



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY  
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ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: # 19-16A To be assigned by Agency Date of Receipt: ST HLTH PLNG & DEV. AGENCY

APPLICANT PROFILE

Project Title: Establishment of additional dialysis services in Kalihi

Project Address: 2055 N. King Street, Suites 100 and 200

Honolulu, Hawaii 96819

Applicant Facility/Organization: Kalihi 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

10/3/2019 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:   X
- 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)

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 Honolulu 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. Kalihi Dialysis Hawaii, LLC is a member-managed LLC of which Bio-Medical Application 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.
- Operating Agreement – Not applicable.
- Tax Key Number (project's location) –

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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
<b>TOTAL</b>			

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## 6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:	AMOUNT:
1. Land Acquisition	_____
2. Construction Contract	<u>\$2,105,527</u>
3. Fixed Equipment	_____
4. Movable Equipment	<u>\$364,474</u>
5. Financing Costs	_____
6. Fair Market Value of equipment acquired by lease	<u>\$216,000</u>
7. Other: Value of site lease	<u>\$1,284,075</u>
<b>TOTAL PROJECT COST:</b>	<b><u>\$3,970,076</u></b>

B. Source of Funds	
1. Cash	<u>\$2,470,001</u>
2. State Appropriations	_____
3. Other Grants	_____
4. Fund Drive	_____
5. Debt	_____
6. Other: Fair market value of leased premises and equipment to be paid over the lease term	<u>\$1,500,075</u>
<b>TOTAL SOURCE OF FUNDS:</b>	<b><u>\$3,970,076</u></b>

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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 or 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:  
9/10/2019
- b) Dates by which other government approvals/permits will be applied for and received:  
Building Permit – 8/1/2020  
Certificate of Occupancy – 6/1/2021  
Certificate from CMS – 12/1/2021
- c) Dates by which financing is assured for the project:  
Not applicable.
- d) Date construction will commence:  
10/1/2020
- e) Length of construction period:  
6 months
- f) Date of completion of the project:  
4/1/2021
- g) Date of commencement of operation:  
7/1/2021

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.

**EXECUTIVE SUMMARY**

Kalihi Dialysis Hawaii, LLC ("KDH") seeks approval to establish a 16-station dialysis center (the "Clinic") at 2055 N. King Street, Suite 100 and 200, Honolulu, Hawaii 96819 (the "Proposed Additional Location"). KDH 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, KDH is under common control with the Liberty Subsidiaries (KDH and the Liberty Subsidiaries are collectively referred to herein as "Liberty"). The sole member of KDH 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, KDH 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 and the Proposed Additional Location will permit KDH to expand its learned proficiencies and care offerings to a new market on Oahu.

- a) Relationship to the State of Hawai'i Health Services and Facilities Plan

The target service area for the Proposed Additional Location is the Kalihi corridor on the Island of Oahu (comprised of Kalihi, Middle Street, and Kapalama), the nearby downtown/Chinatown neighborhoods, and other surrounding communities to the west of the Proposed Additional Location (the "Target Area").

The State of Hawaii Health Services and Facilities Plan ("HSFP") 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 "HSFP Threshold"). The HSFP Threshold has been established to guide the initial determination of need for a service area. It has long been recognized that Oahu's dialysis facilities are operating far in excess of the HSFP Threshold. Utilization data compiled by LDH during the preparation of CON Application No. #19-03A is shown in Table 1, below:

Table 1. Utilization Data for Select Oahu Dialysis Facilities			
Location	Number of Stations	Total Treatments/Year	Treatments/ Station/ Year
DSI Kapolei	24	20,250	844
DSI Pearlridge	48	51,000	1,063
LDH Waipahu	36	30,696	852
DSI Wahiawa	24	20,550	856
DSI Kapahulu	24	15,000	625

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Table 1. Utilization Data for Select Oahu Dialysis Facilities

Location	Number of Stations	Total Treatments/Year	Treatments/ Station/ Year
DSI Honolulu	48	41,550	866
DSI Aloha	24	16,950	706
DSI Windward	24	15,908	663
DSI Koolau	24	12,600	525
DSI Waipahu	24	16,224	676
LDH Waianae	20	16,505	825
LDH Leeward	24	20,596	858
LDH Siemens (East)	48	40,764	849
LDH Kaimuki	24	21,477	894
LDH Kailua	12	9,471	789
USRC West Oahu	24	10,450	435

As the newest operating location for which there is reliable data available, USRC West Oahu has a suboptimum utilization rate, but is poised to meet the HSFP Threshold by its third year of operation. Nonetheless, utilization at every facility except DSI Koolau and USRC West Oahu Dialysis Center exceeds the HSFP Threshold. Furthermore, the utilization of all these facilities has increased since this data was compiled. Other dialysis facility operators are in agreement that the demand for dialysis services exceeds accessible capacity throughout most of Oahu. See CON Application #18-11A at 10-11. In two of its 2018 CON applications to implement dialysis services in Waianae and Waipio, USRC stated that it expects to meet the HSFP Threshold for each facility within three years of their openings. USRC also noted that it does not anticipate the opening of the new facilities to bring any of its existing facilities' utilization levels below the HSFP Threshold. *Id.* and CON Application #18-13A at 10-11. A third application submitted by USRC in 2018 to implement dialysis services in Ewa Beach acknowledged that USRC's proposed new Ewa Beach facility would not meet the HSFP Threshold within three years of its opening; however, it argued that the overall need for dialysis services is expected to increase because of a multitude of factors. CON Application #18-12A at 10-11. SHPDA granted all three of USRC's 2018 CON applications.

KDH agrees that there continues to be a high demand for dialysis services and expects such demand to climb for the foreseeable future. Therefore, KDH is confident it will meet the HSFP Threshold within three years of the Proposed Additional Location's opening and that its opening will not affect the utilization levels of any existing dialysis facility on Oahu.

Even if the Proposed Additional Location were unable to meet the HSFP Threshold within three years, SHPDA has stated that utilization thresholds merely guide the initial determination of need for the service area and applications are neither approved nor disapproved solely on the basis of whether the utilization thresholds are met. The HSFP states that utilization thresholds may be modified to allow for suboptimum utilization if a proposal's benefits clearly outweigh the costs to the community of duplicating or under-using services, facilities, or technologies. The HSFP further states that such benefits may include improved access for the service area combined with significant improvements in quality of care. Thresholds may also be modified to incorporate current and best clinical practices. Best practice requires minimizing the distance that a dialysis patient must travel for treatment in order to reduce the incentive to miss treatment sessions.

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While there may be some available capacity at certain existing dialysis clinics on Oahu, this capacity is not effectively available to individuals residing in and around Kalihi, especially those who lack personal vehicles and must make the lengthy trip on public transportation for their three-times weekly treatments, which may last for three to five hours. These facts justify suboptimal utilization, even if the HSFP Threshold is not satisfied.

Accessibility is especially important to senior citizens. End stage renal disease ("ESRD") is most prevalent in individuals over the age of 65. One of the priorities of the Honolulu Subarea Council ("SAC") is to increase the availability of supportive services and control escalating costs in the senior care industry and other needed services (to, for example, reduce the need for institutionalized care). Inability to easily access dialysis services can lead to ESRD complications, which can force seniors into nursing homes. This proposal will advance these SAC priorities and help seniors avoid nursing care by promoting access to needed dialysis care for seniors residing in the service area.

Finally, by ensuring adequate access to dialysis services, this proposal will advance the following Statewide Health Coordinating Council priorities:

- Promote and support the long-term viability of the health care delivery system;
- Ensure that patients' access to dialysis services is maintained at a reasonable cost;
- Maintain equitable access to health care services; and
- Support the regional and statewide continuum of care.

b) Need and Accessibility

As discussed in part (a), above, the dialysis centers in close proximity to the Proposed Additional Location are operating at utilization levels in excess of the HSFP Threshold. More importantly, however, the Proposed Additional Location 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.<sup>1</sup>

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

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



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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. The increasing prevalence of P2R46 secondary to DM will cause Oahu's demand for dialysis services to rise for the foreseeable future.

While it is expected that the Proposed Additional Location will primarily meet the needs of residents of the Target Area, KDH will make the Proposed Additional Location's services available to all Oahu residents, 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. KDH will continue to provide this same level of exceptional care to its patients at the Proposed Additional Location.

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

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

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

Accordingly, a registered nurse will be on duty anytime the Proposed Additional Location 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 KDH 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 \$3,970,076, which includes \$2,105,527 for construction costs and \$364,474 for movable equipment. The Proposed Additional Location will be financed through cash reserves and a committed working capital line. Additionally, dialysis equipment valued at \$216,000 will be leased, with costs to be paid over the term of the lease. Although the Proposed Additional Location will operate 16 dialysis stations, two extra dialysis machines will be leased as reserves. Therefore, the \$216,000 in equipment costs is based on the rental of 18 dialysis machines. The site lease, valued at \$1,284,075, will

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be paid over the five-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
<b>Total Operating Revenue</b>	\$577,893	\$2,682,801
<b>Operating Expenses</b>		
Salaries and wages	(\$263,381)	(\$1,017,270)
Expenses	(\$1,072,651)	(\$1,464,079)
Depreciation	(\$142,480)	(\$150,525)
<b>Total Expenses</b>	<b>(\$1,478,512)</b>	<b>(\$2,631,873)</b>
<b>Net Income (Loss) from Operations</b>	<b>(\$900,619)</b>	<b>\$50,928</b>
<b>Add Back: Depreciation</b>	<b>\$142,480</b>	<b>\$150,525</b>
<b>Excess (Deficit) Fund from Operations</b>	<b>(\$758,139)</b>	<b>\$201,453</b>

e) Relationship to the existing health care system

No significant negative impact on the existing health care system is expected from the Proposed Additional Location. This project will add new capacity to address the need that has already been established. Current providers in the service area are operating near or above the HSFP Threshold and these providers expect to maintain these utilization figures despite an increase in capacity stemming from the Additional Proposed Location.

Establishment of an additional dialysis facility in Kalihi will have a positive impact on the existing health care system as it will increase access to care for the residents of Kalihi 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 Additional Location will be paid for with cash reserves or through a committed working capital line, which KDH has dedicated to this project.

Liberty seeks new employees on an ongoing basis through local and national advertisements. Liberty engages in extensive local recruitment and conducts in-house nurse and technician training programs to ensure that its personnel are qualified to provide high quality care to its dialysis patients. Liberty has partnered with local educators to provide clinical training opportunities for new nurses and technicians. Liberty has also expanded its in-house training efforts and has increased recruitment of local dialysis nurses and technicians in order to maintain a consistent supply of qualified personnel to provide patient care in its dialysis facilities.

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

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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.

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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.