



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number: #07-33A

Applicant: Bio-Medical Applications of California, Inc.
95 Hayden Avenue
Lexington, Massachusetts 02420

Phone: 808 674-9450 Ext 11

Project Title: Establishment of a 24 station hemodialysis facility

Project Address: 94-862 Kahuailani Street, Waipahu HI

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1. **TYPE OF ORGANIZATION:** (Please check all applicable)

- Public
- Private
- Non-profit
- For-profit
- Individual
- Corporation
- Partnership
- Limited Liability Corporation (LLC)
- Limited Liability Partnership (LLP)
- Other: _____

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STATE OF HAWAII
DEPARTMENT OF HEALTH

2. **PROJECT LOCATION INFORMATION**

A. Primary Service Area(s) of Project: (please check all applicable)

- Statewide: _____
- O`ahu-wide: _____
- Honolulu: _____
- Windward O`ahu: _____
- West O`ahu:
- Maui County: _____
- Kaua`i County: _____
- Hawai`i County: _____

3. **DOCUMENTATION** (Please attach the following to your application form):

- A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)
- B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)

<u>Type of Permit</u>	<u>Government Agency</u>
Medicare Certification	Hawaii Department of Health
Building Permit	City and County of Honolulu
Electrical	
Plumbing	
Mechanical	
Certificate of Occupancy	City and County of Honolulu
Fire Marshall Approval	City and County of Honolulu Fire Marshall

C. Your governing body: list by names, titles and address/phone numbers

See attached Exhibit A

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D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:

- Articles of Incorporation
See Exhibit B
- By-Laws
See Exhibit C
- Partnership Agreements
N/A
- Tax Key Number (project's location)
9-4-013-004

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4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "x" in the appropriate box.

	Used Medical Equipment (over \$400,000)	New/Upgraded Medical Equip. (over \$1 million)	Other Capital Project (over \$4 million)	Change in Service	Change in Beds
Inpatient Facility					
Outpatient Facility				X	
Private Practice					

5. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved

7. **CHANGE OF SERVICE:** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please reference the Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

This project is the development of a 24 station, 10,400 sq. ft. free standing Chronic Renal Dialysis clinic. This new facility is an expansion of the FMC-Dialysis Services of Kapolei, which at present is operating at 122%. Currently Bio-Med applications of California, Inc. (BMA) dba Fresenius Medical Care North America-Hawaii Area (FMCNA Hawaii) have six (6) clinics on the island of Oahu. Liberty Dialysis also has four (4) clinics on the island. FMC Hawaii has one (1) clinic, FMC-Dialysis Services of Pearlridge, located at 98-1005 Moanalua Road, Suite 420, Aiea, HI, which also services this area, is operating at 100% utilization. There is also a clinic, FMC-Wahiawa Dialysis Center, located at 850 Kilani Avenue, which is operating at 94% capacity, and currently receiving the overflow from the Kapolei facility. There are 2 other clinics that receive patients from this area because of the utilization problems that are both running at greater than 100% of capacity. They are FMC-Dialysis Services of Kapolei and the Leeward Dialysis Center. The other three (3) Fresenius facilities that service the East Oahu area are, FMC-Honolulu Dialysis Center located at 226 N. Kuakini Street, Honolulu, HI is currently operating at 99% utilization. FMC-Aloha Dialysis Center, located at 1520 Liliha Street, is operating at 75% capacity and currently receiving the overflow from the Honolulu facility. Another clinic, FMC-Windward Dialysis Center, located at 45-480 Kaneohe Bay Drive, Kaneohe, HI, is operating at 112% utilization. The utilization were calculated using the Hawaii State formula of number of stations x 3.5 x 6 x4 or 5.

8. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:
- a) Date of site control for the proposed project
February 2nd, 2007
 - b) Dates by which other government approvals/permits will be applied for and received
April 30th, 2007

c) Dates by which financing is assured for the project

N/A

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d) Date construction will commence

Construction Start date: **December 6th, 2007**

e) Length of construction period

8 months

f) Date of completion of the project

Construction End date: **August 6th, 2008**

g) Date of commencement of operation

Medicare Survey/Approval date: August 31st, 2008.

Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the certificate of need.

9. EXECUTIVE SUMMARY: Please present a brief summary of your project. In addition, provide a description of how your project meets each of the certificate of need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

- a) Relationship to the Hawai'i Health Performance Plan (H2P2), also known as the State of Hawai'i Health Services and Facilities Plan.
- b) Need and Accessibility
- c) Quality of Service/Care
- d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
- e) Relationship to the existing health care system
- f) Availability of Resources.

10. Eligibility to file for Administrative Review. This project is eligible to file for Administrative review because: (Check all applicable)

_____ It involves bed changes, which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.

It involves service changes which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.

It is an acquisition of a health care facility or service, which will result in lower annual operating expenses for that facility, or service.

It is a change of ownership, where the change is from one entity to another substantially related entity.

It is an additional location of an existing service or facility.

The applicant believes it will not have a significant impact on the health care system.

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 9. **Executive Summary:**

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 Bio-Medical Applications of California, Inc. seeks approval from the State Health Planning and Development Agency to operate a dialysis facility in Waipahu, Hawaii., (Central Oahu). See **Exhibit D** for the map of the island and where the facility will be located.

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 This facility will have twenty four (24) hemodialysis stations. The facility will be located at 94-862 Kahuailani St., Waipahu, Hawaii 96797 with approximately 10,400 square feet. Water, sewer and electric will be hooked up to the facility.

Providing dialysis services from this location will improve access to service for End-Stage Renal Disease (ESRD) population living in the Central Oahu area of Honolulu, who currently must travel to another facility further from their homes.

Dialysis is a life sustaining treatment required by patients with End-Stage Renal Disease. These patients are required to receive treatment usually on a three time a week schedule. Each treatment last from 3 to 5 hours depending on the amount of normal kidney function remaining. The patients are connected to the Dialysis machine by qualified Nurses and Technicians and monitored throughout the treatment.

a) Relationship to the Hawaii Health Performance Plan

The Waipahu Dialysis Facility project meets the H2P2 goals of increasing the span of healthy life and reducing health disparities among Hawaii's residents. The proposal will provide classes on health, living, and life style changes to patients and families of patients who in early stages of renal disease. The proposal also meets the H2P2 objective of reducing the effects of chronic disease and prolonging health related quality of life by offering the services of the company's Chronic Kidney Disease (CKD) program which goal is to prevent, delay and prepare those patients with End-Stage Renal Disease to survive with their chronic disease.

b) Need and Accessibility

1. Description of the Service Area

The primary service area will be Central Oahu consisting of Waipahu, Waikele, Mililani and Waipio. The facility will provide dialysis for the residents of this area. The facility allows the patients to be closer to home instead of traveling a great distance to their current facility. Also, there are several patients on the waiting list from this area that will now have a facility closer to home to dialyze. There are currently nine (9) dialysis facilities located on the island of Oahu owned by two (2) organizations. The facilities owned by BMA, are now at maximum capacity at three (3)

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shifts per day six (6) days a week. Two of the facilities, which includes the current Windward facility and the Kapolei facility are operating at four shifts per day, which BMA considers an emergency situation. Those patients on the fourth shift start their treatments between 8pm and 9pm. This means their scheduled treatments are not completed until 12am to 2am. The majority of these patients are diabetic and have vision problems, which causes difficulty with driving at night. The quality of life for these patients will be diminished and can cause transportation issues.

These patients receive dialysis treatments three times weekly for three to five hours per treatment. This new twenty-four station (24) facility will be adequate to meet both the current and future demand for the Central Oahu section of Honolulu and the surrounding area.

The H2P2's criteria for the development of a new Hemodialysis facility is stated as: For a new service, the minimum average annual utilization rate for all other providers in the service area is 80 %, and the utilization of the new service is projected to meet 75 % utilization rate by the third year of operation. FMC-Dialysis Services of Pearlridge is currently operating 100% utilization rate, FMC-Dialysis Services of Kapolei, which is the closest to servicing this area is operating at a utilization rate of 122% per year, and FMC-Wahiawa Dialysis Center is currently operating at 94% utilization rate and will be at a 100% capacity by the time the facility is open in the 2nd quarter of 2008. FMC-Honolulu Dialysis Center is currently operating at a utilization rate of 99%. The FMC-Windward Dialysis Center is operating at 112% utilization rate.

As of December 2006 statistics from the Trans Pacific Renal Network 17, the organization responsible for collecting this data for the Center for Medicare and Medicaid, reports a utilization rate of 90% for Liberty Dialysis. These are the latest statistics and are probably well over that number as of the date of this application.

Fresenius Medical Care by policy has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.

Fresenius Medical Care makes every responsible effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school, or patients who work. This facility will provide dialysis three (3) days per week with three patient shifts per day to start in order to accommodate these patients.

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Fresenius Medical Care does not require payment upon admission to its services, therefore its services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons. It is our policy that if a patient is determined to be indigent, we will assist the patient to obtain state funded medical coverage (Medicaid). In most States, including Hawaii, Medicaid reimburses for the services we provide, until the patient becomes eligible for Federal Assistance from the Medicare program. All patients will continue to be treated while applications are being reviewed by the State, as we assume that coverage will eventually be obtained on behalf of the patient. In most cases patients become Medicare eligible in just a few months.

2. Estimate of Need, Demand and Supply

National and local incidence rates of renal dialysis have increased steadily. We can anticipate continued increases according to the U.S. Renal Data System Report. They report increases might be due to an aging population, and/or better survival rates of potential ESRD patients.

Hawaii has had a significant increase in incident patient growth rates from 2000 to 2004. From 2000 to 2004 the growth rate was 15.0%. According to the 2004 United States Renal Data System Report (USRDSR). The population of ESRD patients in the West O'ahu area is projected to increase based on trends and increases in the elderly population. For the State of Hawaii it is estimated there are 200,000 citizens in stage 3-4 Renal Failure who have not been diagnosed to this point according to statistics from the National Kidney Foundation of Hawaii.

In the 2005 and 2006 there were 310 patient referrals that came through Fresenius Medical Care Central Admissions Office that were noted to be residents in the Central Oahu Area. 70 of these referrals lived in the Waipahu area. Majority of these patients started dialysis where the vacancy was at that time of referral.

Presently there are 50 patients who live in and around the Central O'ahu area and have voiced their request to have a facility close to their homes. 45 of these patients will be relocated to this facility to start with as well as patients on waiting lists from other facilities wishing to begin their dialysis.

c) Quality of Service/Care

Bio-Medical Applications of California, Inc. must comply with the Centers for Medicare and Medicaid's conditions of participation and standards of care in order to qualify for reimbursement. The Company's Quality

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Management Program, Outcomes Measurement, Monitoring and Management Program, and UltraCare concept exemplify the active role played in helping physicians and clinicians effectively care for their ESRD patients. The development and implementation of these programs is overseen by J. Michael Lazurus, M.D., Fresenius Medical Care North America Vice President. Dr. Lazurus provides FMCNA with overall clinical leadership.

Fresenius Medical Care Quality outcome Goals are as follows:

Adequacy of Dialysis (eKdrt/v) 90% of pts. ≥ 1.2
 Hemoglobin (Hgb) 80% of pts. $\geq 11\%$
 Albumin (Alb) 65% of pts. ≥ 3.8 g/dl

The results for the Hawaii Region area as follows:

Adequacy of Dialysis (eKdrt/v) 87.5% of pts. ≥ 1.2
 Hemoglobin (Hgb) 82.8% of pts. $\geq 11\%$
 Albumin (Alb) 61.4% of pts. ≥ 3.8 g/dl

Fresenius Medical Care facilities are non-reuse which means that we do not reuse the hemodialysis filters but use a new one with each treatment. Fresenius Medical Care is the only dialysis provider in the State of Hawaii that provides this option to physicians and patients who require it. Research has shown that non-reuse is safer than reprocessing the hemodialysis filters.

d) Cost and Finances (include revenue/cost projections for the first and third year of operation)

The start-up costs for this facility will be paid through retained earnings from the parent company Fresenius Medical Care Holdings, Inc. The project costs are approximately \$6,522, 378.00 for construction, equipment and furnishings. The projected revenue for year one (1) is \$1,502,436 and total expenses of \$ 1,612,24, year (2) revenues will total \$1,896,825 and total expenses of \$ 1,874,841, year (3) revenues will total \$2,298,952 and total expenses of \$ 2,143,939.

e) Relationship to the existing health system

The project will have a two-fold effect of improving access to services for ESRD patients in the Central Area of Oahu. First, the facility will relieve the current facilities, which provides for these patients, of the need for more than three (3) shifts per day, which will allow patients to start their

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treatments at an earlier hour. Second, it increases the capability of these facilities to meet future demand for dialysis services in this area.

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f) Availability of Resources

Availability for this new facility includes strong support services from various medical offices located in the service area. There are also several skilled nursing facilities in the area. Staffing for this facility will come from recruiting out of local nursing programs as well as training personnel through our extensive training programs. There is also potential for hiring staff from FMCNA Company network through its' Intranet and other listings throughout the company.

Fresenius Medical Care North America uses the following staffing ratios for all of its dialysis facilities:

Charge nurse (registered nurse)	-	1.0 FTE per 12 patients
Patient Care Technician	-	1.0 FTE per 4 patients
Social Worker	-	1.0 FTE per 125 patients
Registered Dietitian	-	1.0 FTE per 150 patients

For a 24 station facility, we will need 5 RN's, 13 PCTS, 1.2 Social Work, and 1 Registered dietitian.

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