



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

LINDA LINGLE
GOVERNOR OF HAWAII

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DIRECTOR OF HEALTH

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October 10, 2006

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Rick Duckworth
CEO West Business Division
Bio-Medical Applications of California, Inc.
95 Hayden Avenue
Lexington, MA 02420

Dear Mr. Duckworth:

The State Health Planning and Development Agency has evaluated Certificate of Need application #05-19A from Bio-Medical Applications of California, Inc. (the "applicant") for the establishment of a twenty-four (24) station hemodialysis and two (2) peritoneal dialysis facility at 750 Palani Avenue, Honolulu, Hawaii, at a capital cost of \$3,495,716.

1. Pursuant to Title 11, Chapter 186 of the Hawaii Administrative Rules (HAR), the Agency has determined that this proposal is eligible for administrative review as it meets the criteria in Sections 11-186-99.1(b)(5) and (6).
2. The applicant states that its "...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 (sic) in the early stages of renal disease."
3. The applicant states that its "...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."
4. The applicant states that as of June 2006, the dialysis utilization at its Oahu facilities (based on 3.5 treatments per day for 6 days per week and 4 or 5 weeks per month calculation) were: FMS Honolulu-87%, FMS Aloha-65%, FMS Windward-105%, FMS Kapolei -114%, FMS Pearlridge-101%, FMS Wahiawa-73%.
5. In Exhibit "B" to its testimony dated July 17, 2006, Liberty Dialysis – Hawaii, LLC states that, as of June 2006, the dialysis utilization at the St. Francis-Liliha campus was 70%.

6. The applicant states that "Although the Aloha Dialysis Center is currently operating at 65% utilization, we have 33 patients on our waiting list that will be admitted on a third shift after the completion of some facility upgrades."
7. The applicant states that "Over the past two years, because of our utilization, it has been difficult to give a schedule to patients referred by the physicians and hospital discharge planners...We have added a fourth shift to the Windward and Kapolei facilities, which puts an enormous strain on the facilities resources, human and material...In light of the current trend towards increased treatment times, to an average of over 4 hours per treatment, it is very difficult to operate a facility at four shifts effectively."
8. Josephine G. Rejante, Manager, Queen's Medical Center, Case Management, Social Work & Nursing Home, states (in testimony dated July 18, 2006) "One of our major obstacles is obtaining Outpatient Hemodialysis (HD) slots for our patients with End Stage Renal Disease (ESRD). We have been successful at finding an appropriate Nursing Home or Foster Home for this population, but due to the limited number of available Outpatient HD slots in the community have caused an impact in our ability to provide beds for our acute patients in the Emergency Room (ER). Currently, we have patients on a lower level of care occupying our acute beds that are on the waitlist for the next available HD slot...We simply cannot ignore this issue of limited outpatient HD slot tremendously affecting our bed capacity."
9. June Williamson, Director of Case Management, Kapiolani Medical Center at Pali Momi, states (in testimony dated July 17, 2006) "As you know, our current facilities do not have the capacity to continue servicing new dialysis patients. . . and they often remain in the hospital longer than medically necessary simply waiting for an outpatient dialysis slot."
10. The applicant states that "The Fresenius Hawaii Region is operating at 94.9 percent utilization as of June 2006. And the actual utilization for year-to-date 2006 is 93.3 percent."
11. The applicant states that "Presently there are 97 patients who live in and around the East O'ahu area and have voiced their request to have a facility close to their homes. 63 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."
12. The applicant states that ". . . 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."
13. The applicant states that "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."

14. The applicant states that "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."
15. The applicant states that "Fresenius continues to comply with all federal and state licensure requirements. Fresenius Hawaii Region is currently sixth in the country of 50 regions in meeting or exceeding the quality outcomes as prescribed by the K/DOQI guidelines."
16. The applicant states that "The start-up costs for this facility will be paid through retained earnings from the parent company Fresenius Medical Care Holdings, Inc."
17. The applicant states that "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."

CONCLUSIONS

The Agency finds that the proposal meets the following certificate of need criteria: need and accessibility, quality of service/care, cost and finances, and availability of resources.

With respect to the need and accessibility criterion, the Agency finds that there is a need for additional dialysis units on Oahu. Josephine G. Rejante, Manager, Queen's Medical Center, Case Management, Social Work & Nursing Home, states (in testimony dated July 18, 2006):

"One of our major obstacles is obtaining Outpatient Hemodialysis (HD) slots for our patients with End Stage Renal Disease (ESRD). We have been successful at finding an appropriate Nursing Home or Foster Home for this population, but due to the limited number of available Outpatient HD slots in the community have caused an impact in our ability to provide beds for our acute patients in the Emergency Room (ER). Currently, we have patients on a lower level of care occupying our acute beds that are on the waitlist for the next available HD slot...We simply cannot ignore this issue of limited outpatient HD slot tremendously affecting our bed capacity."

June Williamson, Director of Case Management, Kapiolani Medical Center at Pali Momi, states (in testimony dated July 17, 2006):

"As you know, our current facilities do not have the capacity to continue servicing new dialysis patients . . . and they often remain in the hospital longer than medically necessary simply waiting for an outpatient dialysis slot."

While there are three facilities reporting utilization near the H2P2 threshold of 80%, there are four facilities reporting utilization in excess of the H2P2 threshold, with three of these in excess of 100% utilization.

With respect to the relationship to the existing health care system of the area, the Agency finds that the applicant has not proven by a preponderance of the evidence that its proposal relates favorably to the existing healthcare system of the area. The applicant has not shown that its proposal will alleviate the utilization disparities among existing dialysis facilities (FMS Kapolei - 114%, FMS Aloha-65%).

The Agency finds that the proposal, if modified in accordance with the conditions below, would meet this criterion.

With respect to the application's relationship to the health services and facilities plan or ("H2P2"), the plan states in Chapter II, Part G:

"Each new, expanded, or otherwise modified health care facility, service, or technology is designed primarily to add value to the health care delivery. Value is measured in terms of the appropriateness and extent to which the project improves access, quality, and/or cost-effectiveness as a means of achieving good patient health care outcomes."

The utilization thresholds in II-6 through II-11 guide the initial calculation of need related value for the proposed facility.

Based upon the information provided by the applicant and Liberty Dialysis-Hawaii, LLC, the most recent utilization numbers for dialysis units on Oahu are:

FMS Honolulu-87%,
FMS Windward-105%,
FMS Kapolei -114%,
FMS Pearlridge-101%,
FMS Wahiawa-73%
FMS Aloha-65%,
St. Francis-Liliha campus-70%.

FMS Wahiawa is not in the service area of the proposed facility and therefore is not taken into account for H2P2 threshold purposes.

With respect to FMS Aloha, the applicant states "Although the Aloha Dialysis Center is currently operating at 65% utilization, we have 33 patients on our waiting list that will be admitted on a third shift after the completion of some facility upgrades."

In application #06-24A, Liberty Dialysis-Hawaii, LLC proposes to encourage better utilization of its facilities by relocating eight dialysis stations to Waialae Avenue in East Honolulu. In a letter to SHPDA dated July 17, 2006, Liberty also proposes to relocate four stations to the Hyatt Regency in Waikiki.

Accordingly, the Agency finds that the proposal, if modified in accordance with the conditions below, would add value to health care delivery in accordance with Chapter II, Part G of H2P2 and would meet this criterion.

Conditional Certification

ORDER

The State Health Planning and Development Agency hereby APPROVES and ISSUES a CONDITIONAL Certificate of Need to Bio-Medical Applications of California, Inc. for the proposal described in Cert. #05-19A.

In order to ensure that the proposal:

1. adds value to health care delivery pursuant to Chapter II, Part G of H2P2 (that the proposal improves access, quality, and/or cost-effectiveness as a means of achieving good patient health care outcomes) and
2. enhances the health care delivery system of the area (pursuant to HAR 11-186-15 (10)),

the conditions are that: On or before January 15, 2007, the applicant shall submit to the Agency, for Agency approval, a written analysis and proposal for:

- Optimizing utilization at FMS Aloha:
 1. by admitting existing waitlisted patients to FMS Aloha (as discussed in the application), or
 2. by relocating FMS Aloha dialysis units to the proposed Palani Street facility, FMS Windward, FMS Pearlridge and/or FMS Kapolei, or,
 3. by such other optimization plans approved by the Agency.
- Optimizing utilization at FMS Windward, FMS Pearlridge and FMS Kapolei:
 1. by allocating patients, where practicable, to the proposed Palani Street facility, or
 2. by such other optimization plans approved by the Agency.

These modifications are required for the application to successfully meet the criteria in Sections 11-186-15 (9), and (10) HAR.

As provided under Section 323D-46, HRS and Section 11-186-77 HAR, the Agency establishes November 13, 2006 as the date by which the applicant must certify, in writing, that it accepts these conditions otherwise this application shall be deemed to be DENIED as provided under Section 11-186-77 HAR.

The Agency has determined that the applicant has proven by a preponderance of evidence that its proposal, if modified as specified in the above Order, meets the Cert. criteria in Section 11-186-15, HAR.

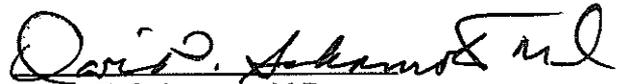
There is no compelling public interest which will be served by requiring the application to go through the standard review process.

As required under Section 323D-43(b), Hawaii Revised Statutes (HRS), the Agency finds that, if modified as specified in the above Order:

1. There will be a public need for this proposal.
2. The cost of the service will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

The maximum capital expenditure allowed under this approval is \$3,495,716.

Please be advised that pursuant to Section 323D-47, HRS and Section 11-186-99.1(g) HAR, any person may, for good cause shown, request in writing a public hearing for reconsideration of the Agency's decision within ten working days from the date of this decision. Accordingly, if no person makes such a timely request for reconsideration, this decision shall become final immediately after the deadline for making such a request has expired.


David T. Sakamoto, M.D.
Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Administrative Review Decision was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on October 10, 2006:

Rick Duckworth
CEO West Business Division
Bio-Medical Applications of California, Inc.
95 Hayden Avenue
Lexington, MA 02420

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



David T. Sakamoto, M.D.
Administrator