



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM P1 52

Application Number: # 21-08A
To be assigned by Agency

Date of Receipt: 21 MAR 2021
STATE HEALTH PLNG & DEV. AGENCY

APPLICANT PROFILE

Project Title: Establishment of additional chronic renal dialysis location and services in Lihue, Hawaii

Project Address: 4303 Nawiliwili Road, Unit J1A
Lihue, Hawaii 96766

Applicant Facility/Organization: Lihue Dialysis Hawaii, LLC

Name of CEO or equivalent: Jocelyn Saccamago

Title: Regional Vice President

Address: 2226 Liliha Street, Suite 226, Honolulu, Hawaii 96817

Phone Number: (808) 585-4600 Fax Number: (808) 585-4601

Contact Person for this Application: J. George Hetherington, Esq.

Title: Attorney

Address: 700 Bishop Street, 15th Floor, Honolulu, Hawaii 96813

Phone Number: (808) 523-6000 Fax Number: (808) 523-6001

CERTIFICATION BY APPLICANT

I hereby attest that I reviewed the application and have knowledge of the content and the information contained herein. I declare that the project described and each statement amount and supporting documentation included is true and correct to the best of my knowledge and belief.

Jocelyn M Saccamago

Signature

March 3, 2021

Date

Jocelyn Saccamago

Name (please type or print)

Regional Vice President

Title (please type or print)

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

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

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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: _____ X _____
- 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)

See Attachment 1.

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.)

Building Permit from Kauai County
Certificate of Occupancy
Certification from the Centers for Medicare and Medicaid Services ("CMS")

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

See Attachment 2. The individuals listed in Attachment 2 represent the governing body of Bio-Medical Applications of California, Inc. Lihue Dialysis Hawaii, LLC is a member-managed LLC of which Bio-Medical Applications of California, Inc. is the sole member.

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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:

- Certificate of Formation – See Attachment 3.
- By-Laws – Not applicable.
- Partnership Agreement – Not applicable.
- Tax Key Number (project's location) – 3-3-003-034

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 |
|--------------|-------------------|--------------------------------|---|
| | | | |
| | | | |
| | | | |
| | | | |
| TOTAL | | | |

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6. PROJECT COSTS AND SOURCES OF FUNDS

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A. List All Project Costs:

AMOUNT:

| | | |
|----|--|-----------------------|
| 1. | Land Acquisition | _____ |
| 2. | Construction Contract | <u>\$3,487,017.00</u> |
| 3. | Fixed Equipment | <u>\$500,000.00</u> |
| 4. | Movable Equipment | <u>\$508,471.00</u> |
| 5. | Financing Costs | _____ |
| 6. | Fair market value of equipment acquired by lease | <u>\$367,200.00</u> |
| 7. | Other: Fair market value of site lease | <u>\$4,870,525.25</u> |

TOTAL PROJECT COST: \$9,733,213.25

B. Source of Funds

| | | |
|----|---|-----------------------|
| 1. | Cash | <u>\$4,495,488.00</u> |
| 2. | State Appropriations | _____ |
| 3. | Other Grants | _____ |
| 4. | Fund Drive | _____ |
| 5. | Debt | _____ |
| 6. | Other: Fair market value of leased equipment to be paid over the lease term | <u>\$367,200.00</u> |
| 7. | Other: Fair market value of site lease to be paid over the lease term | <u>\$4,870,525.25</u> |

TOTAL SOURCE OF FUNDS: \$9,733,213.25

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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.

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Establishment of 16-station chronic renal dialysis service.

Reference HAR 11-186-5(4)(A).

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:
April 22, 2021
- b) Dates by which other government approvals/permits will be applied for and received:
Building Permit – December 2021
Certificate of Occupancy – November 2022
Certificate from CMS – February 2023
- c) Dates by which financing is assured for the project:
Not applicable.
- d) Date construction will commence:
March 2022
- e) Length of construction period:
6 months
- f) Date of completion of the project:
August 2022
- g) Date of commencement of operation:
December 2022

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.

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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.

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EXECUTIVE SUMMARY

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Lihue Dialysis Hawaii, LLC ("LDH") seeks approval to establish a 16-station dialysis center equipped with two home training rooms at 4303 Nawiliwili Road, Unit J1A, Lihue, Hawaii, 96766 (the "Proposed Clinic"). LDH is an affiliate of Liberty Dialysis-Hawaii, LLC and Liberty Dialysis-North Hawaii LLC (together, the "Liberty Subsidiaries"), which operate hemodialysis clinics in Hawaii (the "Liberty Clinics"). Specifically, LDH is under common control with the Liberty Subsidiaries (LDH and the Liberty Subsidiaries are collectively referred to herein as "Liberty"). The sole member of LDH is Bio-Medical Applications of California, Inc. ("BMAC"). BMAC is wholly owned by Bio-Medical Applications Management Company, Inc. ("BMAMC"). The Liberty Subsidiaries are both indirect subsidiaries of Liberty Dialysis Holdings, Inc. ("Liberty Dialysis Holdings"). Liberty Dialysis Holdings is a wholly owned subsidiary of BMAMC.

As a result of the common ownership it shares with the Liberty Subsidiaries, LDH will operate under the same policies, procedures, and protocols utilized at other Liberty Clinics throughout the state.

The Liberty Subsidiaries are established and well-respected providers of dialysis services in Hawaii, including through the two clinics it already operates on Kauai, one being in Lihue approximately 1.5 miles from the Proposed Clinic ("Liberty Kauai") and the other being in Waimea ("Liberty West Kauai"). The Proposed Clinic will permit Liberty to expand its ability to offer its services to Kauai patients.

a) Relationship to the State of Hawaii Health Services and Facilities Plan

The State of Hawaii Health Services and Facilities Plan (the "State Plan") states that prior to the establishment of a new chronic renal dialysis service, the minimum annual utilization for each provider in the service area should be 600 treatments per unit, and the utilization of the new service should be projected to meet the minimum utilization rate by the third year of operation (the "State Plan Threshold"). The State Plan Threshold has been established to guide the initial determination of need for a service area.

The target service area for the Proposed Clinic is the community of and around Lihue, one of the largest towns on Kauai (the "Target Area"). Liberty operates the only other dialysis clinic in the Target Area (Liberty Kauai), which has 11 stations that serve a total population of about 67 patients. Currently, Liberty Kauai operates at a high capacity, offering 3 shifts per day Monday/Wednesday/Friday and four shifts per day on Tuesday/Thursday/Saturday. This equates to approximately 938 treatments per station annually. The next closest dialysis clinic to the Proposed Clinic, Liberty West Kauai, has 8 stations that serve a total population of about 46 patients. Liberty West Kauai offers four shifts on Monday/Wednesday/Friday and three shifts on Tuesday/Thursday/Saturday, for an annual utilization rate of 796 treatments per station. Accordingly, based on the relevant data, both Liberty Kauai and Liberty West Kauai operate well above the State Plan Threshold.

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The State Plan also established statewide and regional priorities that are to be considered when evaluating certificate of need applications. The Proposed Clinic will include the dedication of two specific rooms to Home Training. Home Training will involve LDH educating and training patients and any care partners to empower patients to dialyze at home. In some cases, this would eliminate (or at least reduce) the need for patients to visit the dialysis center for treatments, thereby improving the overall health care delivery system. For patients who have mobility or transportation difficulties, the ability to receive dialysis in the comfort of their own home could be life changing. Furthermore, the Proposed Clinic's Home Training component will also contribute positively to the fulfillment of the specific priorities set forth in the State Plan as detailed below.

The Proposed Clinic supports the Kauai Subarea Planning Council's ("KSAC") priorities of striving for a system of comprehensive care on Kauai, promoting island sustainability and local control of Kauai health services, increasing supply of in-home care options for seniors at all economic levels, and improving accessibility to medical services as soon as feasible. The Proposed Clinic also furthers the KSAC priority of supporting efforts to recruit/retain personnel in areas of health care experiencing shortages who will live on Kauai. LDH will undertake purposeful recruiting and retention initiatives to adequately staff the Proposed Clinic, as explained more thoroughly in part (f), below.

As recognized both explicitly and implicitly in several of the KSAC priorities, accessibility is especially important to senior citizens. End stage renal disease ("ESRD") is most prevalent in individuals over the age of 65. Inability to easily access dialysis services can lead to ESRD complications, which can force seniors into nursing homes. This Proposed Clinic will help to avoid that by ensuring that dialysis care is available for seniors residing in the Target Area when they need it.

By laying the foundation to supply sufficient dialysis services, the Proposed Clinic will advance the Statewide Health Coordinating Council priorities by:

- Promoting and supporting the long-term viability of the health care delivery system;
- Ensuring that patients' access to dialysis services is maintained at a reasonable cost;
- Maintaining equitable access to health care services; and
- Supporting the regional and statewide continuum of care.

b) Need and Accessibility

As discussed in part (a), above, the other dialysis centers on Kauai operate at utilization levels far in excess of the State Plan Threshold. More importantly, however, the Proposed Clinic will provide extra capacity that will be needed to meet anticipated increasing demand for dialysis services.

In a 2013 report to the Hawaii Legislature, the National Kidney Foundation of Hawaii stated that the latest statistics showed that more than 162,000 people in Hawaii were fighting chronic kidney disease. One in every seven people is dealing with this illness, which is 30%

higher than the national average. Asians and Pacific Islanders are two to four times more likely to develop end stage kidney disease.¹

Moreover, the increased incidence of Diabetes Mellitus ("DM") among both seniors and the younger population suggests that the incidence of ESRD is likely to increase, because ESRD is a common complication of poorly controlled DM. In fact, DM is the most common cause of ESRD. The Centers for Disease Control and Prevention ("CDC") has reported that from 1999 to 2009, the total number of adults in Hawaii diagnosed with DM nearly doubled from 48,000 to 80,000. Six thousand new cases of DM were reported in Hawaii every year from 2006 to 2009. The increased number of cases of DM is reflected in Hawaii's utilization of dialysis services. In 2005, Hawaii had the third highest incidence of ESRD in the nation, with over 2,800 individuals receiving dialysis.

In Kauai County specifically, the recent growth trajectory in patient numbers indicates a 5.23% Compound Area Growth Rate for in-service dialysis patients. It is evident that Kauai's patient demographics, geographic layout, and the increasing prevalence of ESRD secondary to DM will cause Kauai's demand for dialysis services to continue rise for the foreseeable future.

When evaluating need, it is also important to consider the impact that COVID-19 has had on the provision of dialysis services. Although Kauai County has one of the lowest COVID positivity rates in the state, Liberty is prepared to offer infection isolation and implement safety protocols at its Kauai clinics if it becomes necessary. In other counties, Liberty has been able to easily isolate COVID positive dialysis patients by opening a fourth shift. These adjustments are relatively simple to make in other areas because the utilization rates at those clinics are at much more manageable levels, allowing for a lot of flexibility. However, on Kauai, both of Liberty's existing clinics already operated four shifts before the pandemic. Therefore, clearing out the fourth shift for COVID patients requires Liberty to rearrange schedules for patients and staff. Given the high utilization rate among dialysis stations on Kauai, the opening of the Proposed Clinic would greatly alleviate the challenges associated with safely caring for all patients in the midst of the pandemic.

While it is expected that the Proposed Clinic will primarily meet the needs of residents of the Target Area, LDH will make the Proposed Clinic's services available to all Kauai residents and visitors, including low-income individuals, racial and ethnic minorities, women, individuals with disabilities, other underserved groups, and the elderly.

c) Quality of Service/Care

Liberty provides the highest quality of dialysis services to its patients and is in full compliance with all applicable federal and state regulations at all of the Liberty Clinics. LDH will continue to provide this same level of exceptional care to its patients at the Proposed Clinic.

The Liberty Clinics are CMS certified and observe the standards set by both the CDC and CMS in their operations. Liberty's quality improvement program was developed in accordance with CMS and the National Kidney Foundation's Disease Outcomes Quality Initiative guidelines. In keeping with the Liberty Dialysis Quality Improvement Program, each Liberty Clinic monitors the quality of care it provides in each of the following areas: anemia

¹ <http://www.bigislandvideonews.com/2013/03/14/new-statistics-show-rise-in-kidney-disease-in-hawaii/>

management, bone management, adequacy of dialysis, patient satisfaction and technical management.

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Staffing at the Proposed Clinic will meet the same standards for ratio of clinical staff to patients that Liberty maintains at all of the Liberty Clinics:

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Charge Nurse (RN) 1.0 FTE per 12 patients
 Patient Care Technicians 1.0 FTE per 4 patients

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Accordingly, a registered nurse will be on duty anytime the Proposed Clinic is open. The on-duty RN will be assisted by patient care technicians, as patient volume requires.

All Liberty nurses are licensed in Hawaii and all patient care technicians are nationally certified. All nurses and hemodialysis technicians must complete Liberty's training program prior to being assigned patient care duties. All LDH patient care staff will participate in regular in-service training to maintain the highest quality of competency.

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

The total cost of the project is estimated at approximately \$9,733,213.25, which includes \$3,487,017.00 for construction costs, \$500,000.00 for fixed equipment, and \$508,471.00 for movable equipment. The Proposed Clinic will be financed through cash reserves and a committed working capital line. Additionally, dialysis equipment valued at \$367,200.00 will be leased, with costs to be paid over the term of the lease. Although the Proposed Clinic will operate 16 dialysis stations, two extra dialysis machines will be leased as reserves. Therefore, the \$367,200.00 in equipment costs is based on the rental of 18 dialysis machines. The site lease, valued at \$4,870,525.25, will be paid over the ten-year initial term of the lease. A copy of the site lease is included with this application as Attachment 1.

The table below summarizes projected revenues and costs for the first and third years of operation:

| | Projected 1st Full Year Operations | Projected 3rd Full Year Operations |
|--|------------------------------------|------------------------------------|
| Total Operating Revenue | \$741,836.00 | \$3,417,950.72 |
| Operating Expenses | | |
| Salaries and wages | (\$301,958.00) | (\$1,140,301.38) |
| Expenses | (\$785,673.00) | (\$1,628,304.24) |
| Depreciation | (\$103,653.00) | (\$426,201.85) |
| Total Expenses | (\$1,191,284.00) | (\$3,194,807.48) |
| Net Income (Loss) from Operations | (\$449,448.00) | \$223,143.24 |
| Add Back: Depreciation | \$103,653.00 | \$426,201.85 |
| Excess (Deficit) Fund from Operations | (\$345,795.00) | \$649,345.10 |

e) Relationship to the existing health care system

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No significant negative impact on the existing health care system is expected from the Proposed Clinic. This project will add new capacity to address the need that has already been established through the current utilization figures described herein. Liberty's other clinics in or near the Target Area are operating near or above the State Plan Threshold and Liberty expects to maintain these utilization figures despite an increase in capacity stemming from the Proposed Clinic because of the positive CAGR for the Target Area.

Establishment of an additional dialysis facility in Lihue will have a positive impact on the existing health care system as it will increase access to care for the residents of Lihue and surrounding areas by providing them with more options for scheduling their dialysis treatments.

f) Availability of Resources

There are no financial obstacles to this proposal. The Proposed Clinic will be paid for with cash reserves or through a committed working capital line, which LDH has dedicated to this project.

Because of Liberty's longstanding role as a provider in the Target Area, it understands the types of initiatives required to recruit and retain qualified personnel on Kauai. For Kauai County, Liberty seeks new employees on an ongoing basis through local recruitment efforts and advertising on a local and national scale. Liberty has developed extensive training and education programs for its new hires and invests significant time and capital to ensure the preparedness of each member of its team. Liberty's partnerships with local educators also provide clinical training opportunities for new nurses and technicians. These programs have directly boosted recruitment of local dialysis nurses and technicians and helped to maintain a consistent supply of qualified personnel for Liberty's Kauai clinics. In fact, Liberty's Kauai clinics currently boast a 0.0% employee turnover rate. Finally, Liberty will make efficient use of its staffing resources by utilizing an internal float staffing pool to provide extra support at the Proposed Clinic, as needed.

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.