. Fusté held several senior positions within the company in Latin America and the Asia-Pacific region.

**Dr. Emanuele Gatti**  
**Region Europe, Latin America,**  
**Middle East and Africa**

Dr. Emanuele Gatti is Chief Executive Officer for Europe, Latin America, Middle East and Africa. After completing his studies in bioengineering, Dr. Gatti lectured at several biomedical institutions. He continues to be involved in comprehensive research and development activities focusing on dialysis and blood purification, biomedical signal analysis, medical device safety and health care economics. Dr. Gatti has been with the company since 1989. Before being appointed to the Management Board of Fresenius Medical Care in 1997, he was responsible for the dialysis business in Southern Europe.

**Dr. Rainer Runte**  
**Law and Compliance**

Dr. Rainer Runte is a Member of the Management Board for Law and Compliance of the Fresenius Medical Care Management AG, the general partner of Fresenius Medical Care AG & Co. KGaA. Dr. Runte has worked for the Fresenius group for 14 years. Previously he served as scientific assistant to the law department of the Johann Wolfgang Goethe University in Frankfurt and as an attorney in a law firm specialized in economic law. Dr. Runte took the position as Senior Vice President for Law of Fresenius Medical Care in 1997 and was appointed as deputy member of the Management Board in 2002. Dr. Runte became a full member of the Management Board in early 2004.

**Lawrence A. Rosen**  
**Finance**

Lawrence A. Rosen joined Fresenius Medical Care on November 1, 2003 as Chief Financial Officer. Prior to that, he worked for Aventis S.A., Strasbourg/France, and its predecessor companies, including Hoechst AG, beginning in 1984. His last position was Group Senior Vice President for Corporate Finance and Treasury. He holds a Masters of Business Administration (MBA) from the University of Michigan and a Bachelor of Science in Economics from the State University of New York at Brockport.

The Supervisory Board members of Fresenius Medical Care AG & Co. KGaA are as follows:

**Dr. Gerd Krick**

Chairman

Former Chief Executive Officer of Fresenius AG

Königstein, Germany

**Dr. Dieter Schenk**

Vice Chairman

Attorney and Tax Advisor

Munich, Germany

**Prof. Dr. Bernd Fahrholz**

Attorney

Frankfurt am Main, Germany

**Dr. Walter L. Weisman**

Former President and Chief Executive

Officer of American Medical International, Inc.

Los Angeles, USA

**John Gerhard Kringel**

Durango, Colorado, USA

**William P. Johnston**

Former Chairman of Board of Directors

of Renal Care Group, Inc.

Nashville, Tennessee, USA

**C. Accreditation Information**

Dialysis facilities are not accredited by any specific accrediting entity. Rather, they are certified by Medicare for participation in the Medicare and Medicaid programs.

Fresenius is proposing the establishment of a new facility, FMC Cook Inlet. As such, this facility has no prior operating history. However, Fresenius currently operates four facilities in the State of Alaska. These facilities were acquired by Fresenius in April 2006 as part of the purchase of the stock of Renal Care Group. All four of these facilities are currently certified by Medicare. In fact, the FMC Fairbanks facility was surveyed by Health Facilities Licensing and Certification as recently as early April 2007. Information regarding all four facilities and their recent survey history is included on page 34.

Fresenius will secure all required certifications prior to commencing service at the FMC Cook Inlet facility.

**SECTION II**  
**Summary Project Description**

## **1. Summary of Proposed Project**

Fresenius is proposing to establish a 20 station dialysis facility in Anchorage. This facility will offer in-center hemodialysis, back-up and training for home dialysis<sup>1</sup> patients, self-care dialysis and visitor dialysis capacity. This facility will be known as FMC Cook Inlet. The new facility will be constructed to the national standards of Fresenius (modified as needed for the appropriate building requirements in Anchorage), including specifications for patient space per station, water treatment requirements/space, and facility flow designs to enhance patient care and the patient care environment, as well as the implementation of operational and mechanical technologies. A listing of the equipment needed is included in Table 2.

Fresenius is in the process of evaluating three sites for this project. All three of these sites are located in West Anchorage, and include:

- Site 1: Located at Blackberry Road and West Dimond Road, this site will require the construction of a building. Fresenius would lease this to-be-constructed building from the developer.
- Site 2: Located at 200 West International Airport Road. This is an existing building that Fresenius would lease.
- Site 3: Located at West Dimond Road near Jewel Lake this site will require the construction of a building. Fresenius would lease this to-be-constructed building from the developer.

At any site, the facility would have approximately 10,000 square feet and would require an estimated capital expenditure of nearly \$4.9 million. The project will be financed with reserves from Fresenius. The estimated completion date is September 2008. A decision regarding a specific site will be made by mid-May.

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<sup>1</sup> Includes both home hemodialysis and peritoneal patients.



**SECTION III**  
**Description of Facilities and Capacity Indicators**

**A. Are there proposed changes in service capacity? Provide either the number of beds, surgery suites, rooms, pieces of equipment, or other service.**

As depicted in Table 1 below, FMC Cook Inlet will provide 20 new incenter dialysis stations to serve the greater Anchorage dialysis community.

**Table 1**  
**Proposed Distribution of Service Capacity**

<b>Type of Service</b>	<b>Current Capacity</b>	<b>Added, Expanded, or Replacement Capacity</b>	<b>Total Proposed Capacity</b>
<b>THERAPEUTIC CARE</b>			
Radiation Therapy			
Lithotripsy			
Renal Dialysis <sup>2</sup>	0	20	20
Other (List)			
<b>Total Capacity</b>	<b>0</b>	<b>20</b>	<b>20</b>

*Source: Applicant*

**B. Provide a detailed narrative description of each service identified in "A" above, including the type of change (addition, expansion, conversion, reduction, replacement, elimination). Include, as appropriate, detailed information relative to the scope and level of service.**

Fresenius is proposing the establishment of a 20-station dialysis center in Anchorage to be known as FMC Cook Inlet. This facility will offer incenter hemodialysis to end stage renal disease patients residing in the greater Anchorage area. FMC Cook Inlet will also offer home dialysis training and support for patients choosing home hemodialysis or peritoneal dialysis. The proposed new facility will complement the existing dialysis services currently available in Anchorage at FMC Anchorage (a 35-station facility owned and operated by Fresenius). In addition to incenter hemodialysis, FMC Anchorage also offers home peritoneal dialysis training and support as well as a dedicated pediatric dialysis program. Both of the home programs serve and/or will serve residents throughout the State of Alaska who elect one of the home modalities. Finally, it is anticipated that the proposed new facility, will also provide services to dialysis patients visiting Alaska. In 2006, an additional 43 visitor patients were served by FMC Anchorage. While detailed records were not kept, we believe that we were unable to accommodate all patients. Nearly 70% of these patients received dialysis served between May and September. FMC Cook Inlet is specifically requesting that it be approved for additional dialysis capacity to serve visitors.

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<sup>2</sup> Includes only the incenter dialysis stations. FMC Cook Inlet will also offer home dialysis training and backup support.

**C. Provide in the following table information regarding equipment to be purchased.**

The equipment needed to operate the 20 stations is detailed below:

**Table 2**  
**Equipment to be Purchased**

<b>Equipment Description</b>	<b>Make</b>	<b>Model</b>	<b>Cost/Unit</b>	<b>Total Cost</b>
<b>Furniture &amp; Equipment</b>				
Exam Room Furniture	UMF	5140	\$1,410	\$2,820
Dietician Office Furniture	HON	38000 Series	\$1,600	\$1,600
DON	HON	38000 Series	\$1,600	\$1,600
Social Worker Office	HON	38000 Series	\$1,600	\$1,600
Doctor Office	HON	38000 Series	\$2,500	\$2,500
All other Clinic Furniture & Equipment	HON	38000 Series		\$24,200
<b>Dialysis Equipment<sup>3</sup></b>				
Dialysis Chairs	Champion	54	\$825	\$19,800
Dialysis Machines <sup>4</sup>	Fresenius	2008 K	\$18,000	\$432,000
Solution Delivery Systems	THERAPURE	250 G	\$24,250	\$24,250
Bi-Carb Mixers	MARCORE	MCB231-1000		\$0
Granule Flow	Fresenius	N/A	\$12,680	\$12,680
RO Equipment	R.O. GE Osmonics	Z-16000	\$41,940	\$41,940
RO Equipment for home hemodialysis			\$2,500	\$5,000
<b>Other Costs</b>				
Computer Network			\$19,000	\$19,000
T.V.'s & Accessories	KTV Global	K-10 300	\$1,850	\$44,400
Telephone System	NEC	ELHE IPK	\$7,831	\$7,831
Other facility costs (drains, etc.)			\$3,870	\$3,870
<b>Total</b>				<b>\$645,091</b>

*Source: Applicant*

**D. Provide in the following table information regarding equipment to be replaced or retired.**

No equipment is to be replaced or retired. Therefore, this question is not applicable.

<sup>3</sup> Please note that Fresenius intends to purchase two additional incenter dialysis stations to serve only as backup when machines are in need of service or repair.

<sup>4</sup> Includes home hemodialysis machines.

**E. Describe replacement or upgrading of utilities including the electrical, heating, ventilation, and air conditioning systems.**

If Fresenius selects either Dimond Road sites, a new building will be constructed. Therefore, no replacement or upgrading of facilities will be needed. If Fresenius selects the International Airport Road site, a 2" water line will be brought in specifically for use by the proposed dialysis facility. In addition, the ventilation system will be upgraded and fire sprinklers will be added to the building.

**F. Describe the structural framing, floor system, and number of floors (including the basement).**

All sites will be one-story. The International Airport Road site has brick facing on a wood structure building. Both sites on West Dimond Road would be a steel frame building.

**G. Total square footage in current facility/project.**

Not applicable.

**H. Total square footage of proposed facility/project.**

The proposed facility will contain approximately 10,000 square feet.

**I. Area per bed, service unit, or surgery suite (if applicable).**

The proposed facility will have approximately 120 square feet per incenter dialysis station, or 2,400 square feet (X 20) in total devoted to direct incenter dialysis service. In addition, about 700 square feet will be used for the home dialysis training program.

**J. Percentage of total floor area used for direct service (non-bed activity).**

In addition to the 2,400 square feet noted above, approximately 1,500 square feet of additional square footage (15% of the total area), will be used for housing the water treatment system. The remaining 5,400 square feet (54% of the total) will be used for a reception/waiting area, exam room, patient education areas (including required nutrition and social services), staff spaces, equipment maintenance and cleaning, restrooms, and storage.

**K. Additional volume of service (non-bed activity) expected.**

Consistent with Medicare requirements, FMC Cook Inlet will provide education, dietary, and social services support. In addition, physicians will round on the incenter patients about 4 times per month. Dialysis patients typically receive an initial consultation and evaluation and ongoing services. These services will be provided at the facility.

**L. Provide a brief history of expansion and construction for the past five years, including new equipment purchases, additional beds, and new services. Describe how this project fits into the facility's long-range plans, including potential projects planned for development within the next five years.**

As stated in response to previous questions, the FMC Cook Inlet will be a new facility. And while Fresenius per se is new to Alaska, our predecessor organizations have a long and proven history of developing and operating needed dialysis services for Alaska residents. Like these organizations, Fresenius is committed to continually improving access to dialysis services for residents with end stage renal disease in Alaska. To this end, Fresenius is seeking certificate of need approval to establish two dialysis centers in 2007. This application for Anchorage is the first. A second application will be submitted shortly, and it will propose to establish a dialysis facility in Soldotna.

By way of background, Fresenius acquired the four dialysis facilities it currently operates in Alaska in April 2006 when it purchased the stock of Renal Care Group. In terms of expansion over the past five years, our existing Anchorage facility received certificate of need approval in October 2003 to relocate and expand to 35 stations. This facility is now above optimal occupancy levels.

In 2002, the Fairbanks dialysis facility received certificate of need approval to relocate and expand to 17 stations. In 2003, approval was also granted to establish a new 12-station facility in Wasilla. In 2004, the new Reifenstein Dialysis Center in Juneau was opened.

In summary, Fresenius is committed to meeting the present and future needs of dialysis patients in Alaska. Fresenius has an outstanding history of developing and operating high quality dialysis facilities throughout the United States. Fresenius is confident that the proposed new facility will be operated efficiently while simultaneously providing high quality patient care.

**SECTION IV**  
**Narrative Review Questions**

#### **A. Describe the relationship to applicable plans and national trends.**

Fresenius is committed to providing optimal care for patients with chronic and acute renal disease, our philosophy is that optimal care is attained, in part, through application of state-of-the-art technology/facilities. The current facility, at 35-stations, does not have any additional space available for expansion. Even if space were available, the construction required would be very disruptive to patients and staff. Conversely, a second facility in West Anchorage best meets the growing dialysis need while improving local access to services.

Fresenius has identified a critical mass of approximately 60 current patients for whom the proposed FMC Cook Inlet would be closer to where they reside and/or work<sup>5</sup>. In addition, with this project, Fresenius is proposing to include a home dialysis program. The program will serve ESRD patients throughout the State of Alaska who choose one of the home dialysis modalities.

This project also supports the larger vision of the Division of Public Health in “assuring the conditions for a healthy population”. The Division has identified four key components in protecting and promoting the public health, the first of which is access to care. The Division further states that its “...principle responsibility...is to assure access to quality care...” (Division of Public Health, Strategic Plan 2004-2006)<sup>6</sup>. The proposed FMC Cook Inlet will improve access to dialysis services and will provide quality care.

While the *HEALTHY ALASKANS 2010* does not specifically identify any specific goals for reducing end stage renal disease or the number of patients needing dialysis services, it does have a specific goal to: reduce the physical, emotional and economic burden of diabetes and improve the overall quality of life of all persons who have or are at risk for diabetes. As indicated in the *HEALTHY ALASKANS 2010* plan, diabetes is the leading cause of end stage renal disease in adults<sup>7</sup>.

Application of the current *Alaska Certificate of Need Review Standards and Methodologies* (detailed in Section VI) demonstrates that additional dialysis stations are needed in Alaska. This is underscored by the current high utilization of the existing FMC Anchorage facility (90% utilization at 12/31/06). Establishing a second facility in Anchorage is consistent with the current certificate of need standards and methodologies and will improve access to services for residents needing both incenter and home dialysis services.

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<sup>5</sup> Fresenius has assumed that approximately 40 patients would transfer to FMC Cook Inlet.

<sup>6</sup> This is the most current strategic plan.

<sup>7</sup> Healthy Alaskans 2010 Volume 1, p. 23-3.

## **B. Demonstration of need.**

### **1. Is this project for (a) a new service; (b) an expanded service; or (c) an upgrade of an existing service?**

Fresenius is currently the only dialysis provider in the Anchorage Borough, operating a 35 station facility in Anchorage. This facility is operating above what we consider optimal capacity with a current census of 158 incenter patients<sup>8</sup>, or 90% utilization. Growth at the existing Anchorage facility was up by nearly 15% from year end 2005. While 2005 year end patient census was down from 2004, it is important to note that the year end facility data does not always reflect the ebbs and flows of a facility's census. During various periods of 2005, census varied by as much as 13 patients, or 9%. With the current census and utilization pressures, Fresenius has concluded that the establishment of a new facility will be beneficial to the community as it will provide improved access to dialysis services for patients residing in and around the Anchorage Borough.

Furthermore, our records indicate that at our current occupancy levels we are not always able to accommodate patients that are in need of "transient" dialysis while traveling to Anchorage for tourism or work. Additional capacity will help us accommodate these patients.

### **2. How does this project (a) address an unmet community need; (b) satisfy an increasing demand for services; (c) follow a national trend in providing this type of service; or (d) meet a higher quality or efficiency standard.**

As stated above, the existing facility in Anchorage is operating at or above optimal capacity levels. As detailed in this Section, there is a documented need for additional dialysis stations in Anchorage both from a facility perspective and from a statewide perspective (application of the methodology contained in the Certificate of Need standards and detailed later in this Section demonstrates the need for additional dialysis stations within Alaska). In addition, data from the United State Renal Data System indicates that, nationally, incidence rates increased by about 7% annually between 1992 and 2000. These increasing incidence rates are attributed to increases in survival as well as the increase in the number of people with diabetes. More specific to this project is the fact that the overall incidence (number of new diagnoses of ESRD) of end-stage renal disease in Alaska has increased by an average of almost 4% since 2001.

The establishment of a new facility was determined to be a superior solution to meeting this need as there is no space within and/or adjacent to the existing facility for expansion. Even if space were available for expansion, the construction required would be very disruptive to patients and staff. A second facility, on the other hand, meets the identified need while improving access to services. Lastly, Fresenius has identified a critical mass of patients for whom the proposed FMC Cook Inlet would be closer to where they reside and/or work.

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<sup>8</sup> Northwest Renal Network 12/31/06 modality reports.



**3. Describe any internal deficiencies of the facility that will be corrected, and document which of these deficiencies have been noted by regulatory authorities.**

This project does not propose to correct any deficiencies. Therefore, this question is not applicable.

**4. Identify the target population to be served by this project.**

As detailed in Table 3, the current (2006) total population of Alaska is approximately 670,000. The population is projected to grow by another 43,000 people (+6.4%) through 2012.

With a current total population of 283,000, Anchorage (see Table 4) accounts for more than 42% of the State's total. The city will add almost 17,000 more people by 2012 (+5.9%).

**Table 3**  
**Current and Projected State of Alaska Population**

	<b>2000</b>	<b>% of Tot. Pop.</b>	<b>2006</b>	<b>% of Tot. Pop.</b>	<b>Change, 2000-06</b>	<b>2012</b>	<b>% of Tot. Pop.</b>	<b>Change, 2006-12</b>
TOTAL	626,932	100.0%	670,053	100.0%	6.9%	713,002	100.0%	6.4%
Age								
0-19	208,117	33.2%	215,820	32.2%	3.7%	222,024	31.1%	2.9%
20-44	243,414	38.8%	233,384	34.8%	-4.1%	239,448	33.6%	2.6%
45-64	139,702	22.3%	175,437	26.2%	25.6%	188,344	26.4%	7.4%
65+	35,699	5.7%	45,412	6.8%	27.2%	63,187	8.9%	39.1%

*Source: Alaska Dept. of Labor and Workforce Development*

**Table 4**  
**Current and Projected Anchorage Borough Population**

	<b>2000</b>	<b>% of Tot. Pop.</b>	<b>2006</b>	<b>% of Tot. Pop.</b>	<b>Change, 2000-06</b>	<b>2012</b>	<b>% of Tot. Pop.</b>	<b>Change, 2006-12</b>
TOTAL	260,283	100.0%	282,813	100.0%	8.7%	299,636	100.0%	5.9%
Age								
0-19	83,063	31.9%	89,983	31.8%	8.3%	88,782	29.6%	-1.3%
20-44	106,017	40.7%	105,408	37.3%	-0.6%	101,756	34.0%	-3.5%
45-64	56,961	21.9%	69,875	24.7%	22.7%	83,603	27.9%	19.6%
65+	14,242	5.5%	17,547	6.2%	23.2%	25,495	8.5%	45.3%

*Source: Alaska Dept. of Labor and Workforce Development*

More specific to this project, however, is the distribution of dialysis patients by geographic community. Table 5 details the percentage of patients by area. While Anchorage has 42% of the general population, it has 59% of the dialysis population. This is likely due to the fact that some patients may choose to move to Anchorage if dialysis services are not available in their local community.

**Table 5**  
**2006 Alaska Dialysis Patients by County**

	<b>Current No. of Dialysis Patients (12/31/06)</b>	<b>Percent of Total Statewide Patients</b>
Anchorage Borough	191	58.8%
Kenai Peninsula	15	4.6%
Mat Su Borough	32	9.8%
Fairbanks North Star Borough	40	12.3%
Juneau Borough	14	4.3%
Other Alaska	33	10.2%
<b>Total Alaska</b>	<b>325</b>	<b>100.0%</b>

*Source: Northwest Renal Network, Modality Reports*

This project will significantly benefit the large minority populations in Anchorage as they are more likely to require ESRD and to suffer from diabetes leading to ESRD.

Nationally, American Indian/Alaska Native adults are 2.3 times as likely as white adults to be diagnosed with diabetes. As of 2005, almost 13% of the American Indian and Alaska Natives aged 20 years or older and receiving care from the Indian Health Service had been diagnosed with diabetes. American Indians/Alaska Natives were twice as likely as non-Hispanic whites to die from diabetes in 2003<sup>9</sup>.

Additionally, the National Healthy People 2010 plan finds that, *"Kidney disease has a disproportionate impact on certain racial and ethnic groups, especially African Americans and American Indians or Alaska Natives....American Indians or Alaska Natives have a much higher risk of chronic kidney disease due to diabetes than whites."*

As can be seen below, not only does Anchorage account for almost 42% of the State's total population, it is home to one-quarter of the State's American Indian/Alaska Native population, and over half of Alaska's African American and Hispanic populations.

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<sup>9</sup> U.S. DHHS Office of Minority Health, citing CDC 2005. Health Characteristics of the American Indian and Alaska Native Adult Population: United States, 1999-2003. *Advance Data*

**Table 6**  
**American Indian/Alaska Native Population Distribution**

	<b>Alaska</b>		<b>Anchorage</b>		
	<b>2005 Pop.</b>	<b>Pct of AK Pop.</b>	<b>2005 Pop.</b>	<b>Pct of Anchorage Pop.</b>	<b>Pct. of Anchorage of AK Pop.</b>
White	484,673	73.0%	214,050	76.9%	44.2%
American Indian/Alaska Native	117,743	17.7%	28,579	10.3%	24.3%
Black or African American	25,970	3.9%	16,319	5.9%	62.8%
Other	35,275	5.3%	19,293	6.9%	54.7%
<b>Total</b>	<b>663,661</b>	<b>100.0%</b>	<b>278,241</b>	<b>100.0%</b>	<b>41.9%</b>
Hispanic	26,413	4.0%	14,310	5.1%	54.2%

*Source: Alaska Dept. of Labor and Workforce Development.*

While specific data for Anchorage is not available, data is available regarding the ethnic distribution of the dialysis patients in Alaska. As Table 7 details, the percentage of dialysis patients who are American Indian/Alaska Native and/or African American is higher than the percentages found in the general population.

**Table 7**  
**American Indian/Alaska Native Dialysis Population Distribution**

	<b>2005 Dialysis Patients</b>	<b>% of Total</b>
White	175	59.5%
American Indian/Alaska Native	41	13.9%
Black or African American	38	12.9%
Asian	18	6.1%
More than one race selected	1	0.3%
Native Hawaiian or Other Pacific Islander	21	7.1%
<b>Total</b>	<b>294</b>	<b>100.0%</b>

*Source: Northwest Renal Network, 12/31/06 Modality Reports*

Table 8 below details the number of dialysis patients by community in Alaska for 2000 and 2006. As Table 8 indicates, the number of dialysis patients in Anchorage has increased by nearly 33% since 2000.

**Table 8**  
**Dialysis Patients by Area**  
**2000 – 2006**

	<b>2000 No. of Dialysis Pts (all Modalities)</b>	<b>% of Total</b>	<b>2006 No. of Dialysis Pts (all Modalities)</b>	<b>% of Total</b>	<b>Total chg 2000-2006</b>
Anchorage Borough	144	66.7%	191	58.8%	32.6%
Kenai Peninsula	10	4.6%	15	4.6%	50.0%
Mat Su Borough	14	6.5%	32	9.8%	128.6%
Fairbanks North Star Borough	16	7.4%	40	12.3%	150.0%
Juneau Borough	7	3.2%	14	4.3%	100.0%
Other Alaska	25	11.6%	33	10.2%	32.0%
<b>Total Alaska</b>	<b>216</b>	<b>100.0%</b>	<b>325</b>	<b>100.0%</b>	<b>50.5%</b>

*Source: Northwest Renal Network, Modality Reports, 2000 and 2006*

A review of the current patient census for the existing FMC Anchorage indicates that all of the current patients reside in the Anchorage Borough; with 97% residing in the City of Anchorage.

**5. Describe the projected utilization of the proposed services and the method by which this projection was derived.**

As stated in earlier sections of this application, FMC Cook Inlet is not an existing facility; therefore, it has no operating history. However, Fresenius does operate all four of the dialysis facilities in Alaska; including the existing center in Anchorage. Historic utilization for FMC Anchorage is detailed in Table 9 below:

**Table 9**  
**Historic Utilization for FMC DS Anchorage**  
**2002-2006**

	2002	2003	% Change	2004	% Change	2005	% Change	2006	% Change	Avg. 2004- 2006	Avg Change
No. of Patients	137	160	16.8%	154 <sup>10</sup>	-3.8%	138	-10.4%	158	14.5%	153	4.3%
Percent Utilization	86%	100%	16.8%	96%	-4.0%	79%	17.7%	90%	13.9%	91%	2.1%
No. of Treatments	21,904	23,408	6.9%	22,956	1.9%	21,892	-4.6%	22,370	2.2%	22,406	0.6%
No. of Stations	32	32	0.0%	32	0.0%	35	0.0%	35	0.0%	35	2.3%
Percent Utilization	88%	94%	6.6%	92%	-1.9%	80%	-4.8%	82%	2.5%	82%	-1.7%

*Source: Applicant and Northwest Renal Network Modality Reports, 2002-2006*

<sup>10</sup> Census declined due to the opening of the Wasilla facility.

As stated in earlier sections of this application, Fresenius currently has identified a critical mass of patients who live or work closer to the proposed FMC Cook Inlet facility than to the existing FMC Anchorage and have indicated that they may have an interest in relocating to the new facility. It is anticipated that approximately 40 patients would transfer to the new facility when it opens in 2008. For each subsequent year, Fresenius has projected 10% growth patients, based upon average historic growth since 2003 (8%) (detailed in Table 11) in the Anchorage Borough. In addition, Fresenius has assumed additional activity for home training back up and support as well as visitor patients.

Table 10 below details the projected number of patients and treatments for the proposed FMC Cook Inlet:

**Table 10**  
**Projected Patient and Treatments at proposed FMC DS Cook Inlet**  
**2008-2012**

	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
<b>No. of Incenter Patients</b>	40	44	48	53	58
<b>No. of Home Dialysis Patients</b>	14	15	17	19	21
<b>Total Patients</b>	<b>54</b>	<b>59</b>	<b>65</b>	<b>72</b>	<b>79</b>
<b>No. of Incenter Treatments for Incenter Patients</b>	6,240	6,864	7,488	8,268	9,048
<b>Estimated Visitors Treatments</b>	62	69	75	83	90
<b>Total Treatments<sup>11</sup></b>	<b>6,302</b>	<b>6,933</b>	<b>7,563</b>	<b>8,351</b>	<b>9,138</b>

*Source: Applicant*

**6. Provide calculations of numerical need for each proposed activity for your service area.**

Fresenius applied the methodology contained in 7 AAC 07.025, which identifies an unadjusted need for 16 new stations in Anchorage by 2012. With several reasonable modifications, explained in detail below, the 20 stations we are requesting are fully justified:

The methodology is restated below:

---

<sup>11</sup> Excludes home dialysis treatments.

**STEP ONE:** Determine the projected ESRD caseload using the formula:

$$C = P \times UR$$

**C** (caseload) = the number of ESRD patients three years from the project implementation date.

**P** (projected population) = the official State population projected for the fifth year following implementation of the project.

**UR** (end stage renal disease prevalence rate) = persons diagnosed with ESRD per 10,000 population.

Table 11 below details historic prevalence point data for Alaska residents using data from the Northwest Renal Network. Point Prevalence data is not yet available for 2006<sup>12</sup>. However, data for 2002-2005 indicates that the year end patient numbers and the point prevalence data have been nearly identical. Therefore, Fresenius concludes that the year end patient numbers are a good proxy for the point prevalence data for 2006.

**Table 11**  
**Historic Utilization Rates for ESRD Dialysis**  
**2002-2006**

	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Average Change</b>
<b>No. of Patients (12/31)</b> <sup>13</sup>	237	272	304	297	325	8.41%
<b>Point Prevalence</b> <sup>14</sup>	237	272	304	294	NA	7.75% <sup>15</sup>
<b>Est. Alaska Adult Population</b> <sup>16</sup>	640,544	647,747	655,435	662,604	670,053	1.13%
<b>ESRD Dialysis Utilization Rate (per 10,000 population)</b>	3.70	4.20	4.64	4.44	4.85	7.23%

*Source: Applicant*

Based on the above data from Northwest Renal Network, the estimated Alaska utilization rate for 2006 was 4.85 per 10,000 population, trending upward by 7.2% annually between 2002 and 2006.

Table 12 below details the estimated number of ESRD dialysis patients for the years 2007-2012; the fifth year following project implementation<sup>17</sup>.

<sup>12</sup> According to staff at Northwest Renal Network, 2006 point prevalence data will not be available until July 2007.

<sup>13</sup> Northwest Renal Network, Year End Modality Reports, 2002-2006

<sup>14</sup> Northwest Renal Network, Point Prevalence Reports, 2002-2005

<sup>15</sup> Average is for 2002-2005 only.

<sup>16</sup> Alaska Dept. of Labor and Workforce Development, Middle Series, Feb. 2005.

<sup>17</sup> Step One of the dialysis methodology contains two different points in time (three years following project implementation for estimating the caseload) and five years from project implementation for estimating population. To be consistent, Fresenius has based its projections for five years from certificate of need approval or 2012.

**Table 12**  
**Projected Utilization Rates for ESRD Dialysis**  
**2007-2012**

	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
<b>Est. Alaska Adult Population<sup>18</sup></b>	677,362	684,714	692,001	699,207	706,344	713,393
<b>ESRD Dialysis Utilization Rate (per 10,000 population)</b>	4.85	4.85	4.85	4.85	4.85	4.85
<b>Est. ESRD Dialysis Patients</b>	329	332	336	339	343	346
<b>ESRD Trended Use Rate</b>	5.03	5.21	5.40	5.59	5.79	6.00
<b>Estimated ESRD Patients (trended use rate)</b>	340	357	373	391	409	428

*Source: Applicant*

**STEP TWO:** Determine the projected number of chronic renal dialysis treatments required to meet projected demand using the formula:

$$\text{DTR} = \text{C} \times \text{PTR}$$

**DTR** = Dialysis treatments required

**C** (caseload) = Projected ESRD Caseload

**PTR** = Average ESRD patient treatment rate, defined as 3.0 treatments per patient per week or 156 treatments per patient annually

Using the information from Table 12 above, for 2012, the estimated number of treatments are calculated as follows:

$$53,979 \text{ (DTR)} = 346 \text{ (Caseload)} \times 156 \text{ (PTR)}$$

**STEP THREE:** Determine the number of ESRD dialysis stations required to meet the projected number of treatments using the formula:

$$\text{DSR} = \text{DTR} / \text{DSC} / \text{TSO}$$

**DSR** = Dialysis stations required

**DTR** = Dialysis treatments required

**DSC** = Average dialysis station capacity, defined as 15.0 treatments per week or 780 treatments per year

**TSO** = Target ESRD station occupancy, defined as 80% (0.80)

Using information from Step Two above, for 2012, the estimated number of dialysis stations are calculated as follows:

$$87 \text{ (DSR)} = 53,979 \text{ (DTR)} / 780 \text{ (DSC)} / 80\% \text{ (TSO)}$$

<sup>18</sup> Alaska Dept. of Labor and Workforce Development, Middle Series, Feb. 2005.



**STEP FOUR:** Determine unmet ESRD station need, if any, by subtracting number of existing and CON-approved ESRD stations from the number projected to be needed. Bed need estimates will be made for proposed service areas based on current share of the state's adult population by region or census area/borough included in the service area.

Table 13 below details the estimated dialysis station need for 2012, the current number of CON-approved stations and an estimated share by community. Fresenius has estimated the shares by geography based upon the percentage of the dialysis population in each distinct area.

**Table 13**  
**Estimated Net Station Need by Geographic Area**  
**2012**

	<b>Current No. of Dialysis Patients (12/31/06)</b>	<b>Percent of Total Statewide Patients</b>	<b>Current No. of Stations</b>	<b>Est. Dialysis Stations needed (per percentage of dialysis population)-current prevalence rate</b>	<b>Net Station Need By 2012</b>
Anchorage Borough	191	58.8%	35	51	16
Kenai Peninsula	15	4.6%	0	4	4
Mat Su Borough	32	9.8%	12	9	0
Fairbanks North Star Borough	40	12.3%	17	11	0
Juneau Borough	14	4.3%	9	4	0
Other Alaska	33	10.2%	0	9	9
<b>Total Alaska</b>	<b>325</b>	<b>100.0%</b>	<b>73</b>	<b>87</b>	<b>29</b>

*Source: Applicant*

As Table 13 indicates, there is a net need for an additional 16 stations in the Anchorage Borough. Fresenius is proposing the establishment of a 20-station facility. The additional stations will allow Fresenius to operate more cost efficiently and effectively. Fresenius is requesting four additional stations for the following reasons:

- Consistent with the 2003 certificate of need application submitted by Renal Care Group, FMC Anchorage has two stations that have been constructed and set up specifically for pediatric patients. FMC Anchorage now has a dedicated pediatric program (the first of its kind in Alaska). Having specialized facilities for children (separate and distinct from the adults) is important to ensuring high quality patient care. Therefore, Fresenius has "excluded" two stations from the existing supply as they are not available for the general dialysis population.

- An additional station for visitors: every year, some number of tourists needing dialysis travel to Alaska. Last year, FMC Anchorage provided dialysis services to 43 visitor patients with the vast majority, 70%, needing dialysis between the months of May and September. Generally, travelers spend about 1-2 weeks dialyzing at our facility. Some, however, have stayed as long as 1-2 months. During peak months, utilization at our facility increases by an additional 6% or an additional 1-2 stations.
- 3) A dedicated isolation station. Fresenius has at least one dedicated isolation station in each of its facility in order to serve patients needing dialysis who need to be isolated from other patients because of a communicable illness.

Lastly, since 2002, the prevalence rates in Alaska have increased by an average of 7.2% per year. While the methodology in 7 AAC 07.025 holds the prevalence rate flat; if this increasing prevalence continues, all of Alaska would need additional dialysis station capacity. Detailed in Exhibit 1 is an application of the methodology contained in 7 AAC 07.025 using an increasing prevalence rate. In an effort to be conservative, Fresenius has adjusted the prevalence rate by one half of the historic average annual growth (or, 3.6%). As Exhibit 1 indicates, the total number of dialysis patients would be Anchorage would be 24% higher than estimated using the current prevalence rate.

### **C. Discuss the availability of less costly or more effective alternatives.**

#### **1. Describe the different alternatives considered in developing this project.**

Fresenius considered the following options prior to the development of this proposal:

- Do nothing.
- Expand the existing FMC Anchorage facility.
- Pursue the project described in this proposal.

Among the three options considered, the first - doing nothing - was not given serious consideration as FMC Anchorage is now regularly operating at or above optimal capacity levels. This has a direct and adverse impact on access for ESRD patients. As the facility approaches 100% utilization, it becomes increasingly difficult to meet the needs of all patients seeking care. Doing nothing would compromise access to services to patients needing dialysis.

The second alternative, to expand the existing facility, was ruled out for several reasons. First and foremost, the facility has no room for expansion. Even if space were available, the required construction would result in significant inconvenience and disruption for patients and staff. Lastly, it was determined that given the extent of the unmet need, a new facility at a different site could improve access to a larger percentage of our patients.

For all of the reasons cited above, Fresenius made the decision that the establishment of a new facility in Anchorage would be the most efficient and cost effective solution to improving access to dialysis services for residents of the Anchorage Borough with end stage renal disease.

**2. Describe any special needs and circumstances.**

This project does not include any special needs or circumstances. Therefore, this question is not applicable.

**D. Describe the relationship of the proposed project to existing health care system and to ancillary or support services.**

- 1. Identify any existing comparable services within the service area and describe any significant differences in population served or service delivery. If there are no existing comparable services in the area, describe the unmet need and how the target population currently accesses the services.**

As stated in other sections of this application, Fresenius operates the only comparable service within the proposed service area (the existing 35 station dialysis facility in Anchorage). The establishment of FMC Cook Inlet will improve access to dialysis services and will meet a portion of the projected need for additional dialysis capacity in Alaska. In addition, the new facility will offer home dialysis training and support. This program would serve dialysis patients throughout the State of Alaska for whom home dialysis is the preferred modality of treatment.

- 2. Describe the probable effect on other community resources, including any anticipated impact on existing facilities offering the same/similar services or alternatives locally or statewide if applicable. Describe how each proposed new or expanded service will:**
  - a. Complement existing services.**
  - b. Provide an alternative or unique service.**
  - c. Provide a service for a specific target population.**
  - d. Provide needed competition.**

The new Center will:

- a. Complement existing services.**

As stated in response to previous questions, while there is an existing facility in Anchorage, it is nearing capacity. Rather than expand this facility, Fresenius has elected to establish a second facility. The new facility in Cook Inlet will complement the existing services offered at the Anchorage facility by expanding total capacity in the service area and ensuring continued access to dialysis services throughout Anchorage; offering patients a choice in site; allowing patients in

West Anchorage the opportunity to receive services closer to home; enhancing capacity at the existing Anchorage site; and offering additional services including home and visitor capacity. These home and visitor services will increase capacity and availability of these services to patients throughout Alaska.

**b. Provide an alternative or unique service.**

In addition to increasing general access, this new facility in Cook Inlet offers an alternative location for receiving dialysis for patients in the service area. Fresenius currently estimates that approximately 40 patients will likely transfer to the new facility as it will be closer to their homes or work. As a result, the existing FMC Anchorage facility will have expanded capacity to serve new patients.

**c. Provide a service for a specific target population.**

As stated above, placing the facility in Cook Inlet will allow local access to dialysis services for patients residing in West Anchorage. In addition, this facility will specifically enhance access to patients desiring to receive dialysis services at home and for visitors to the Anchorage community. It also increases general access to the Anchorage community, which as described above, includes a large American Indian/Alaska Native, African American, and Hispanic Population. Also, as demonstrated above, these minority populations are much more likely to require ESRD due to diabetes and other health issues.

**d. Provide needed competition.**

Given the limited dialysis population and high cost of operating within Alaska, Fresenius believes that access and quality are more important than competition simply for the sake of competition. The establishment of a second Fresenius facility in Anchorage will improve access to care while not jeopardizing the existing high quality delivery system. Fresenius already has in place the infrastructure that will enable it to simply add a new facility. If a second competing provider were to enter the Anchorage market place, significant duplication could occur with replication of management and administrative systems and competition for limited staff. Furthermore, the patient population that would benefit by a new facility is already being cared for by Fresenius. These patients are satisfied with and desire to remain within the Fresenius system. A second provider could significantly destabilize the dialysis system of care.

**3. Identify existing working relationships the applicant has with hospitals, nursing homes, and other resources serving the target population in the service area.**

Fresenius enjoys a close working relationship with Providence Alaska Medical Center, Alaska Native Hospital, Alaska Regional Hospital, and St. Elias Specialty Hospital. In addition, as necessary, staff work with hospitals in other communities for patients residing in those areas (these are typically home and PD patients). These include Yukon-Kuskoquim Delta Hospital in Bethel, Kanakanak Hospital in Dillingham, Central Peninsula Hospital in Soldotna, Providence Hospital in Seward, Valley Hospital in Palmer, and Valdez Hospital in Valdez.

Fresenius has consulted with various staff from all these facilities and all are aware and supportive of the proposed establishment of FMC Cook Inlet.

FMC Anchorage has a patient transfer agreement with Providence Alaska Medical Center.

#### **E. Financial Feasibility.**

- 1. Demonstrate how the project will ensure financial feasibility, including long-term viability, and what the financial effect will be on consumers and the state, region, or community served.**

Fresenius has a documented history of successfully operating dialysis facilities throughout the United States. Under Medicare, incenter dialysis is primarily paid for on a per treatment basis. As such, Fresenius does not expect this project to have a significant financial effect on either the consumers or the state. As detailed in Schedule VI, 87% of dialysis patient care is projected to be paid for by Medicare (per diem). Fresenius is confident that we will be able to operate the proposed facility within these reimbursement levels. In addition, the facility is expected to operate within the high quality standards that Alaska patients have come to expect with existing dialysis services. Lastly, it should be noted that Fresenius' charges are set nationally. Therefore, the overall charges for its services are not based upon this project.

- 2. Discuss how the project construction and operation is expected to be financed. Demonstrate access to sufficient financial resources and the financial stability to build and operate this project.**

Fresenius will use existing reserves to finance the capital expenditure associated with this project. Fresenius will submit documentation of its financial commitment to this project once the site has been selected.

- 3. Provide a description and estimate of:**

- a. The probable impact of the proposal on the annual increase on the overall costs of the health services to the target population to be served;**

As stated in response to previous questions, dialysis is paid on a fixed per treatment basis. This project is, therefore, not expected to have a significant increase in the overall costs of the health services provided to the target population. As stated above, Fresenius' charges are set nationally. Therefore, this project alone is not expected to increase the overall costs of services to the target population. In other words, Fresenius' charges for services will be the same with or without this project.

- b. If applying to build a residential psychiatric treatment centers, nursing homes, or additional nursing home beds the annual increase to Medicaid required to support the new project, and the projected cost of and charges for providing the health care services in the first year of operation (per diem rate, scan, surgery etc).**

This question is not applicable as it does not propose any psychiatric treatment beds or nursing home beds.

- c. The immediate and long-term financial feasibility of continuing operations of the proposal.**

As demonstrated by the income statement contained in Schedule I, this project is expected to be able to meet the immediate and long term financials obligations through operations.

#### **Access to Service by the General Population and Under-Served Groups.**

- 1. Provide information on service needs and access of under-served groups of people such as low-income persons, racial and ethnic minorities, women, and persons with a disability.**

The State Health Plan is modeled on the national Healthy People 2010 plan, but does not include a corresponding chapter specifically regarding chronic kidney disease. The National Plan finds that, *"Kidney disease has a disproportionate impact on certain racial and ethnic groups, especially African Americans and American Indians or Alaska Natives....American Indians or Alaska Natives have a much higher risk of chronic kidney disease due to diabetes than whites. Overall, the rates of new cases are 4 times higher in African Americans and American Indians or Alaska Natives. Rates of new (End-Stage Renal Disease) are increasing by 7 percent per year for African Americans, 10 percent per year for American Indians or Alaska Natives, and 11 percent for Asians or Pacific Islanders, compared to 6 percent per year for whites...Projections indicate that increases in the rates of new cases will continue in American Indians or Alaska Natives."*

As stated in response to previous questions, Fresenius is well aware of these trends in the incidence of kidney disease, especially given that almost 14% of the dialysis population is Alaska Native/American Indian and another 14% is African American. We are committed to providing care to anyone needing dialysis services, regardless of ability to pay, ethnicity or any other categorization.

A copy of Fresenius' admission and charity care policies are included in Exhibit 2.

**2. Indicate the annual amount of charity care provided in each of the last five years with projections for the next three years.**

The FMC Cook Inlet facility is not an existing facility. However, the existing FMC Anchorage facility has historically provided an estimated 1% of its total revenue as charity care. In the pro forma financials (contained in Schedule 1), Fresenius has estimated charity care to be 1.5% of revenue.

**3. Address the following access issues:**

**a. Transportation and travel time to the facility;**

Patients utilizing the proposed FMC Cook Inlet facility will utilize the same sources of transportation as are used by patients traveling to and from FMC Anchorage. Table 14 below demonstrates that all three (3) sites are conveniently located within Anchorage.

**Table 14**  
**Approximate Travel Time (Minutes)**

<b>Potential Site</b>	<b>Mode of Transportation</b>	<b>From Downtown (99501)</b>	<b>From Dimond Center Mall (99515)</b>
West International Airport Road.	People Mover Route 7 & 7A *	20	30 (Express = 20)
	Private Car **	9	10
Jewell Lake/Blackberry Road Sites	People Mover Route 7 & 7A *	40	5
	Private Car **	12	6

*Source: \* Municipality of Anchorage. \*\* Microsoft Mapoint*

In addition to the routes referenced in the table, the Municipality of Anchorage People Mover transit service also offers AnchorRIDES, a shared ride service providing curb-to-curb trips in compliance with various funding sources for people with disabilities, senior citizens and other contracted trips. AnchorRIDES specifically contracts to provide transportation for individuals authorized under the Medicaid Home and Community Based Waiver program.

**b. Special architectural provisions for the aged and persons with a disability;**

The proposed FMC Cook Inlet will meet all applicable codes for access to persons with disabilities.

**c. Hours of operation:**

Anticipated hours of operation are: 5:00 AM to 5:00 PM, Monday through Saturday.

**d. The institution's policies for nondiscrimination in patient services**

As stated in response to previous questions, Fresenius is committed to providing services to all patients needing dialysis services. A copy of Fresenius' admission policies were included in Exhibit 2.



**SECTION V**  
**Consideration of Quality, Effectiveness, Efficiency, and Benefits of the Applicant's Services**

**1. Accreditation and Licensure – What is the current status, source, date and length of the applicant’s license and certification.**

The FMC Cook Inlet is not an existing facility. Alaska does not license dialysis facilities. Fresenius will seek Medicare and Medicaid certification for the facility upon completion. Fresenius currently operates four dialysis facilities in Alaska. Specific detail regarding the existing four facilities is included in Table 15 below:

**Table 15  
Existing Fresenius Alaska Facilities**

<b>Facility</b>	<b>Initial Medicare Certification</b>	<b>Recent Survey (date)</b>	<b>Recertified During Latest Survey</b>
FMC Anchorage	9/1/1977	July 2005	Yes
FMC Wasilla	3/29/2004	June 2006	Yes
FMC Fairbanks	6/27/1985	April 2007	Yes
Reifenstein Dialysis Center, Juneau	3/26/2004	April 2006	Yes

*Source: Applicant*

**2. Quality Control - How the applicant plans to ensure high quality service?**

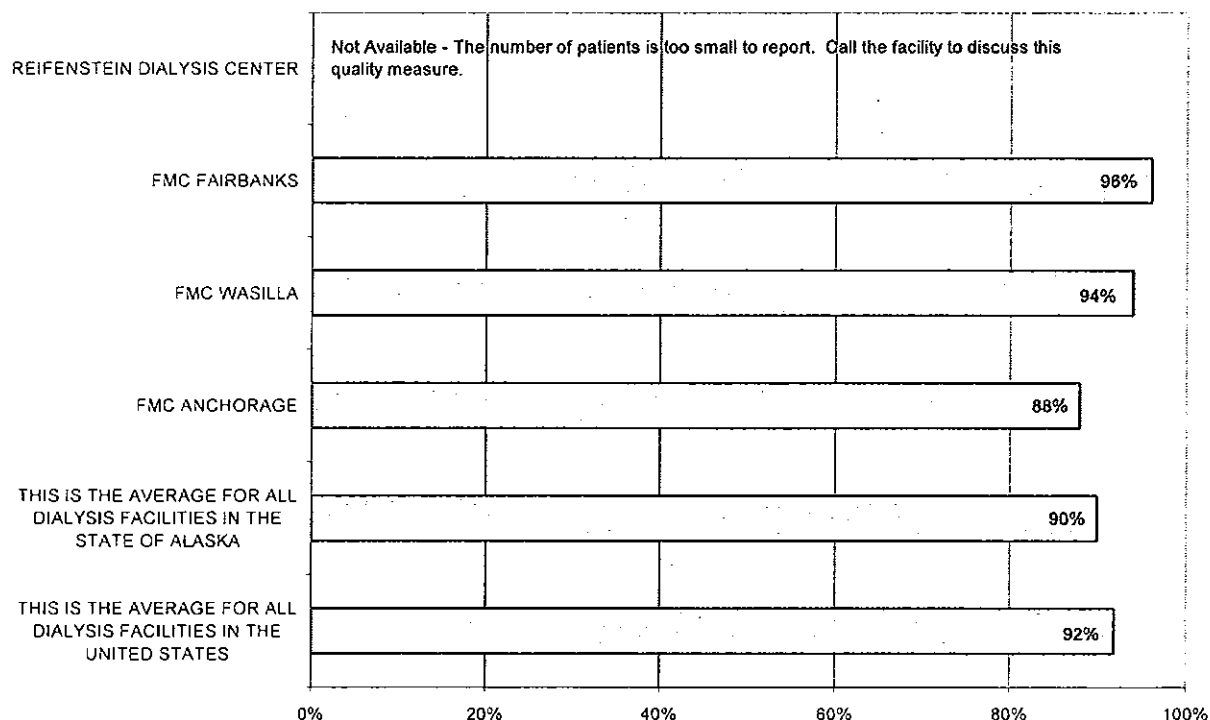
Fresenius is committed to providing excellent care to patients with a focus on superior customer service. This is based on extensive training for ALL clinic staff in the areas of Clinical Leadership, Team Approach to Care, Exemplary Customer Service, Innovative Technology and Individualized Patient Care. These five main elements of training allow Fresenius staff and physicians to deliver excellent care to patients through innovative methods, the latest technology, and a shared focus on superior customer service.

In addition, Fresenius has a documented history of developing and operating high quality dialysis centers—nationally, internationally and now within the State of Alaska. This history demonstrates that we provide superior outcomes attained through the application of staff education, patient/family education, and state-of-the-art technology.

Optimal care is achieved through a continual quality improvement process focused on superior patient outcomes and patient satisfaction. This process is integrated into the day to day facility operations and the activities of caregivers and patients. Fresenius has set goals for quality indicators with additional indicators measured at the facility level. These quality indicators are carefully selected to reflect current medical evidence and to meet or exceed current standards of practice. On a monthly basis, the quality indicators are measured at the facility level. Methods of measurement are clearly defined to ensure uniformity of these methods throughout all Fresenius facilities. Results of these measurements are reviewed by the facility and compared to optimal standards. Fresenius has developed protocols and recommendations in key areas of patient care such as delivery of optimal dialysis dose, anemia management, management of calcium/phosphorus balance and dialysis access. Similarly, Medicare (through Dialysis

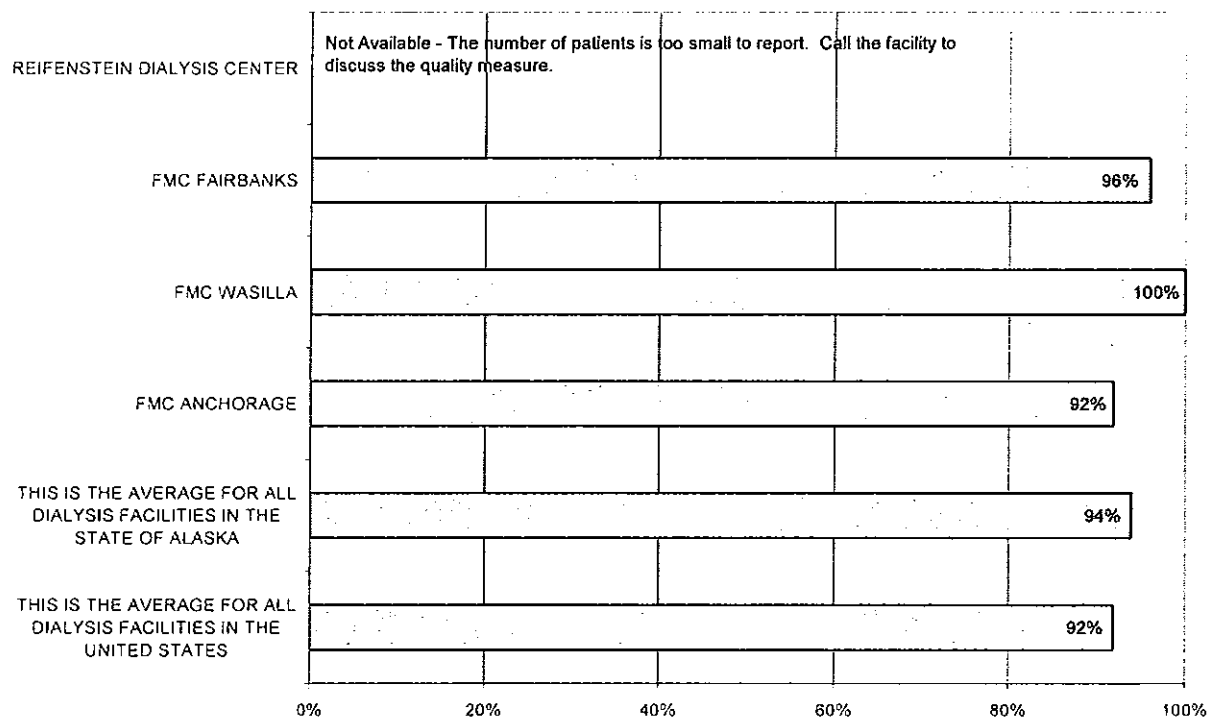
Compare) collects some of the same data. The following tables show how each of the Alaska facilities compares on the key data elements collected and reviewed by Medicare. However, it is important to note that the two tertiary hospitals and all the nephrologists in Alaska are located in Anchorage. Therefore, the majority of new dialysis patients begin their dialysis in Anchorage at FMC Anchorage. New patients typically suffer from low hemoglobin. Fresenius believes that the slightly lower rates at its facility are due to the fact that it cares for patients new to dialysis (when they are often the sickest) and they also care for patients both pre and post hospitalization (again, during periods of time when they may be quite ill). Therefore, it is not surprising that FMC Anchorage's measurements are slightly lower than the state and national averages. Please note, however, that in February 2007, FMC Anchorage had increased its overall clinic average on anemia to 91%.

**Chart 1**  
**Percentage of Medicare Patients that have their**  
**Anemia (low red blood cell count) under control in 2005**



*Source: Dialysis Compare, June 2005-July 2006*

**Chart 2**  
**Percentage of Medicare Patients who had Enough Wastes Removed from their Blood**  
**During Dialysis (Dialysis Adequacy) in 2005**



*Source: Dialysis Compare, June 2005-July 2006*

**Table 16**  
**Patient Survival for January 2002 to December 2005**

	<b>Better Than Expected**</b>	<b>As Expected</b>	<b>Worse Than Expected**</b>
Survival Categories for the 4315 facilities with available data in the US	100	4038	177
Survival Categories for the 3 facilities with available data in Alaska	0	3	0
<i>FMC Anchorage</i>		√	
<i>FMC Wasilla</i>		√	
<i>FMC Fairbanks</i>		√	
<i>Reifenstein Dialysis Center, Juneau</i>	<i>Not Available - The number of patients is too small to report. Call the facility to discuss this quality measure.</i>		

\* The most recent data available. If a facility was not open during this period, information will not be available on this Website. (Contact the facility for the most current information).

\*\* At least 20% better or worse than the "As Expected" survival category. For more detail about this information, please view the Patient Survival Frequently Asked Questions.

Source: *Dialysis Compare, June 2005-July 2006*

As the above indicates, with the exception of the Reifenstein Dialysis Center (numbers were too small to include), the Fresenius Alaska facilities, were at or above the average for all dialysis facilities in the United States.

Lastly, Fresenius has a proven track record in complying with applicable state and federal rules and regulations.

### **3. Personnel – Describe plans for optimum utilization and appropriate ratios of professional, sub-professional and ancillary personnel.**

Table 17 below details the ratios for the types of staffing proposed for FMC Cook Inlet:

**Table 17**  
**Staffing Ratios**

<b>Position</b>	<b>Ratio (staff to patients)</b>
Clinic Manager	1.0 FTE per 20 stations
RN	1 RN to 12 patients
Patient Care Technician	1 PCT to 4 patients
Dietician	1 to 125
Social Worker	1 to 125
Secretary	1.0 secretary per 20 stations

*Source: Applicant*

**4. Appropriate Utilization – Discuss the development of programs such as ambulatory care, assisted living, home health services, and preventive health care that will eliminate or reduce inappropriate use of inpatient services.**

FMC Cook Inlet proposes to establish a dialysis center to provide incenter hemodialysis and home therapy to residents of Anchorage with end stage renal disease. This program does not propose the development of ambulatory care, assisted living, home health services and preventive health care. Therefore, this question is not applicable.

**5. New Technology and Treatment Modes – Discuss plans to use modern diagnostic and treatment devices to enhance the accuracy and reliability of diagnostic and treatment procedures.**

Fresenius uses its own dialysis equipment in all of its facilities. In the late 1970's Fresenius introduced the first dialysis machine with volumetric fluid balancing, allowing precise water removal and increasing patient comfort during the dialysis treatment. Continuing in its tradition of technological innovation to enhance patient care, Fresenius USA's hemodialysis machines are available with treatment modules designed to monitor a patient's biophysical parameters, including body temperature, blood pressure, and level of clearance achieved during dialysis therapy.

The early introduction of advanced dialysis machines made it possible to introduce dialyzer membranes made of polysulfone, a synthetic material producing outstanding clearance performance coupled with superior biocompatibility.

Increased middle molecule clearances achieved with Fresenius Polysulfone®, in combination with the volume-balancing dialysis machine, aided in the establishment of high-flux dialysis treatment therapies.

Today, Fresenius Polysulfone® dialyzers are available in a wide range of sizes and permeabilities to meet the clinical needs of all ESRD patients. Fresenius continues to strive to ensure that its equipment and treatment regimens promote high quality patient care.

**6. Labor Saving Devices and Efficiency – Describe the employment of labor-saving equipment and programs to provide operating economies.**

Fresenius is itself a proven leader in the development of dialysis equipment, and continuously evaluates the latest dialysis equipment, techniques, and systems on both a national and international basis. As a manufacturer of dialysis equipment, FMC is on the leading edge of new technologies and modalities. As new equipment and/or treatments are developed, these are actively deployed into our delivery system.

**7. Program Evaluation – Describe future plans for evaluation of the proposed activity to ensure that it fulfills present expectations and benefits.**

Fresenius conducts a variety of formal evaluations for each facility. It consistently evaluates patient satisfaction, patient outcomes, quality of care as well as self audits. In addition, Fresenius will work closely with the State Office of Health Facilities and Licensure to achieve exemplary Medicare facility surveys. If any issues are identified by surveyors, Fresenius will work quickly to address these issues.

**8. Organizational Structure - Include an organizational chart, descriptions of major position requirements and board representation; show representation from community economic and ethnic groups.**

An organizational chart is included as Exhibit 3. We do not have local board—information regarding the Management board was described Section 1B.

**9. Staff Skills - Provide descriptions of major position requirements, appropriate staff-to-patient ratios to maintain quality, and the minimal level of utilization that must be maintained to ensure that staff skills are maintained.**

The staffing standards were previously provided in Question 3 and are based upon Fresenius' experience as well as industry standards.

A brief description of the clinical and staff is included below:

Fresenius employees are subject to extensive competency, accountability, and professional development requirements. Primary qualifications for major positions at the proposed FMC DS Cook Inlet facility are as follows:

### ***Clinical Manager***

Bachelors Degree preferred. Minimum of three years work experience related to dialysis care and leadership. Thorough knowledge of operations, including staffing and scheduling, budget management, and workflow planning. Management experience required. Ability to manage a broad span of control through implementation of a self-directed team approach. Strong communication and leadership skills, and a willingness to lead by example. For Clinical Manager of Dialysis Facility: State of Alaska Nursing License.

### ***Patient Care Technician***

The Patient Care Technician must have a good basic understanding of human anatomy and physiology. He/she will have training in dialysis or will be scheduled for training early in employment. He/she must have completed a course in CPR (Cardio-Pulmonary Resuscitation). At least two years of college is preferred.

### ***Staff RN***

Must be a graduate from an accredited school of nursing and be currently licensed by the State of Alaska.

### ***Dialysis Charge Nurse***

The Dialysis Charge Nurse shall be a registered nurse currently licensed in the State of Alaska. The Charge Nurse must have completed orientation and know and be able to perform all nursing and patient care policies and procedures. The Charge Nurse must be able to perform normal staff nurse tasks in the Dialysis Unit while taking additional responsibility for directing the daily workflow in the Unit.

### ***Renal Social Worker***

Licensed Clinical Social Worker, Master of Social Work degree. Knowledge of human behavior. Counseling skills for individuals, groups, and families. Communication skills to effectively interact with multidisciplinary team members, patient/family, and community service liaisons.

### ***Clinical Dietician***

Bachelor's Degree in Dietetics. American Dietetic Association registration. State licensure required. Minimum one year Nephrology experience. Good oral and written communication skills. Knowledge of educational methods to relate nutritional information to patients, families, and other health professionals. Knowledge of enteral and parenteral supplementation. Good judgment and problem-solving ability. Complies with Standards of Practice as set forth in the Federal Registry for ESRD, JCAHO, HCFA, and Standards of Practice for Nutritional Care of Renal Patients.

The conditions of participation for participation in the Medicare program require dialysis facilities to have a full time registered nurse responsible for nursing services. For other staff, CMS requires that an adequate number of personnel be available to meet the dialysis care needs of patients. To ensure an adequate number of patient care staff, Fresenius staffs, for patient care technicians, at a ratio of 1 to 4. Fresenius has found that this ratio allows it to meet the patient care needs of its patients and believes that this is consistent within the industry.



**10. Economies of Scale - The minimum and maximum size of facility or unit required to ensure optimum efficiency.**

There are no nationally accepted standards for optimally efficient dialysis units. However, a report prepared by MedPac regarding Medicare payment policies indicated that while the demand for dialysis has grown, the average size of the facility has not. The average size of dialysis facilities in the United States is 21 stations<sup>19</sup>. Fresenius staffs its patient care technicians at a ratio of one to four; therefore, the 20-station facility provides operational efficiencies. In addition, Fresenius has also found that a 20-station facility is sufficiently sized to justify a full time manager.

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<sup>19</sup> MedPac, “Assessing Payment Adequacy and Updating Payments for Outpatient Dialysis Services”, p. 128.

**SECTION VI**  
**Consideration of Quality, Effectiveness, Efficiency, and Benefits of the Applicant's Services**

1. Describe how the proposed project meets each review standard applicable to all activities, and each specific review standard applicable to the proposed activity.

**Review Standards:**

1. Dialysis facilities must contain a minimum of six dialysis stations.

The proposed FMC Cook Inlet facility will have 20 stations. Therefore, this standard is met.

2. No new dialysis services will be approved unless existing services located in the service area in which the proposed new service is to be located operated at an average annual use rate of at least 80% of capacity over the last three years.

Table 18 below demonstrates that utilization at the existing FMC Anchorage has operated at an average annual utilization of at least 80% for the last three years.

**Table 18**  
**Average Utilization Rates at FMC Anchorage Dialysis Center**  
**2004 - 2006**

	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Average</b>
No. of Patients	154	138	158	150
Percent Utilization	96%	79%	90%	86%
No. of Treatments	22,956	21,892	22,370	22,406
No. of Stations	35	35	35	35
Percent Utilization	84%	80%	82%	82%

*Source: Applicant*

3. No proposal to expand an existing dialysis service will be approved unless each station operated by the applicant provided at least 12 treatments per week over the preceding year.

This application does not propose an expansion, therefore, this question is not applicable. However, FMC Anchorage provided 12.3 treatments per station per week during 2006.

4. The applicant demonstrates that the dialysis center will provide education and services for home and peritoneal dialysis patients, as well as incenter patients.

In addition to providing incenter hemodialysis, FMC Cook Inlet will offer home dialysis training and support. As outlined above, education is provided to all patients.

Detailed projections applying the review methodology were previously included in Section IV.

**SECTION VII**  
**Construction Data**

**A. Please check appropriate boxes.**

- |                      |   |                                    |  |
|----------------------|---|------------------------------------|--|
| 1. Construction type | <input checked="" type="checkbox"/> New | <input type="checkbox"/> Expansion | <input checked="" type="checkbox"/> Renovation |
| 2. Basement          | <input type="checkbox"/> Full           | <input type="checkbox"/> Partial   | <input checked="" type="checkbox"/> None       |

**B. Project development schedule.**

- |  |                          |
|--|--------------------------|
| 1. Estimated completion of final drawings and specifications | May 2008                 |
| 2. Estimated construction begun by                           | April 2008 <sup>20</sup> |
| 3. Estimated construction complete by                        | September 2008           |
| 4. Estimated opening of proposed services                    | October 2008             |

**C. Facility site data: Provide the following as attachments.**

- 1. A legal description and area of the proposed site. Is the site now owned by the facility? If not, how secure are the arrangements to acquire the site?**

A letter of intent to lease the building will be submitted by mid-May once a site has been selected.

- 2. Diagrammatic plan showing:**
- a. Dimensions and location of structures, easements, rights-of-way or encroachments;**
  - b. Location of all utility services available to the site; and**
  - c. Location of service roads, parking facilities, and walkways within site boundaries.**

A diagrammatic plan will be provided once the site has been selected.

- 3. Document clearances regarding zone restrictions, fire protection, sewage, and other waste disposal arrangements (under special circumstances, it is acceptable to present evidence of conditional approvals from local government and regulatory agencies).**

Information regarding the above will be provided in mid-May once a site has been selected.

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<sup>20</sup> Assumes site work commenced by April 2008.

**4. An architectural master plan including long-range concept and development of total facility.**

Fresenius intends to lease the space (10,000 square feet) in any of the three options. Therefore, no architectural master plan or long-range concept and development plan has been prepared for this project.

**5. Schematic floor plan drawings (or conceptual drawings) of proposed activity, including functional use of various rooms.**

Line drawings for the proposed FMC Cook Inlet will be provided once a site has been selected.

**D. Describe the plan for completing construction and the effect (disruption) construction activities will have on existing services.**

As FMC Cook Inlet is a new facility, this project will not have any impact or effect on the existing facilities. Therefore, this question is not applicable.

**SECTION VIII A**  
**Financial Data - Acquisitions**

**1. Acquisition type.**

☒ Lease    ☐ Rent    ☐ Donation    ☐ Purchase    ☐ Stock Transaction

**2. Cost data.**

a. Total acquisition cost	\$
b. Amount to be financed	\$
c. Difference between items (a) and (b) (list available resources to be used, e.g. available cash, investments, grants, etc.)	\$
d. Anticipated interest rate	%
Term	Years
e. Total anticipated interest amount	\$
f. Total of (a) and (e)	\$
g. Estimated annual debt service requirements	\$

This project does not involve the acquisition of a building. Therefore, this question is not applicable.

**3. Describe how you expect to finance the project.**

This project will be financed using existing reserves of Fresenius. Documentation demonstrating Fresenius' commitment to the establishment of the proposed FMC Cook Inlet will be provided once the site has been selected.



**SECTION VIII B**  
**Financial Data – Construction Only\***

## 1. Construction Method.

- a. ☐ Conventional bid                      ☐ Contract management                      ☐ Design and build  
b. ☐ Phased                                      ☒ Single project                                      ☐ Fast Track

## 2. Construction Cost (New Activity)

a. Site acquisition (Section VIIIA.2.f)	\$
b. Estimated general construction**	\$1,507,368 <sup>21</sup>
c. Fixed equipment, not included in a**	\$
d. Total construction costs (sum of items a, b, and c)**	\$1,507,368
e. Major movable equipment**	\$645,091
f. Other cost:**	
(1) Administration expense	\$
(2) Site survey, soils investigation, and materials testing	\$
(3) Architects and engineering fees	\$
(4) Other consultation fees (preparation of application included)	\$20,000
(5) Legal fees	\$
(6) Land development and landscaping	\$
(7) Building permits and utility assessments (including water, sewer, electrical, phones, etc.)	\$
(8) Additional inspection fees (clerk of the works)	\$
(9) Insurance (required during construction period)	\$
g. Total project cost (sum of items d, e, f)	\$2,172,459
h. Amount to be financed	\$0
i. Difference between 2.g and 2.h (list, as Schedule 1, available resources to be used, e.g., available cash, investments, grants funds, community contributions, etc.)	\$2,172,459
j. Anticipated long-term interest rate	NA
k. Anticipated interim (construction) interest rate	NA
l. Anticipated long-term interest amount	\$0
m. Anticipated interim interest amount	\$0
n. Total items g, l, and m	\$0
o. Estimated annual debt service requirement	\$0
p. Construction cost per sq. ft.	\$150.74
q. Construction cost per station	\$75,368
r. Project cost per sq. ft.	\$217.25
s. Project cost per station (if applicable)	\$108,623

<sup>21</sup> For leasehold improvements.

\*Site acquisition should be stated as "book" value, i.e., actual purchase price (or estimate of value if donated) plus costs of development. If desired, the applicant may elect to state as "fair market value" (in which case, so indicate). A form for use in calculating fair market value is included on page 31 of this packet. Include your calculations as part of this section of your application.

\*\* Items must be certified estimates from an architect or other professional. Major medical equipment may be documented by bid quotes from suppliers.

## FAIR MARKET VALUE – HOW TO CALCULATE

Fair market value is the price that the property would sell for on the open market. It is the price that would be agreed on between a willing buyer and a willing seller, with neither being required to act, and both having reasonable knowledge of the relevant facts.

To determine the fair market value of equipment, using the formula below, first determine the number of years of estimated useful life of the equipment, as described in the AHA publication *Estimated Useful Lives of Depreciable Hospital Assets* to achieve an annual depreciation amount. Include your calculations as part of this section of your application.

**Table 19**  
**Fair Market Value of Lease**

1	Lease expense per square foot	\$28.00
2	Estimated Square Footage	10,000
3	Annual Lease Expense	\$280,000
4	Term of Lease	10 years
5	Fair Market Value	\$2,800,000

*Source: Applicant*

The fair market value of land or buildings is the value contained in a current appraisal of the land or building from a licensed real estate appraiser who has no financial or other interest in the transaction. Attach the appraisal as an appendix to the application.

There is no acquisition.

**SECTION IX**  
**Financial Data – All Proposed Activities**

**A. Schedule I - Facility Income Statement.**

Schedule I is provided in Exhibit 5. FMC Cook Inlet is not an existing facility, therefore, no historical data is provided. FMC Cook Inlet will not provide services during the construction period. Financial projections for the first five years of the project are included in Exhibit 4.

**B. Schedule II - Facility Balance Sheet.**

FMC Cook Inlet is not an existing facility, therefore, no current or historical balance sheet information is provided.

**C. Schedule III - Average Patient Cost Per Day (Per Diem Rate if applicable) and Revenue Amounts.**

Schedule III is provided in Exhibit 5.

**D. Schedule IV – Operating Budget.**

**E. Schedule V – A. Debt Service Summary, and B. New Project Debt Service Summary.**

This project does not involve any debt service. Therefore, this question is not applicable.

**F. Schedule VI - Reimbursement Sources**

Schedule VI is provided in Exhibit 6.

**G. Attach Schedule VII – Depreciation Schedule**

Schedule VII is provided in Exhibit 7.

## Application Fee – Determination and Certification of Amount

### How to Determine the Amount of the Application Fee Required Under 7 AAC 07.079

(1) For a project that does not include a lease of a facility or equipment, the value of the project is:

- A. the amount listed on page 20 of this packet under Section VIIIA, Financial Data – Acquisitions, subsection (2), item “a” (total acquisition cost of land and buildings): \$0

**plus**

- B. the amount listed on page 21 of this packet under Section VIIIB, Financial Data – Construction Only, item “g” (total project cost, which is the sum of items d, e, and f): \$2,172,459

Estimated Value of the Activity for (1)  
(sum of A & B above) \$2,172,459

(2) For a project that has a component that is leased, the fair market value of the leased equipment, facility, or land must be considered in addition to the acquisition cost. See the form on page 31 of this packet for how to determine fair market value.

Estimated Fair Market Value for (2): \$2,800,000

Estimated Value for (1) from above: \$2,172,459

Total Estimated Value of the Activity  
(sum of (1) and (2): \$4,972,459

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Amount of Application Fee submitted with this application  
(see 7 AAC 07.079 to calculate amount due):

\$4,972.00

**Certification of Individual Determining Application Fee**

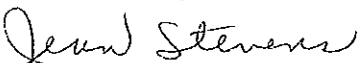
I certify that, to the best of my knowledge, as of this date, the estimated value and fee for this certificate of need activity are accurate.

**Date:** April 25, 2007

**Facility Name and Address:** Fresenius Medical Care  
2121 SW Broadway, Suite 111  
Portland, OR 97201

**Name and Title of Person Determining Application Fee:**

Jean Stevens, Regional Vice President

  
\_\_\_\_\_  
Signature of Certifying Officer of the Organization



**Exhibit 1**  
**CN Dialysis Methodology**

**STEP ONE:** Determine the projected ESRD caseload using the formula:

$$C = P \times UR$$

**C** (caseload) = the number of ESRD patients three years from the project implementation date.

**P** (projected population) = the official State population projected for the fifth year following implementation of the project.

**UR** (end stage renal disease prevalence rate) = persons diagnosed with ESRD per 10,000 population.

Table 20 below details historic prevalence point data for Alaska residents using data from the Northwest Renal Network. Point Prevalence data is not yet available for 2006<sup>22</sup>. However, data for 2002-2005 indicates that the year end patient numbers and the point prevalence data have been nearly identical. Therefore, Fresenius concludes that the year end patient numbers are a good proxy for the point prevalence data for 2006.

**Table 20**  
**Historic Utilization Rates for ESRD Dialysis**  
**2002-2006**

	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Average Change</b>
<b>No. of Patients (12/31)<sup>23</sup></b>	237	272	304	297	325	8.41%
<b>Point Prevalence<sup>24</sup></b>	237	272	304	294	NA	7.75% <sup>25</sup>
<b>Est. Alaska Adult Population<sup>26</sup></b>	640,544	647,747	655,435	662,604	670,053	1.13%
<b>ESRD Dialysis Utilization Rate (per 10,000 population)</b>	3.70	4.20	4.64	4.44	4.85	7.23%

*Source: Applicant*

Based on the above data from Northwest Renal Network, the estimated Alaska utilization rate for 2006 was 4.85 per 10,000 population, trending upward by 7.2% annually between 2002 and 2006.

Table 21 below details the estimated number of ESRD dialysis patients for the years 2007-2012; the fifth year following project implementation<sup>27</sup> using a trended use rate.

<sup>22</sup> According to staff at Northwest Renal Network, 2006 point prevalence data will not be available until July 2007.

<sup>23</sup> Northwest Renal Network, Year End Modality Reports, 2002-2006

<sup>24</sup> Northwest Renal Network, Point Prevalence Reports, 2002-2005

<sup>25</sup> Average is for 2002-2005 only.

<sup>26</sup> Alaska Dept. of Labor and Workforce Development, Middle Series, Feb. 2005.

<sup>27</sup> Step One of the dialysis methodology contains two different points in time (three years following project implementation for estimating the caseload) and five years from project implementation for estimating population. To be consistent, Fresenius has based its projections for five years from certificate of need approval or 2012.

**Table 21**  
**Projected Utilization Rates for ESRD Dialysis**  
**2007-2012**

	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
<b>Est. Alaska Adult Population<sup>28</sup></b>	677,362	684,714	692,001	699,207	706,344	713,393
<b>ESRD Trended Use Rate-3.6% annual growth</b>	5.03	5.21	5.40	5.59	5.79	6.00
<b>Estimated ESRD Patients (trended use rate)</b>	340	357	373	391	409	428

*Source: Applicant*

**STEP TWO:** Determine the projected number of chronic renal dialysis treatments required to meet projected demand using the formula:

$$\text{DTR} = \text{C} \times \text{PTR}$$

**DTR** = Dialysis treatments required

**C** (caseload) = Projected ESRD Caseload

**PTR** = Average ESRD patient treatment rate, defined as 3.0 treatments per patient per week or 156 treatments per patient annually

Using the information from Table 21 above, for 2012, the estimated number of treatments are calculated as follows:

$$66,768 \text{ (DTR)} = 428 \text{ (Caseload)} \times 156 \text{ (PTR)}$$

**STEP THREE:** Determine the number of ESRD dialysis stations required to meet the projected number of treatments using the formula:

$$\text{DSR} = \text{DTR} / \text{DSC} / \text{TSO}$$

**DSR** = Dialysis stations required

**DTR** = Dialysis treatments required

**DSC** = Average dialysis station capacity, defined as 15.0 treatments per week or 780 treatments per year

**TSO** = Target ESRD station occupancy, defined as 80% (0.80)

Using information from Step Two above, for 2012, the estimated number of dialysis stations are calculated as follows:

$$107 \text{ (DSR)} = 66,768 \text{ (DTR)} / 780 \text{ (DSC)} / 80\% \text{ (TSO)}$$

<sup>28</sup> Alaska Dept. of Labor and Workforce Development, Middle Series, Feb. 2005.

**STEP FOUR:** Determine unmet ESRD station need, if any, by subtracting number of existing and CON-approved ESRD stations from the number projected to be needed. Bed need estimates will be made for proposed service areas based on current share of the state's adult population by region or census area/borough included in the service area.

Table 22 below details the estimated dialysis station need for 2012, the current number of CON-approved stations and an estimated share by community. Fresenius has estimated the shares by geography based upon the percentage of the dialysis population in each distinct area.

**Table 22**  
**Estimated Net Station Need by Geographic Area**  
**2012**

	<b>Current No. of Dialysis Patients (12/31/06)</b>	<b>Percent of Total Statewide Patients</b>	<b>Current No. of Stations</b>	<b>Est. Dialysis Stations needed (per percentage of dialysis population)- trended prevalence rate</b>
Anchorage Borough	191	58.8%	35	63
Kenai Peninsula	15	4.6%	0	5
Mat Su Borough	32	9.8%	12	11
Fairbanks North Star Borough	40	12.3%	17	13
Juneau Borough	14	4.3%	9	5
Other Alaska	33	10.2%	0	11
<b>Total Alaska</b>	<b>325</b>	<b>100.0%</b>	<b>73</b>	<b>107</b>

**Exhibit 2**  
**Charity Care and Admissions Policy**

## ADMISSION, TRANSFER, AND DISCHARGE POLICY

## 1. ADMISSION

It is the policy of this dialysis facility to admit and to treat all patients referred by physician members of its Medical Staff without regard to race, creed, color, age, sex, handicap, disability, national origin or social status. All persons and organizations having the occasion to refer patients to physician members of this facility's medical staff for admission to this dialysis facility are advised to do so without regard to the patient's race, creed, color, age, sex, handicap, disability, national origin or social status.

Each patient admitted will be followed by a physician member of the facility's Medical Staff. Prior to admission to this dialysis facility, or with reasonable concurrence thereto, there shall be documented consideration of the most appropriate mode of treatment, including full-maintenance hemodialysis, self-care hemodialysis, home training and home dialysis, renal transplantation, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis and intermittent peritoneal dialysis. The patient shall be made aware and afforded access to all of the above modes of treatment provided by other facilities that are not provided by this dialysis facility.

Patients shall be medically cleared for treatment in this dialysis facility when such treatment is deemed indicated and appropriate according to the clinical judgment of that patient's attending physician. No arbitrary criteria with respect to patient's age or magnitude of complicating medical problems are established. It is intended that appropriateness of dialysis shall be a decision to be made by the patient's attending physician in accordance with his or her best clinical judgment, and in compliance with the ESRD program and the facility's policies.

Prior to admission to this dialysis facility, all appropriate paperwork must be completed as outlined in section 122-040-020 of the FMCNA Financial Procedure Manual. All appropriate medical and financial records must be received prior to the patient's admission to the facility. Upon referral, the Admissions Coordinator collects all demographic and insurance information from the referral source and the prospective patient and forwards it immediately to the designated staff at the billing group office. Within two days, the billing group staff will verify the patient's insurance coverage and identify any

coverage gaps which exist. Billing office staff will then notify the Admissions Coordinator of the results of the insurance verification and will discuss with the Coordinator the facility's plans for obtaining appropriate coverage, as necessary.

Financial approval for admission is based upon the patient's insurance coverage and his/her willingness to pursue enrollment in insurance or assistance programs for which he/she qualifies.

The billing office will deny financial clearance to individuals who a) cannot obtain Medicare or other coverage or b) indicate an unwillingness to enroll in programs for which he/she is potentially eligible or c) are uncooperative and refuse to disclose insurance information.

In such an event, the billing office representative will notify the Admissions Coordinator, the Administrator and the Region Manager. The patient's physician should be contacted to obtain his/her assistance. The final decision concerning the admission will be made in such cases by the Region Manager.

Medical clearance and financial approval are required prior to admission. Once admission approval has been granted, the Admissions Coordinator must forward the following items from the Patient Admissions Checklist to the billing group office:

- Signed Admission Agreement
- Signed Release of Information/Assignment of Benefits
- Signed LifeChem Assignment of Benefits Form
- Copies of all insurance cards
- Dates of application for Medicare and/or other Insurance

For Home Patients only:

- Signed ESRD Beneficiary Selection Form
- MPD/ERIKA Assignment of Benefits Form

Medical Records, which must be sent to the facility prior to the patient's admission, will contain at least the following:

Long Term Program, Patient Care Plan, History and Physical, Discharge Summary if transferring from hospital unit, Physician's Progress Notes, Social Service Summary, Dietary History, Current Labwork including Chemistries and CBC. HbsAg

results within 30 days unless the patient has HBV antibodies, then an HbsAg is not needed, but a documented HbsAb within the past 12 months is required instead, EKG, Chest X-Ray reports if available or most recent, and Hemodialysis Sheets.

A Consent for Chronic Hemodialysis (or consent appropriate for modality chosen) must be signed by the patient prior to the patient's first treatment at the facility. The signed consent form is binding until the patient is discharged from the facility, withdraws consent for treatment, or his/her dialysis modality changes at which time a new consent must be signed. Consent forms from other FMCNA facilities or non-FMCNA's shall not be used as consent for treatment at this facility.

Each patient shall be evaluated annually by an interdisciplinary team as to appropriateness and effectiveness of the treatment modality received, and the need for continuation of or change in treatment. This team will consist of at least a physician, transplant surgeon or his/her designee, nurse, social worker, dietitian and patient.

Patients who exhibit inappropriate behavior such that they constitute a danger to themselves or to others, or who do not agree to follow the policies and procedures of this facility, may be denied admission to this dialysis facility or may be discharged for same, at the discretion of the Medical Director.

The Director of Nursing or designee shall be responsible for checking the patient's incoming medical records for completeness, and for opening the patient's medical record. The Director of Nursing or designee shall attempt to obtain missing information, and shall notify the patient's physician and/or the Medical Records Supervisor as to any unobtainable data.

The Director of Nursing or designee shall be responsible for scheduling the patient for dialysis treatments in a manner consistent with the attending physician's dialysis prescription, patient needs, and with regard to available time slots.

The patient and/or his or her family shall designate a person to notify in case of emergency. This dialysis facility shall make every effort to notify the appropriate person of any change in a patient's condition considered significant by the physician.

## 2. TRANSFER AND DISCHARGE

Patients temporarily admitted to the hospital, or in a transient



## ADMISSION, TRANSFER, AND DISCHARGE POLICY

138-020-010

status at another out-patient hemodialysis facility, shall not be discharged from this dialysis facility. In these cases, and in the case of a patient being discharged for permanent transfer to another facility, this dialysis facility shall provide the hospital or the receiving facility with appropriate records summarizing the interim medical course and records concerning the patient's dialysis treatments. These include, but are not limited to: Long Term Program and Patient Care Plans, Hemodialysis Sheets, History and Physical, Physician Progress Notes, Social Services Summary, Dietary History, Current Labwork and Physician Order Sheets. Transfer of such records shall occur within one working day after the patient transfers. Should a patient be permanently transferred to another facility, transplanted, discontinue dialysis or expire, the patient's medical record shall be closed by the Medical Records Supervisor within 30 days from the time the patient leaves the facility. The patient's primary physician shall complete a Patient Discharge Summary within 30 days of the patient's discharge. (Exhibit-Discharge Summary). This discharge summary shall be placed at the front of the patient's closed medical record. The billing office should immediately be notified of all temporary/permanent transfers or discharges.

All patients admitted to this dialysis facility are admitted voluntarily. Any patient who insists on terminating a treatment early will be asked to sign an "Against Medical Advice" form. If a patient cancels a scheduled dialysis treatment, either by calling to inform the dialysis facility, or by not showing up for a scheduled treatment, the charge nurse or other licensed nurse shall attempt to inform the patient of the consequences of missing a scheduled treatment. The patient's physician should be notified of the cancellation, and should make the decision as to whether the treatment needs to be rescheduled. (See Early Termination or Cancellation of Treatment Policy).

If a patient chooses to withdraw from dialysis, every effort will be made to ensure the patient has been informed of his/her treatment options and understands the consequences of withdrawing from dialysis. (See Withdrawal From Dialysis Policy).

The Charge Nurse shall be responsible for immediately notifying the attending physician, the Director of Nursing and/or Administrator at any time a patient leaves the Hemodialysis Unit against medical advice.

In cases of patient emergencies occurring at this dialysis facility, the physician responsible for the patient's care at

the time of the emergency shall arrange for the transfer of the patient to the hospital. He or she shall notify the attending physician, if applicable, and this dialysis facility shall promptly provide the hospital with appropriate medical records.

When circumstances warrant, these responsibilities shall be carried out by the Charge Nurse on duty at the time of the emergency.

Personal effects of a patient who is transferred to a hospital and/or expires will be recorded on a "Patient's Personal Effects" check list, placed in an envelope or bag, and stored in a safe location in the facility. The Administrator, Director of Nursing, or Charge Nurse will contact the patient's family and request that they pick up the personal effects. (See Patient's Personal Effects Policy).

In the event of death occurring at the facility, the patient's next of kin or responsible party, as designated, shall be promptly notified. The attending physician shall sign the death certificate, as appropriate. Remains shall be released to the appropriate undertaker only after the persons responsible have signed a release form.

If required by state and/or local law, the Department of Health and/or County Coroner will be notified of a death on-site within the mandated time frame.

Request for and permission for autopsy should be referred to the Administrator. Arrangements for the examination are the responsibility of the attending physician.

## EXHIBIT

## "DISCHARGE SUMMARY"

**FMCNA****DISCHARGE SUMMARY**

ADDRESSOGRAPH

Date of Discharge: \_\_\_\_\_

Discharge to:

1. Transferred to \_\_\_\_\_ Dialysis Unit  
Address \_\_\_\_\_  
Reason for transfer \_\_\_\_\_  
Date records sent \_\_\_\_\_
2. Transplant Surgery Date \_\_\_\_\_ Hospital \_\_\_\_\_
3. Discontinued Dialysis Date \_\_\_\_\_  
Reason \_\_\_\_\_
4. Expired Caused of Death: \_\_\_\_\_  
Date of Death: \_\_\_\_\_  
Place of Death: \_\_\_\_\_

Final Diagnosis: (includes both primary and secondary diagnoses)

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

Prognosis: \_\_\_\_\_

Brief Summary: \_\_\_\_\_

PERSON COMPLETING SUMMARY/TITLE

DATE

ATTENDING PHYSICIAN

DATE

FMCNA CS-I-112 (1/01)

## EMERGENCY TRANSFER GUIDELINES

Facilities may experience emergencies caused by severe weather, fire or other serious facility operating problems such as water treatment failure or other unexpected problems. These problems may require construction or repairs that are believed to be short-lived and may necessitate closure of a facility. Inability of facilities to provide services can result in the need for subsequent temporary arrangements for patients to be dialyzed at another FMCNA "host" facility. In addition, patients may require temporary care at another FMCNA facility based on their inability to safely get to their "home" facility.

Emergency Transfer is defined as:

- Not expected to extend beyond 30 days.
- Patients are expected to return to their "home" facility to continue their treatments when operations are able to resume.

The treating clinic or "host" facility or facilities will provide services for the "home" facility according to the company wide agreement "Dialysis Unit Emergency Back Up Agreement" (established by Corporate Law Department). A fully executed "Dialysis Unit Emergency Back Up Agreement" is included with this policy.

Following the activation of the Emergency Back Up Agreement, the "home" facility patients must be assigned to a physician with privileges at the "host" facility, unless patient's attending physician already maintains privileges at the "host" dialysis facility. Dialysis treatment orders must be obtained from the assigned physician if the patient is assigned to a physician at the "host" facility.

When possible, copies of Medical Records such as Physician Order Sheets, Hemodialysis Treatment Sheets, current Lab Work, History and Physical, Multidisciplinary Progress Notes (including physician, nursing, social worker and dietary notes), Long Term Program and Patient Care Plans, Psychosocial Assessment (most recent), and Dietary Referral Sheet, must be sent to the "host" facility.

- If patient's paper medical records are destroyed due to fire, water or other serious facility damage, information

available in the Proton Information System should be printed from Proton. When the patient returns to their "home" facility, all medical record documentation that was created at the "host" facility should be copied and transferred to the patient's "home" facility medical record.

When a patient or patients require emergency transfer to another facility, the "home" facility (facility experiencing the emergency) must notify Spectra Customer Service of the emergency transfer in order for Spectra to send any laboratory reports to the "host" facility where patient is being treated.

Under normal facility operating procedures, when new patients are initially admitted into a facility, each patient is set up in the Spectra Lab system in their "home" facility so that lab resulting data and information system notification is sent to the facility of record.

Lab tests that are ordered for the patient while they are located in the "host" facility, should be ordered with the "home" facility number, so the lab results will be downloaded into Proton and can be used for clinical outcome reporting.

Staff can access the "home" facility Proton information and the patient lab results from any Proton facility database. As long as Spectra is notified that the patient is dialyzing in the "host" facility, the printed lab results can be sent directly to the "host" facility printer.

All services performed must be entered into Proton in the "home" facility database, as if the "home" facility provided the services. (Application Instructors should provide direction to the facility on performing the following procedures.)

- Patient information can be accessed in Proton from any facility database.
- The treatment sheet can print to the "host" facility.
- The "host" facility name must be written on the top of the treatment sheet and all medical records created at the "host" facility.
- A daily validation must be run on the "home" facility database.

NOTE: If patients are at several different local facilities, the Clinical Manager or Area Manager must communicate with each "host" facility to ensure treatment information has been entered into the correct Proton "home"

facility information system before validating treatments.

If the facility closure/emergency transfer exceeds **30 days**, the continuation of the "Dialysis Unit Emergency Back Up Agreement" must be reviewed and approved. The Regional Vice President must contact the FMS Vice President of Operations Support and the FMS Vice President of Clinical Services and provide a report on the status of the "home" facility. The need to extend the time of the Emergency Back Up Agreement will be approved on a case-by-case basis depending on the length of time that the "home" facility can return to normal operations.

If the "Dialysis Unit Emergency Back Up Agreement" continues past thirty days, Subpart U documentation requirements (such as Short Term Care Plan, Long Term Program, Progress notes) must be completed at the "host" facility according to the usual schedule.

If it is determined that the "Dialysis Unit Emergency Back Up Agreement" must be discontinued because the "home" facility will not be operational in a reasonable period of time and therefore unable to accept patients, each patient accepted into the "host" facility because of an emergency must be formally transferred to the "host" facility and the appropriate admission, clinical and billing forms (refer to Financial Procedure Manual #122-040-020 for direction on billing forms) must be completed.

Facility Name: \_\_\_\_\_

Facility #: \_\_\_\_\_

☐ New Waiver

☐ Renewal

☐ Transient

### Section I - PATIENT INFORMATION

Please print or type carefully. All fields must be completed

Patient Name \_\_\_\_\_ Patient Account # \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
 Date of Birth \_\_\_\_\_ Age \_\_\_\_\_ Social Security Number \_\_\_\_\_  
 Telephone \_\_\_\_\_ Marital Status \_\_\_\_\_ No. of Dependents / Ages \_\_\_\_\_  
 Spouse's Name (or Parent / Guardian) \_\_\_\_\_  
 First Date of Dialysis \_\_\_\_\_ Admission Date to FMCNA \_\_\_\_\_

### Section II - INSURANCE / ASSISTANCE OPTIONS

Please review this patient's application and provide the following information. This information, will allow for a complete evaluation of the application. Please complete every item - where not applicable put N/A.

Is the patient eligible for the following programs?  
 If Yes, Effective Date \_\_\_\_\_

Medicare ☐ Yes ☐ No \_\_\_\_\_  
 Medicaid ☐ Yes ☐ No \_\_\_\_\_  
 (If yes, spend down amount, if any) \_\_\_\_\_

Medigap Applied For ☐ Yes ☐ No ☐ N/A  
 State Renal Program ☐ Yes ☐ No ☐ N/A  
 Health Insurance Coverage ☐ Yes ☐ No ☐ N/A  
 Safety Net Eligibility ☐ Yes ☐ No

Comments: \_\_\_\_\_

### Section III DOCUMENTATION REQUIREMENTS:

Check below where documentation is included

Income - Verification of all income sources

- ☐ Most Recent Tax Return
- ☐ Pay Stub (patient and spouse)
- ☐ Retirement / Disability Check
- ☐ SSA / SSI Checks
- ☐ SSA / SSI / AFDC Award Letters
- ☐ Other Income, Specify \_\_\_\_\_

Liquid Assets

- ☐ Statements (Savings / Checking)
- ☐ Stock / Bond Statements
- ☐ Tax Bill / Appraisal -  
(owned land/ property- except principal residence)
- ☐ 401K / IRA (if over 65)

Secured Liabilities

- ☐ Mortgage Statement (owned land/ property- except principal residence)
- ☐ Statements / Secured Loans: specify \_\_\_\_\_

Other (If applicable)

- ☐ Medicaid Spend Down Letter
- ☐ Application Copies (Medicare / Medicaid / Medigap)
- ☐ Patient Liability Worksheet (with Documentation)
- ☐ Signed Sliding Fee Scale Program Agreement

Does Patient Have Self-Pay Balance in this Facility?  
☐ Yes ☐ No

If Yes, oldest date of service \_\_\_\_\_

If oldest date > 6 months RVP must approve waiver

### SECTION IV - WAIVER APPROVAL

Social Worker \_\_\_\_\_ ☐ Approved ☐ Denied Date \_\_\_\_\_  
 Area Manager \_\_\_\_\_ ☐ Approved ☐ Denied Date \_\_\_\_\_  
 RVP \_\_\_\_\_ ☐ Approved ☐ Denied Date \_\_\_\_\_  
 RIC \_\_\_\_\_

Approval Period

From \_\_\_\_\_ Through \_\_\_\_\_

Thursday March 28, 2002

**Addendum to Policy #138-020-010 ADMISSION, TRANSFER AND DISCHARGE  
POLICY**

**It is the policy of this dialysis facility to provide care to all residents of the service area – including patients with communicable or infectious diseases where such treatment would not unreasonably endanger the safety and welfare of staff or other patients at the center – regardless of age, gender, race, religion, national origin or ability to pay.**



## INDIGENT WAIVER PROCEDURE

### OVERVIEW

#### POLICY

The company has an indigent waiver program to assist patients who are unable to obtain full insurance coverage and who do not have the financial resources to pay for their portion of medical services provided by FMCNA. The company does not advertise its indigent waiver program and patients are individually assessed for qualification in the program after all other sources of coverage and assistance have been exhausted. Any patients who are believed to be eligible for insurance coverage or assistance of any type are expected to pursue such and should not have an indigent waiver approved unless they provide supporting documentation regarding ineligibility for such coverage or assistance. The company recognizes the financial burdens associated with ESRD but may restrict the number of 100% charity patients who can be admitted.

#### Introduction

This procedure describes the steps for qualifying a patient for an indigent waiver.

#### Indigent Waiver Definition

The indigent waiver program is considered a "last resort". All other avenues for coverage or assistance must first be explored before an indigent waiver can be approved. The Social Worker will work with the patient to obtain insurance coverage or public aid assistance whenever possible.

#### Social Worker

The Social Worker or other designee initiates a Financial Information Form when a gap in coverage is identified. After this assessment is completed, if a patient potentially qualifies for an indigent waiver based upon the FMCNA Indigent Waiver Guidelines, then the patient is required to bring in the supporting documentation in order for an indigent waiver to be approved. Once the documentation is collected and the Financial Information Form is reviewed for completeness by the Social Worker, it is then signed and forwarded to the Area Manager for review and approval. Once approved by the Area Manager, it is then forwarded to the Business Unit for final approval as an indigent waiver.

#### Regional Insurance Coordinator

The Regional Insurance Coordinator (RIC) is responsible for reviewing / approving Financial Information Forms where there is a request for waiver status.

**FMCNA  
Indigent  
Waiver  
Guidelines /  
Sliding Fee  
Scale Matrix**

The FMCNA Indigent Waiver Guidelines and Sliding Fee Scale Matrix are updated annually. The updated guidelines and matrix are posted on the FMCNA intranet once the federal government annual update is available. This is normally late in the first quarter of the new year.

**Partial  
Waiver**

Patients whose income exceeds the FMCNA Indigent Waiver Guidelines for a full waiver may qualify for a partial waiver. Their liability will be determined using the Sliding Fee Scale Matrix.

**Eligibility**

When a patient applies for an indigent waiver, he or she may have accumulated FMCNA bills that cannot be paid. These can be covered by the indigent waiver up to a period of six months prior to the effective date of the waiver. **If there are open balances older than six months, the waiver request must be approved by the Regional Vice President.** If there is any concern regarding whether the patient met the financial qualifications for the prior time period in question, FMCNA reserves the right to request additional back-up documentation for this time period.

**Time Limits**

The effective date of an approved waiver is the first day of the month in which the Regional Insurance Coordinator is approving the waiver. Waivers are normally valid for a 12-month period. For example, if the Regional Insurance Coordinator approves a waiver on May 15<sup>th</sup>, the approval period is from May 1<sup>st</sup> – April 30<sup>th</sup>. FMCNA reserves the right to approve a waiver for a shorter period if a patient will / should become eligible for coverage during the 12-month period. FMCNA also reserves the right to cancel a waiver or request a renewal at any time if changes in financial circumstances occur or we become aware of insurance coverage or assistance programs available to the patient. **Renewal waivers require a complete reassessment of the patient's financial situation. A new Financial Information Form, along with all required documentation, must be completed and approved.**

**Indigent  
Waivers  
granted by  
other FMCNA  
Facility**

An Indigent Waiver approved by one FMCNA Facility shall be honored by all other FMCNA facilities as long as the waiver has not expired and the patient has been approved for admission at the new facility. If a patient is either transferring or traveling to another FMCNA facility, a copy of the approved waiver, along with all corresponding documentation should be provided to the receiving Facility Area Manager and Billing Group by the home Billing Group.

**Note: Most state Medicaid programs will pay for out of state dialysis in emergencies. All avenues should be pursued for out of state Medicaid coverage. If a State Medicaid program will not approve out of state coverage in an emergency, a waiver can be completed. Non-emergency travel that results in a gap in coverage that would not have otherwise occurred is not a valid reason for a waiver and one should not be requested or approved.**

**Forms**

The following forms are part of the waiver process:

- Financial Information Form- always required
- Patient Liability Worksheet- required if the patient has excess income and is requesting a reduction in income based on their medical expenses.
- Sliding Fee Scale Payment Agreement- required if patient is eligible for a partial waiver. The patient must agree to pay the % that is determined by the Sliding Fee Scale Matrix.

**Procedure**

This procedure contains the following topics:

<b>Section</b>	<b>Description</b>	<b>See Page</b>
1	Collecting Required Financial Information	4
2	Determining Indigent Status	7
3	Processing the Approved Indigent Waiver Request	9
4	Waiver Renewal Process	11

## 1) Collecting Required Financial Information

**Purpose** If the initial assessment indicates that the patient may qualify for an indigent waiver, collect the required documentation so that either a full or partial indigent waiver can be approved.

**Responsibility** The **Social Worker** or designee is responsible for all of the steps in this section.

**Procedure** Complete the steps below to collect and review the required financial information for either initial or renewal waiver requests:

Step	Action
1	If the initial assessment indicates that the patient potentially qualifies for an indigent waiver and there are no other avenues for insurance or assistance available, review Section III of the Financial Information Form, Documentation Requirements, with the patient and request that the required documentation be supplied at the next visit. If the patient has excess income and is requesting medical expenses to be taken as a reduction in income, review the Patient Liability Worksheet and the required supporting documentation for this form.
2	<p>Collect the required supporting documentation to support the information entered on the Financial Information Form. Please note that the patient's principle residence and automobile(s) are excluded from assets and liabilities based on being deemed necessary for basic living.</p> <p><b>Income, assets and liabilities for the household (patient and or spouse or if minor, parents) need to be substantiated with copies of the supporting documentation. See below for documentation requirements for each category.</b></p> <p><b>Income: Documentation is required for all sources of income. See examples of acceptable documentation below.</b></p> <ul style="list-style-type: none"> <li>• Copy of patient and or spouse pay stubs (may be retirement or disability income)</li> <li>• Copies of SSA and or SSI check(s)</li> <li>• Copies of SSI, Social Security or AFDC award letter(s)</li> <li>• Copies of other income such as (Interest, Alimony or Rental)</li> <li>• Most recent tax return</li> </ul>

	<p><b>Assets:</b> Documentation is required for all liquid assets with the exception of principal residence, automobile(s) and IRA and 401K accounts for anyone under 65.</p> <ul style="list-style-type: none"> <li>• Bank statements (savings and or checking)</li> <li>• Stock and or bond statements</li> <li>• Copy of property tax bills or property appraisal for all property with an ownership interest</li> <li>• IRA / 401K (if 65 and over)</li> </ul> <p><b>Liabilities:</b> Documentation required for all secured liabilities.</p> <ul style="list-style-type: none"> <li>• Mortgage bill(s) (<b>EXCEPT PRINCIPAL RESIDENCE</b>)</li> <li>• Other secured loans (i.e., equity lines of credit, second mortgages)</li> </ul> <p><b>Monthly Expenses:</b> Documentation of all expenses are required if expenses are greater than 100% of income.</p> <ul style="list-style-type: none"> <li>• Rent or mortgage</li> <li>• Utilities</li> <li>• Taxes</li> <li>• Transportation</li> <li>• Loans</li> </ul> <p><b>Net worth Calculation:</b> Complete Section VI of the Financial Information Form. A patient's net worth may not exceed \$75,000 in order to qualify for an indigent waiver. The patient's principal residence is not included in the calculation formula: [(Assets) - (Liabilities) = Net Worth]. If the Net Worth is &gt; \$75,000, do not submit the waiver request for approval.</p>
3	<p>If a patient's income is in excess of the FMCNA Indigent Waiver Guidelines, the patient should complete the Patient Liability Worksheet to determine if (s) he qualifies for a full or partial waiver, with the deduction for their medical expenses. <b>The medical expenses must be solely for the patient but they are not limited to ESRD related medical expenses.</b> If the patient qualifies for a full or partial waiver based on their medical expenses, supporting documentation for all medical expenses must be provided. If after the deduction of the medical expenses, the patient only qualifies for a partial waiver, determine the correct discount and liability percentages from the Sliding Fee Scale Matrix. A signed Sliding Fee Scale Program Agreement must accompany the Patient Liability Worksheet.</p>

4	Sign and date Section IV of the Financial Information Form for qualified patients. Signature indicates that all forms are fully and accurately completed, that all required documentation is attached and that the patient qualifies for either a full or partial waiver.
5	Forward the Financial Information Form, along with all required documentation and any additional forms as required, to the Area Manager for review and approval.
6	<p>The Area Manager will review the entire package and either approve or deny the waiver request. If the request is approved, forward the entire package to the Regional Insurance Coordinator for review and approval. If the request is denied, note reason why and return package to Social Worker.</p> <p><b>Note: If waiver request is for balances older than 6 months, entire package must be forwarded to the Regional Vice President for approval before forwarding to the Regional Insurance Coordinator. If request is denied by the RVP, note reason why and return package to Social Worker with copy to Area Manager.</b></p>

## 2) Determining Indigent Status

**Purpose** All indigent waiver requests submitted for approval to the Regional Insurance Coordinator will be reviewed to determine whether a patient has met the criteria for waiver status.

**Responsibility** The Regional Insurance Coordinator will review and approve or deny all Financial Information Forms submitted for indigent waiver approval within 30 days of receipt.

**Procedure** Follow these steps to review Financial Information Forms and approve or deny requests for waiver status.

Step	Action
1	Review Section VI of the Financial Information Form to verify that the patient's Net Worth is not > \$75,000. If Net Worth does exceed \$75,000, complete Section IV of the Financial Information Form denying the waiver request. Note the reason and return to the Social Worker with a copy to the Area Manager.
2	Review the remainder of the completed Financial Information Form and all attached documentation. Pay specific attention to Section II, noting whether there are insurance / assistance options that have not been investigated. If all documentation requirements are met and there is no excess income and no options for insurance or assistance identified, sign and date the waiver indicating approval in Section IV of the Financial Information Form. Also, enter the approval period which should never be longer than 12 months but can and should be shorter if the patient will be eligible for insurance / assistance during the 12-month period. If requirements are not met for any reason, complete Section IV of the Financial Information Form denying the waiver request. Note the reason and return to the Social Worker with a copy to the Area Manager.
3	If there is excess income, review the Patient Liability Worksheet and required documentation. If all documentation requirements are met and Yearly Excess Income ( <i>line 15 Patient Liability Worksheet</i> ) is $\leq$ zero, approve waiver and indicate the approval period per guidelines in step 2 above. If requirements are not met for any reason, complete Section IV of the Financial Information Form denying the waiver request. Note the reason and return to the Social Worker with a copy to Area Manager.

4	<p>If Yearly Excess Income (<i>line 15 Patient Liability Worksheet</i>) is &gt; zero, verify that there is a signed Sliding Fee Scale Program Agreement and that it is for the appropriate percentage. If everything is correct, approve waiver and indicate the approval period per guidelines in step 2 above. If requirements are not met for any reason, complete Section IV of the Financial Information Form denying the waiver request. Note the reason and return to the Social Worker with a copy to the Area Manager.</p>
5	<p>For any waiver that is approved, forward a signed copy along with all documentation to the Billing Group. In addition, forward a signed copy to the facility and keep the original, along with a full set of documentation, at the Business Unit.</p> <p><b>Note: For any denied waiver requests that are renewals, forward a copy of page one of the Financial Information Form to the Billing Group.</b></p>
6	<p>The Business Unit should track all approved waivers along with their re-determination date and all denied waivers.</p>
7	<p>Forward a signed copy of all approved waivers, excluding documentation, to the appropriate SPECTRA entity billing department:</p> <p style="padding-left: 40px;">East - 8 King Road, Rockleigh, NJ 07647 West - PO Box 15367, Fremont, CA 94539</p> <p>FMCNA Pharmacy should also be provided with a copy if they request it.</p>
8	<p>For all approved waivers, the Social Worker or designee notifies the patient regarding the approval of their waiver application by providing the patient with a copy of the approved waiver along with the Patient Liability Worksheet and Sliding Fee Scale Program Agreement, if applicable.</p>



### 3) Processing the Approved Indigent Waiver Request

**Purpose** All patients with an approved waiver will be set up to reflect this in Medical Manager.

**Responsibility** When the **Billing Group** receives a Financial Information Form with waiver approval, they will enter the appropriate information in Medical Manager.

**Procedure** Follow these steps for approved waivers:

Step	Action
1	<p>Upon receipt of Financial Information Forms indicating full or partial waiver approval, update the patient's insurance information in Proton appropriately.</p> <ul style="list-style-type: none"> <li>• If patient is Self Pay Primary with an approved discount, set up as claim center 7 and enter approved discount %.</li> <li>• If patient has full waiver approval for balances after insurance, set up as claim center 8.</li> <li>• If patient has partial waiver approval for balances after insurance, set up as claim center 8 or 9. <b>Do not enter the discount % as this will create problems with the charge interface.</b></li> </ul> <p>Note: Claim center 9 in some cases has been used for purposes other than <b>Indigent with Self-Pay</b>. The meaning of a claim center cannot be changed. If claim center 9 has been used for other purposes it cannot be changed and claim center 8 should be used for both <b>Indigent</b> and <b>Indigent with Self-Pay</b>.</p> <ul style="list-style-type: none"> <li>• Regardless of which claim center is used, always enter the waiver approval date and the waiver re-determination date. These dates are the "from" and "through" date of the approval period from Section IV of the Financial Information Form.</li> <li>• Transfer all balances covered by the waiver to the appropriate insurance, (7, 8 or 9).</li> </ul>
2	<p>Upon receipt of a denied renewal request, ensure that the appropriate insurance (7, 8 or 9) is terminated. <b>If a renewal waiver is not approved prior to the expiration date, ensure that the appropriate insurance (7, 8 or 9) is terminated as of the expiration date.</b></p>

3	Follow A/R Write-offs and Recoveries, 422-040-420, for balances covered by the indigent waiver.
4	For patients with partial waivers, the Billing Group will write-off the approved discount % and transfer the balance to the patients in order to bill the patients for the balances that are their responsibility.

#### 4) Waiver Renewal Process

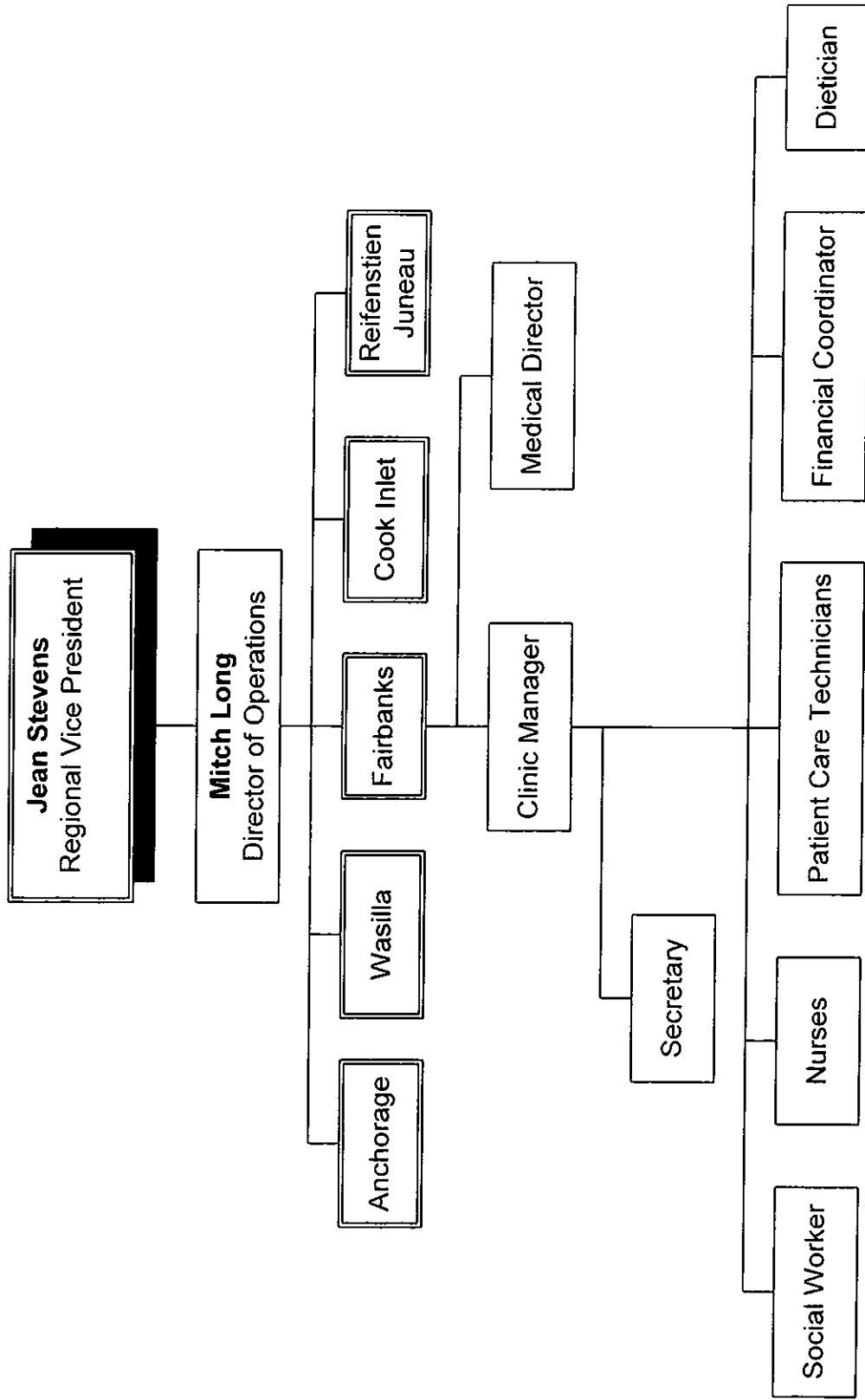
**Purpose** To ensure that waiver requests are reviewed and approved or denied prior to the expiration date of a current waiver.

**Procedure** Follow the steps below to determine which waivers are in need of renewal.

Step	Who	Action
1	Regional Insurance Coordinator	Provide the Social Worker or designee and Area Manager with a list of waivers that require renewal. This report should include all waivers that will expire in the next two months. Notify the RVP of any waivers that have not been renewed by their expiration date.
2	Social Worker or designee	Review the report and begin the renewal process with all patients whose waivers will expire in the next two months. <b>Renewals are treated the same as initial waivers with respect to documentation requirements and the approval process.</b> Notify the Business Unit regarding any patients on the list who are no longer active.

**Exhibit 3**  
**Organizational Chart**

# Fresenius Cook Inlet Facility Organizational Chart



**Exhibit 4**  
**Schedule I – Facility Income Statement**

**Exhibit 5**  
**Schedule III – Average Patient Cost per Day and Revenue Amounts**

**Exhibit 6**  
**Schedule VI – Reimbursement Sources**



**Exhibit 7**  
**Schedule VII – Depreciation Schedule**