



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number: #06-13A

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

Phone: 781 402 9000 ext.4110

Project Title: Establishment of a 24 station hemodialysis and two
peritoneal dialysis facility

Project Address: 47-388 Hui Iwa Street, Kaneohe, Hawaii

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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: _____

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: _____

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

- A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent) – **Exhibit A**
- 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.)

Type of Permit

Government Agency

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

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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
Previously submitted
- By-Laws
Previously submitted
- Partnership Agreements
Previously submitted
- Tax Key Number (project's location)
04-3129981

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. (under \$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

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TOTAL			ST. HLTH. PLNG. & DEV. AGENCY

6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:

AMOUNT:

- | | | |
|----|---|----------------|
| 1. | Land Acquisition | _____ |
| 2. | Construction Contract | \$818,287.00 |
| 3. | Fixed Equipment | \$487,076.00 |
| 4. | Movable Equipment | _____ |
| 5. | Financing Costs | _____ |
| 6. | Fair Market Value of assets acquired by lease, rent, donation, etc. | \$2,500,000.00 |
| 7. | Other: _____ | _____ |

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TOTAL PROJECT COST: \$3,805,363.00

B. Source of Funds

- | | | |
|----|-----------------------------------|----------------|
| 1. | Cash (Retained Earnings) | \$1,305,363.00 |
| 2. | State Appropriations | _____ |
| 3. | Other Grants | _____ |
| 4. | Fund Drive | _____ |
| 5. | Debt | _____ |
| 6. | Other: Fair Market Value of Lease | \$2,500,000.00 |

TOTAL SOURCE OF FUNDS: \$3,805,363.00

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, 10,000 sq. ft. free standing Chronic Renal Dialysis clinic. This new facility is an expansion of the Windward Dialysis Facility and will allow for the excess patients be treated at the new location. As of the date of this application Bio-Medical Applications of California, Inc. (BMA) dba Fresenius Medical Care North America-Hawaii Region (FMCNA Hawaii) has six (6) clinics on the island of Oahu. Liberty Dialysis Hawaii, LLC. also has four (3) clinics on the island. FMC Hawaii has one (1) clinic, FMC-Honolulu Dialysis Center, located at 226 N. Kuakini Street, Honolulu, HI, which is operating at 99% utilization. Another clinic, FMC-Windward Dialysis Center, located at 45-480 Kaneohe Bay Drive, Kaneohe, HI, which also services this area, is operating at 112% utilization. There is also a clinic, FMC-Aloha Dialysis Center, located at 1520 Liliha Street, which is operating at 75% capacity, and currently receiving the overflow from the Honolulu facility. The Pearlridge clinic, located at 98-1005 Moanalua Road, is currently operating at 102%, Kapolei Dialysis Center located at 555 Farrington Hwy is operating at 106% capacity. The Wahiawa facility is operating at 80% of capacity. The utilization calculations were calculated using the Hawaii State formula of number of stations x 3.5 x 6 x 4 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,
January 1, 2007
- b) Dates by which other government approvals/permits will be applied for and received,
March 1, 2007
- c) Dates by which financing is assured for the project,
January 1, 2007
- d) Date construction will commence,
January 2007
- e) Length of construction period
Approximately 12 weeks
- f) Date of completion of the project
March 30, 2007
- g) Date of commencement of operation
Medicare Survey/Approval date April 2007

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& DEPARTMENT OF HEALTH

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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.

9. **Executive Summary:**

Bio-Medical Applications of California, Inc. seeks approval from the State Health Planning and Development Agency to operate a dialysis facility in Kaneohe, Hawaii., (Windward Oahu). See **Exhibit B** 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 and one (1) peritoneal dialysis room to accommodate both CAPD and CCPD patient training. The facility will be located at 47-388 Hui Iwa Street, Hawaii 96744 with approximately 10,000 square feet. Water, sewer and electric will be hooked up to the facility.

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Providing dialysis services from this location will improve access to service for End-Stage Renal Disease (ESRD) population living in the Windward Oahu area 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

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The Ko'olau 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 the 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 Windward Oahu consisting of Kaneohe, Kahuku, Kailua and Waimanalo. 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 (10) 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) shifts per day six (6) days a week. Two of the facilities, which includes the current Windward 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.

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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 Windward Oahu section of Oahu 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 will be at 75 % by the third year of operation. FMC-Honolulu Dialysis Center is currently operating at a utilization rate of 99% per year. The facility will be running at greater than 100% by the time the new facility is open in early 2007. The FMC-Windward Dialysis Center, which also supports this service area, is operating at 118% utilization. These two facilities serve patients six days a week with 3 shifts per day at the Honolulu Center and 4 shifts per day at the Windward facility. By the time the new facility is open for operation both of these facilities will be operating at well over 100% utilization. The Pearlridge clinic, located at 98-1005 Moanalua Road, is currently operating at 102%, Kapolei Dialysis Center located at 555 Farrington Hwy is operating at 106% capacity. The Wahiawa facility is operating at 80% of capacity. The utilization calculations were calculated using the Hawaii State formula of number of stations x 3.5 x 6 x 4 or 5.

As of December 2004 statistics from the Trans Pacific Renal Network 17, the organization responsible for collecting this data for the Centers for Medicare and Medicaid, reports a utilization rate of 85.3% for St. Francis Medical center. This facility also serves the needs of the service area. 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 reasonable 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.

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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.

Hawai'i 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 Windward O'ahu area is projected to increase based on trends and increases in the elderly population. For the State of Hawai'i it is estimated there are 200,000 citizens in stages 3-4 Renal Failure who have not been diagnosed to this point according to statistics from the National Kidney Foundation of Hawai'i.

Presently there are 193 patients who live in and around the Windward O'ahu area and have voiced their request to have a facility close to their homes. 34 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.

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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 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. \geq 1.2
Hemoglobin (Hgb) 80% of pts. \geq 11%
Albumin (Alb) 65% of pts. \geq 3.8 g / dl

The results for the Hawaii Region are as follows:

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

The FMS Hawaii Region finished 5th of 43 Fresenius Medical Care North America (FMCNA) regions for 2005. As of January 2006, the Hawaii region is 2nd of 43 FMCNA regions.

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

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 \$3,805,363.00 for construction, equipment and furnishings. The projected revenues for year one (1) is \$638,208 and total expenses of \$584,165, year two (2) revenues will total \$725,164 with expenses of \$646,488 and total revenue of \$813,795 and total expenses of \$698,648 for year three (3) of the service.

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 Windward Oahu section of Oahu. First, the facility will relieve the current facilities, which provide services for these patients,

of the need for more than three (3) shifts per day, which will allow patients to start their treatments at an earlier hour. Second, it increases the capability of these facilities to meet future demand for dialysis services in this area.

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 @ \$37.26/hr
Patient Care Technician	- 1.0 FTE per 4 patients @ \$17.32/hr
Social Worker	- 1.0 FTE per 125 patients @ \$27.00/hr
Registered Dietitian	- 1.0 FTE per 150 patients @ \$26.00/hr

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