



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: #11-13A Date of Receipt: _____
 To be assigned by Agency

APPLICANT PROFILE

Project Title: Establishment of dialysis services in Hawaii Kai

Project Address: 7192 Kalanianeole Highway, Suite Q-101, Honolulu, Hawaii 96825

Applicant Facility/Organization: Liberty Dialysis—Hawaii, LLC

Name of CEO or equivalent: Mark Caputo

Title: Chief Executive Officer

Address: 3820 East Mercer Way, Mercer Island, Washington 98040

Phone Number: (206)275-2000 Fax Number: (206)275-3500

Contact Person for this Application: Jane Gibbons

Title: Executive Vice President

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

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

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.

Signature

Date

Jane Gibbons
Name (please type or print)

Executive Vice President
Title (please type or print)

REPLACEMENT PAGES

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: _____

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 the City & County of Honolulu
 Certificate of Occupancy from the City & County of Honolulu
 Fire Marshall's Approval from the City & County of Honolulu Fire Department
 Medicare Certification from the State of Hawaii, Department of Health

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

See Attachment 2

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: Not Applicable
- By-Laws: Not applicable
- Partnership Agreements: See Attachment 3 (Operating Agreement)
- Tax Key Number (project's location): 1-3-9-048-009

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			

6. PROJECT COSTS AND SOURCES OF FUNDS**A. List All Project Costs:****AMOUNT:**

1.	Land Acquisition	_____
2.	Construction Contract	<u>\$900,000.00</u>
3.	Fixed Equipment	<u>\$200,000.00</u>
4.	Movable Equipment	<u>\$450,000.00</u>
5.	Financing Costs	_____
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	_____
7.	Other: Site Lease	<u>\$683,730.00</u>

TOTAL PROJECT COST:**\$2,233,730.00****B. Source of Funds**

1.	Cash	<u>\$1,550,000.00</u>
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt	_____
6.	Other: FMV of lease	<u>\$683,730.00</u>

TOTAL SOURCE OF FUNDS:**\$2,233,730.00**

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.

Establishment of dialysis services with 15 stations plus one isolation station
at 7192 Kalaniana'ole Highway as an expansion of Liberty Dialysis—
Hawaii's existing service in Kaimuki (3625 Harding Avenue). 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: September 2011
- b) Dates by which other government approvals/permits will be applied for and received: November 2011
- c) Dates by which financing is assured for the project: September 2011
- d) Date construction will commence: January 2012
- e) Length of construction period: 4 months
- f) Date of completion of the project: May 2012
- g) Date of commencement of operation: June 2012

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.

REPLACEMENT PAGES

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 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.

EXECUTIVE SUMMARY

Liberty Dialysis-Hawaii LLC ("Liberty Dialysis") seeks approval to develop a second location of its East Oahu dialysis center, now located in Kaimuki at 3625 Harding Avenue (Kaimuki Dialysis Facility), in the Koko Marina Shopping Center at 7192 Kalaniana'ole Highway, Suite Q-101. A site map is included in Attachment 4. The new location will include 15 dialysis stations plus one isolation station (isolation station is required by the Centers for Medicare and Medicaid Services).

Liberty Dialysis is a Delaware limited liability company that was established to acquire, own and operate the dialysis centers that were formerly part of the St. Francis Healthcare System ("SFHS"). Liberty currently operates a total of 14 dialysis centers throughout Hawaii.

Liberty Dialysis seeks to open a new dialysis facility to improve access to dialysis services for residents in the East Oahu communities of Hawaii Kai, Kalama Valley, Niu Valley, Aina Haina, Waialae, and Kahala (the "Targeted Service Area").

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

The State of Hawai'i 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.

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

REPLACEMENT PAGES

that 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.

In 2010, Renal Dialysis Network 17 Reported the following utilization data for existing dialysis centers in Honolulu:

Center	Number of Patients*	Number of Treatments, annualized	Number of Stations***	Number of Treatments Per Station
Fresenius Aloha Dialysis Center 1520 Liliha Street	110	16500	20	825
Fresenius Honolulu Dialysis Center 226 North King Street	186	27900	48	581
Fresenius Kapahulu Dialysis Center	89	13350	24	556
Liberty Dialysis Kaimuki Dialysis Center 3625 Harding Avenue	120	18000	24	750
Liberty Dialysis Siemsen Dialysis Center 2230 Liliha Street	311	46650	74	630

*Patient census data is from the ESRD Network 17 2010 Annual Report and it reflects patient census as of December 31, 2010 for all facilities except the Kapahulu Dialysis Center, data for which was obtained from the Center's nurse manager.

** Network 17 does not report actual number of treatments provided at each center. Accordingly, the number of treatments per station was calculated based on the assumption that the average patient receives 150 dialysis treatments per year in order to facilitate accurate comparison of each center's utilization.

*** The number of stations for each facility is as reported on CMS Dialysis Compare website. Five stations at the Siemsen Center are held in reserve for sicker patients that are bedbound and are, therefore, used inconsistently.

The utilization of the new facility is expected to reach the threshold level of 600 treatments per dialysis station by the third year of the center's operation, as illustrated in the table below:

REPLACEMENT PAGES

Year of Operation	1	2	3
Projected Annual Utilization per Station	4,500 treatments 300tx/station (30 patients)	6750 treatments 450tx/station (45 patients)	9750 treatments 650tx/station (65 patients)

This proposal meets the criteria for suboptimum utilization. While the Honolulu Dialysis Center and the Kapahulu Dialysis Center have not yet reached the threshold level of 600 treatment per year, they are located at considerable distance from the Targeted Service Area. Under ideal conditions the drive from the Targeted Services Area takes about 25 minutes. However, the drive time can be considerably longer due to congested traffic conditions. This project will improve access for residents of the Targeted Service Area by reducing the burden of finding transportation for sometimes lengthy trips to dialysis centers located in Honolulu's central core.

It will also improve the quality of care available to residents of the Targeted Service Area and facilitate implementation of current and best clinical practices. Individuals with ESRD typically undergo hemodialysis ("HD") on an out-patient basis three times a week, with each treatment lasting approximately three to five hours. These treatments are widely experienced as disruptive and intrusive to an individual's lifestyle and independence, making compliance a significant issue. Nancy G. Kutner, *Improving Compliance in Dialysis Patients: Does Anything Work?*, 14 Seminars in Dialysis, 324, 324 (No. 5, Sept.-Oct. 2001). Noncompliance with HD treatment regimens increases the risk of infection, cardiovascular and neurological complications, multi-organ system involvement and ultimately death from ESRD. *Id.* Moreover, individuals with ESRD are typically not able to drive and often face challenges in coordinating transportation with family members, friends, the Handi-Van and/or other sources of public/private transportation. These challenges serve as a barrier to compliance with the HD treatments. By reducing that compliance barrier, this proposal will improve the quality of care available to residents of the Targeted Service Area, especially senior citizens.

This project will advance the Statewide Health Coordinating Council ("SHCC") priority of ensuring maintenance of overall access to quality health care at a reasonable cost by ensuring that residents of the Targeted Service Area have access to dialysis services near their homes. By improving access to dialysis services close to patients' homes, this proposal will reduce this barrier for individuals in the Targeted Service Area, encourage patients' better compliance with their HD treatment schedules, and thereby lower health care costs associated with treating conditions resulting from poor compliance and improve each patient's quality of life.

In addition, this Project will advance the Honolulu Subarea Council's ("SAC") goals by increasing the availability of support services and reducing the cost of senior care. ESRD frequently develops secondary to diabetes mellitus (DM), which is

among individuals between 45 - 64 years of age, with the median age of onset over the age of 55. The costs associated with dialysis are minimal compared to the costs of emergency medical care and/or hospitalization due to complications from ESRD that can result from noncompliance with prescribed dialysis treatment regimens. Additionally complications of ESRD not infrequently make it impossible for seniors to continue living in their homes and necessitate costly nursing home care. By improving access to a dialysis center near their homes, this proposal will assist seniors with ESRD to comply with their HD treatments regimens, thereby helping them to avoid nursing home care and reducing the financial and social costs of ESRD for patients, their families, and the community. Additionally, this dialysis facility will provide dialysis services to the senior population residing in twelve skilled nursing facilities in East Oahu.

This facility will also facilitate adoption of the most current and best clinical practices by providing additional dialysis capacity that may be needed to respond to the emerging clinical trend toward more frequent dialysis sessions. See Glenn M. Chertow, et al., *In-Center Hemodialysis Six Times Per Week Versus Three Times Per Week*, 363 *New Eng. J. Med.*, 2287 (No. 24, Dec. 2010); Chris P. Lee, Stefanos A. Zenios & Glenn M. Chertow, *Cost Effectiveness of Frequent In-Center Hemodialysis*, 19 *J. Am. Soc. Nephrol.* 1792 (Sept. 2008).

b) Need and Accessibility

As discussed in part a, above, as of the end of 2010, all the dialysis facilities in the service area were at or near the HSFP threshold for new service. It is anticipated that all have reached the necessary threshold at this time. In the alternative this proposal satisfies the conditions for suboptimization.

The 2008 USRDS Annual Data Report stated that the ESRD incident population grew by 3.4% in 2006. The greatest growth occurred in the 45-64 year old age group, where the number of people with ESRD increased by 6.1%. Since 2000, the adjusted incident rate for patient in the 45-64 age group has increased by 2.4%.

The impact of these increases in ESRD prevalence in the middle-aged population will be reflected in a growing demand for dialysis services as Oahu's population ages. Between April 1, 2000 and July 1, 2009, the percentage of Oahu residents over age 50 increased from 28.5% to 32.5%. Source: U.S. Census Bureau and State of Hawaii, DBEDT. This percentage is expected to continue to increase as the baby boomers age. By 2035, DBEDT estimates that persons age 50 and older will comprise about 40% of Hawaii's population. The emergence of the baby boomers into a senior population will contribute to the overall ESRD population, even if improved medical care is successful in moderating the disease rate. The neighborhoods in the Targeted Service Area are likely to be particularly affected by the need for additional health care facilities that will develop in response to Oahu's aging population because they have a higher than average concentration of older residents.

The State of Hawaii Data Book for 2009 reports that the median age for all the neighborhoods in the Targeted Service Area was over 42 years in 2000. The Waiialae-Kahala neighborhood had the highest median age of any neighborhood on Oahu, 46.8

REPLACEMENT PAGES

years. This disparity in the concentration of older residents in the Targeted Service Area supports the need for additional dialysis capacity to serve them in coming years.

Moreover, the increased incidence of Diabetes Mellitus (DM) among both seniors and the younger population suggests that the incidence of ESRD likely to increase, because ESRD is a common complication of poorly controlled DM. In fact, DM is the most common cause of ESRD. The 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 2800 individuals receiving dialysis. The increasing prevalence of ESRD secondary to DM will cause Oahu's demand for dialysis services to rise for the foreseeable future. The new facility in Hawaii Kai will provide dialysis capacity that the community will need to meet this projected growing demand.

Finally, although the proposed dialysis center is primarily intended to meet the needs of the Hawaii Kai, Kalama Valley, Niu Valley, Aina Haina, Kahala and Waialae communities, LDH will make its services available to all Oahu residents, including low-income individuals, racial and ethnic minorities, women, individuals with disabilities, other underserved groups, and the elderly. In addition, LDH will maintain its commitment to provide charity care to those otherwise unable to afford dialysis treatment.

c) Quality of Service/Care

Liberty Dialysis provides the highest quality of dialysis services to its patients and is in full compliance with all federal and state regulations at all of its 14 dialysis centers in Hawaii. It will continue to provide the same high quality care to patients at the proposed new location. Liberty's Kaimuki location was rated by CMS as having a better than expected outcome in the area of patient mortality and it is consistently a top performer in quality outcomes; The proposed clinic in Hawaii Kai will serve as an extension of the services provided by Liberty's Kaimuki clinic using many of the same support staff.

Liberty Dialysis is CMS certified, and observes the standards set by both the CDC and CMS in its centers' operations. Copies of Liberty Dialysis' CMS certifications for its existing Hawaii dialysis centers are included in Attachment 5. Liberty Dialysis' quality improvement program was developed in accordance with CMS and the National Kidney Foundation's Disease Outcomes Quality Initiative ("KDOQI") guidelines. In keeping with the Liberty Dialysis Quality Improvement Program, each facility monitors the quality of care in the following areas: anemia management, bone management, adequacy of dialysis, patient satisfaction, and technical management.

All Liberty Dialysis nurses are licensed in Hawaii and all patient care technicians are nationally certified as required by CMS. All nurses and hemodialysis technicians must complete the Liberty Dialysis training program prior to assignment to patient care

REPLACEMENT PAGES

duties. All Liberty Dialysis patient care staff will participate in regular in-service training in order to assure maintenance of the highest level 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 \$2,233,730.00 which includes \$900,000.00 for construction costs, \$200,000.00 for fixed equipment, \$450,000.00 for movable equipment, and \$683,730.00 for the site lease. The project will be financed with cash from retained earnings.

The operating revenue for the first year of operation is projected at \$1,462,500, and operating expenses for the same period are projected at \$1,442,254, resulting in an operating profit of \$20,246. By the third year of operation, revenue is expected to increase to \$3,295,500 with total expenses for year three projected at \$3,163,680, resulting in an operating profit of \$131,820.

e) Relationship to the existing health care system

Because this project will add new capacity, the need for which has already been established, and because current providers in the service area are operating near or above the threshold of 600 treatments/station/year, no significant impact on the existing health care system is expected. There are currently no dialysis services available east of Liberty's Kaimuki location. Kaimuki Dialysis, located at 3625 Harding Avenue is operating at 122% utilization based on HSFP threshold of 600 treatments per station. The project is unlikely to affect dialysis facilities with utilization slightly less than the HSFP threshold because patients for the new facility will be drawn primarily from the Harding Avenue facility which is operating at well above the threshold capacity. This project will increase dialysis stations to meet the growing ESRD population in East Oahu thus lowering the utilization of the Kaimuki Dialysis Center and thereby allowing patients more flexibility in scheduling their dialysis treatments.

Establishment of a dialysis facility in Hawaii Kai will have a positive impact on the existing health care system as it will provide more access to care for the residents of East Oahu and provide them more options for scheduling their dialysis treatments. It will not negatively impact the existing service providers as the facilities in the service area that are closest to the proposed facility are above threshold capacity.

f) Availability of Resources.

There are no financial obstacles to the project. This project will be financed with retained earnings.

LDH expects to assign staffing for the proposed facility from its current pool of employees in addition to seeking new employees through local and national advertisements. LDH engages in extensive local recruitment and conducts in-house nurse and technician training programs to insure that its personnel are qualified to provide high quality care to its dialysis patients. LDH has partnered with local educators

REPLACEMENT PAGES

to provide clinical training opportunities for new nurses and technicians. LDH has also expanded its in-house training efforts and has increased recruitment of local dialysis nurses who have left the field and mainland nurses and technicians in order to maintain a consistent supply of qualified personnel to provide patient care in its dialysis facilities.

LDH maintains the following ratios of clinical staff to patients at all of its facilities:

Charge Nurse (RN):	1.0 FTE per 12 patients
Patient Care Technicians:	1.0 FTE per 4 patients
Registered Dietitian:	1.0 FTE per 120 patients
Social Worker:	1.0 FTE per 140 patients

Upon opening, the Hawaii Kai facility will employ 1 FTE Nurse Manager, 2.0 FTE RNs, 5.0 FTE hemodialysis technicians, a 0.25 FTE social worker, a 0.25 FTE dietitian, and 1.0 FTE bio-medical technical staff. Additional staff will be employed and trained to maintain LDH's staffing ratios as patient census increases.

A registered nurse will be on duty at all times that the facility is open and is assisted by patient care technicians as patient volume requires.

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.