

ORIGINAL



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: #14-14A Date of Receipt: _____
To be assigned by Agency

APPLICANT PROFILE

Project Title: Establishment of additional chronic renal dialysis location and services in Honolulu

Project Address: 1908 South Beretania Street, Suite No. 1, Honolulu, Hawaii 96826

Applicant Facility/Organization: Dialysis Newco, Inc. d/b/a DSI Renal

Name of CEO or equivalent: Craig Goquen

Title: Chief Executive Officer

Address: 424 Church Street, Suite 1900, Nashville, Tennessee 37219

Phone Number: 615-263-4530 Fax Number: 615-234-2418

Contact Person for this Application: Jay Yalowitz

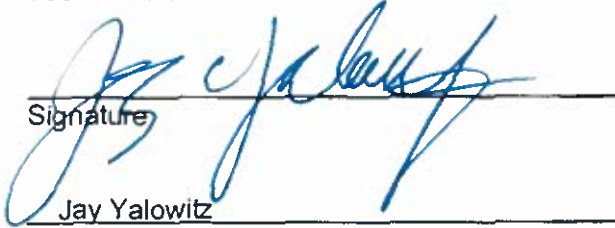
Title: General Counsel

Address: 424 Church Street, Suite 1900, Nashville, Tennessee 37219

Phone Number: 615-234-0951 Fax Number: 615-234-2424

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

9/15/2014
Date

Jay Yalowitz
Name (please type or print)

General Counsel
Title (please type or print)

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

Public _____
Private _____ X _____
Non-profit _____
For-profit _____ X _____
Individual _____
Corporation _____ X _____
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: _____ 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 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.)

Building permit from City and County of Honolulu
Certificate of occupancy from City and County of Honolulu
City and County of Honolulu Fire Department Fire Marshall's approval
Certification from the Centers for Medicare and Medicaid Services

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

Robert Lefton, Director
424 Church Street, Suite 1900
Nashville, Tennessee 37219
615-777-8200

Craig Goguen, Director
 424 Church Street, Suite 1900
 Nashville, Tennessee 37219
 615-263-4530

Jay Yalowitz, Director
 424 Church Street, Suite 1900
 Nashville, Tennessee 37219
 615-234-0951

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 – Filed in 2014 calendar year.
- By-Laws – Filed in 2014 calendar year.
- Partnership Agreements – N/A
- Tax Key Number (project's location) 1281070000

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>\$1,349,530</u>
3.	Fixed Equipment	<u>\$139,742</u>
4.	Movable Equipment	<u>\$414,661</u>
5.	Financing Costs	_____
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	<u>\$1,810,917</u>
7.	Other: _____	_____

TOTAL PROJECT COST: \$3,714,850

B. Source of Funds

1.	Cash	<u>\$1,903,933</u>
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt	_____
6.	Other: Fair market value of lease payments	<u>\$1,810,917</u>

TOTAL SOURCE OF FUNDS: \$3,714,850

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 additional chronic renal dialysis location and services (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: July 2014
- b) Dates by which other government approvals/permits will be applied for and received:
 - Building permits applied - August 2014
 - Building permits received - November 2014
- c) Dates by which financing is assured for the project: August 2014
- d) Date construction will commence: November 2014
- e) Length of construction period: 6 months
- f) Date of completion of the project: May 2015
- g) Date of commencement of operation: July 2015

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.

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

Dialysis Newco, Inc. d/b/a DSI Renal ("DSI") seeks approval to establish an additional location for its dialysis services, located in the McCully/Moilili area of Honolulu at 1908 South Beretania Street, Suite No. 1, Honolulu, Hawaii 96826 (the "Additional Location"). The Additional Location will offer a full range of dialysis services and modalities, including sixteen (16) hemodialysis stations and a home dialysis program. The establishment and operation of the Additional Location will enhance DSI's ability to continue to provide high quality and accessible dialysis services to individuals with End Stage Renal Disease ("ESRD") on Oahu, particularly in the urban Honolulu core.

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

Specific goals of the Health Services and Facilities Plan ("HSFP") reflect current issues facing Hawai'i's health care environment, and include:

- Focus on increasing cost-effective access to necessary health care services. Access is distinguished from convenience.
- Promote the financial viability of the health care delivery system.
- Encourage optimization of services and expensive technology by ensuring that supply meets the need and costs are reasonable.
- Promote regionalization of services where appropriate.¹

This development of the Additional Location furthers those goals. Dialysis services are vitally necessary to the patients who require them and, in keeping with the goals of HSFP, DSI will strive constantly to maintain a high standard of quality care while also being focused on cost-effective access as shown in the Cost and Finances section.

¹ HSFP at page 15 - <http://hawaii.gov/shpda/resources-publications/health-services-and-facilities-plan-2009>.

By improving access to quality services at a reasonable cost and providing health education to assist patients and their families in better understanding and managing their chronic disease, the establishment of the Additional Location will support the general principles of the Statewide Health Coordinating Council ("SHCC") and the priorities of the Honolulu Subarea Health Planning Council ("HONSAC").² DSI acknowledges and represents:

- Dialysis is a supportive service that maintains the quality of life for its patients.
- Nutrition is an important part of a dialysis patient's everyday lifestyle and our nutrition guidelines and support to patients are all based on industry standards and scientifically-based knowledge.
- We aim to be active in community engagement via partnerships with a wide array of organizations such as the National Kidney Foundation, Hawaii Health Systems Corporation, Transpacific Renal Network, the GFR Alliance, HMSA, Kaiser Permanente, the University of Hawaii, Kapi'olani Community College and the National Renal Administrators Association.
- A vital part of our patient and family services will be health education counseling and classes about dialysis care and participation in community preventive health campaigns about kidney disease and diabetes.
- The establishment of the Additional Location will advance the SHCC priorities of ensuring maintenance of overall access to quality health care at a reasonable cost and striving for equitable access to health care services by providing DSI patients residing in the Primary Service Area improved access to dialysis services closer to their homes. By maintaining and improving access, this Additional Location will encourage patients to comply with their dialysis treatment schedules and, thereby, lower health care costs associated with poor compliance.
- The establishment of the Additional Location will advance the HONSAC priorities of increasing the availability of supportive services to help maintain quality of life and controlling escalating costs in the senior care industry and other needed services. Patient counts and prevalence rates for ESRD are highest among those individuals age sixty-five (65) and older.³ The costs associated with dialysis are minimal compared with the costs of emergency medical care and/or hospitalizations due to complications from ESRD that can result from noncompliance with prescribed dialysis treatment regimens. Additionally, complications from ESRD frequently make it difficult for seniors to continue to live in their homes and necessitate costly nursing home care. By improving access to a dialysis center, the proposed project will assist seniors with ESRD to comply with their dialysis treatment schedules and help maintain their quality of life. Such compliance will also help individuals avoid nursing home care and reduce the financial and social costs of ESRD for them, their families and the community.

² See HSFP at pages 33 and 35.

³ See United States Renal Data System 2012 Annual Data Report at Figure 1.12 *Prevalent counts & adjusted rates of ESRD, by age* - http://www.usrds.org/2012/view/v2_01.aspx.

Hawaii Revised Statute §323D-12 mandates that HSFP must include standards for utilization of health care facilities. Chapter 2 of HSFP states that "Capacity (utilization) thresholds for certain standard categories of health care services are established to guide the initial determination of need for a service area." HSFP further provides that:

It is recognized that some service areas may not meet the required threshold for a healthcare service. Sub-optimum utilization may be proposed if the benefits clearly outweigh the costs to the community of duplicating or under-using services, facilities, or technologies.

Benefits are defined as the form of improved access for the service area(s) population combined with significant improvement in quality and/or significant reduction in cost to the public.

In addition, beyond regional factors, thresholds may be modified to:

- Incorporate current and best clinical practices;
- Allow for the cost-effective transition and capital investment in moving traditional inpatient services to outpatient modalities;
- Allow for the cost-effective introduction of modern technology to replace existing technology;
- Address the documented needs of an actual population rather than basing care design on statistical generalizations;
- Create opportunities for price reduction through competition, without sacrificing quality or cost-effectiveness of care; and
- Encourage innovation in improving health care services that contribute to enhancing a community's health status.⁴

Prior to the establishment of a new chronic renal dialysis unit/service, HSFP provides that the minimum utilization of each existing provider in the service area should be six hundred (600) treatments per facility and the utilization of the new chronic renal dialysis unit/service should be projected to meet the minimum utilization rate by the third year of operation. As discussed further below, DSI believes the Additional Location will meet utilization thresholds as provided by the HSFP without causing the census of other facilities in the Primary Service Area to drop below six hundred (600) treatments per station per year. DSI projects a year 1 ending census at the Additional Location of thirty-eight (38) patients (translating into three hundred and fifty-six (356) treatments per station) and a year 3 ending census of no less than sixty-four (64) patients (translating into no less than six hundred (600) treatments per station, which would meet HSFP's minimum utilization threshold). DSI believes that the foregoing patient census assumptions are reasonable and attainable based on the factors discussed below, specifically: (a) the anticipated population increases in the metro Honolulu area, (b) the high prevalence rate of diabetes and incidence rate of ESRD in Hawai'i, (c) the number of chronic kidney disease stage 5 ("CKD 5") and chronic kidney disease stage 4 ("CKD

⁴ HSFP at pages 31-32.

4”) patients residing in the zip code in which the Additional Location will be located and the contiguous zip codes, and (d) the number of patients currently dialyzing at DSI’s other facilities in the Primary Service Area who live in the zip code in which the Additional Location will be located or who live closer to the Additional Location than to the facility where they currently receive dialysis services.

The Primary Service Area for the Additional Location is urban Honolulu with particularly ready access to residents of McCully, Moiliili, and Manoa. Currently there are only six (6) dialysis facilities servicing the wider Primary Service Area, DSI’s Aloha (1520 Liliha Street, Honolulu, 96817), Honolulu (226 North Kuakini Street, Honolulu, 96817) and Kapahulu (750 Palani Avenue, Honolulu, 96816) facilities and Liberty Dialysis’ Kaimuki (3625 Harding Avenue, Honolulu, 96816), Siemsen (2226 Liliha Street, Honolulu, 96817) and Sullivan (2230 Liliha Street, Honolulu, 96817) facilities. All of these facilities are providing treatments in excess of the utilization threshold established by HSFP. The current annualized treatments for DSI’s Aloha, Honolulu and Kapahulu dialysis facilities are 885, 716 and 719 treatments/station, respectively.

Based on information provided by Liberty Dialysis in support of its CON Application No. 12-28A, Liberty Dialysis’ Kaimuki facility is providing approximately eight hundred twenty-four (824) treatments per station and Liberty Dialysis’ Siemsen/Sullivan facility is providing approximately six hundred forty-one (641) treatments per station. In approving CON Application No. 12-28A, SHPDA found that “Island wide, only two dialysis centers are not performing at or above HSFP threshold utilization level,” those clinics being located on the Windward side of Oahu.⁵ Although Liberty Dialysis has obtained CON approval (CON Application No. 12-34A) to establish a twenty-four (24) station facility at 4380 Lawehana Street in the Salt Lake/Radford area at the outer fringe of Honolulu, DSI does not believe that the establishment of that facility will significantly reduce the utilization rates of existing facilities in the Primary Service Area. As Liberty Dialysis stated in its application, the new facility will accommodate dialysis patients displaced by extensive renovation and reorganization of St. Francis Health Systems’ east campus. In seeking approval of CON Application No. 12-34A, Liberty acknowledged that the need for dialysis services exceeded that which would be provided by its Salt Lake facility when completed, and that its own capacity calculations undercounted the total projected need for dialysis services in the near future.⁶

As discussed further below, anticipated growth in the ESRD population in the Primary Service Area will enable the Additional Location to reach HSFP utilization thresholds. In addition, DSI also expects that the Additional Location will garner patients from DSI’s other high utilization facilities in the Primary Service Area. Thirty-one (31) patients currently receiving dialysis services from DSI at other locations in the Primary Service Area live in the 96826 zip code. DSI anticipates that many of those patients will transfer to the Additional Location once it becomes operational due to its

⁵ See letter dated March 19, 2013 from SHPDA to Liberty Dialysis at section 10, page 2 - <http://hawaii.gov/shpda/certificate-of-need/applications-and-decisions/decisions/shd1228a>.

⁶ See Liberty Dialysis-Hawaii, LLC’s Testimony in Opposition to Dialysis Newco Inc.’s Request for Reconsideration of Approval of Certificate of Need Application No. 12-34 A, May 31, 2013.

closer proximity to their homes. Furthermore, of the remaining four hundred twenty (420) patients that currently receive dialysis from DSI's facilities in the Primary Service Area that do not live in the same zip code as the Additional Location, two hundred twenty-six (226) patients (Aloha – 110; Honolulu – 87; Kapahulu – 29) live closer to the Additional Location than they do to their current facility. However, even if one assumes that as much as 25% of each of those patient groups were to transfer to the Additional Location, each of DSI's existing facilities still will be operating in excess of HSFP utilization thresholds based on their current patient census as illustrated below.

<u>Facility</u>	<u>Adjusted Census⁷</u>	<u>Stations</u>	<u>Adj. Ann. Tx</u>	<u>Adj. Tx/station</u>
Aloha	90	20	13,500	675
Honolulu	207	48	31,050	647
Kapahulu	108	24	16,200	675

While DSI believes the utilization of the Proposed Location and all of the other dialysis facilities in the Primary Service Area will exceed utilization thresholds within three (3) years, SHPDA has recognized that sub-optimum utilization is particularly appropriate with respect to dialysis facilities and services since the benefits of improved access, patient compliance with treatment regimen, quality of care, best clinical practice, hospital discharge to outpatient modalities and cost-reduction are so significant.

As dialysis patients receive treatment three (3) times per week, having a close, updated and convenient dialysis facility is beneficial to the lives of these patients. Studies have shown that after only fifteen (15) minutes of travel time to receive dialysis services, morbidity and mortality rates increase, and health related quality of life and treatment adherence decrease.⁸ DSI believes the benefits of providing the Additional Location in the Primary Service Area clearly outweigh the costs to the community of potentially duplicating or under-using services, facilities, or technologies.

b) Need and Accessibility

There is a need for the Additional Location. As noted above, DSI projects a year 1 ending census at the Additional Location of thirty-eight (38) patients⁹ (translating into three hundred and fifty-six (356) treatments per station) and a year 3 ending census of no less than sixty-four (64) patients (translating into no less than six hundred (600) treatments per station, which would meet HSFP's minimum utilization threshold). DSI

⁷ The "Adjusted Census" is the Current Census for the facility (as set forth in Section (b)(2) below) less 25% of the number of patients living closer to the Additional Location, as set out above.

⁸ The medical literature supporting this assertion is discussed further in Section (b).

⁹ As is discussed below, thirty-one (31) patients currently receiving services from DSI's Aloha, Kapahulu and Honolulu facilities live in the 96826 zip code. In addition, two hundred twenty-six (226) additional patients at those facilities live closer to the proposed Additional Location than to their current facility. In calculating the year 1 ending census, DSI has assumed that approximately 50% of the patients in the former category and approximately 10% of the patients in the latter category would transfer to the Additional Location once it becomes operational.

believes that the foregoing patient census assumptions are reasonable and attainable based on the factors discussed in more detail below.

1. Hawai'i's ESRD Incidence Rate, Population Growth and Diabetes Prevalence Rate will Result in Increasing Numbers of Individuals with ESRD

Hawai'i's, and in particular Oahu's, population of individuals with ESRD is large and growing at alarming rates, fueling the need for additional dialysis facilities. Per the United States Renal Data System (USRDS), Hawai'i's incidence rate for ESRD is the sixth highest in the country and is significantly higher than the national rate:

- 2009 – Hawai'i incidence rate of 406.1/million vs. 355.7/million nationally = 14.17% higher than the national rate;
- 2010 – Hawai'i incidence rate of 382.5/million vs. 349.2/million nationally = 9.53% higher than the national rate; and
- 2011 – Hawai'i incidence rate of 373.8/million vs. 336.2/million nationally = 11.18% higher than the national rate.

In 2012, per the Western Pacific Renal Network, LLC ("Network 17"), the incidence rate for ESRD in Hawai'i **increased** to 386.3/million; the figures for 2012 on a national level are not yet available. On a statewide basis, per Network 17, the total number of ESRD patients in Hawai'i being added to the population requiring dialysis services (i.e., the extent to which new ESRD patients exceeds deaths in a given year) was one hundred thirty-one (131) in 2012, one hundred sixty-four (164) in 2011, and one hundred sixty-three (163) in 2010.¹⁰ This effect is cumulative and continuing. In addition, per the 2013 Dialysis Facility Report prepared by CMS for the existing DSI Kapahulu, Aloha and Honolulu facilities, the 2009-2012 standardized mortality ratio reflected 38%, 20% and 11%, respectively, fewer deaths than expected. That means that patients in these facilities are surviving on dialysis longer than statistically predicted, such that the utilization levels of these facilities will remain high in the future.

Hawai'i's high ESRD incidence rate will be exacerbated by the projected population growth in the future (especially in the over sixty-five (65) population) and the prevalence of diabetes and kidney disease in Hawai'i. As reflected by the 2010 U.S. Census and the Census Bureau's estimates since then, Urban Honolulu is the largest population center on Oahu, continues to grow, and is home to at least three hundred thirty-seven thousand two hundred fifty-six (337,256) (over a third) of the island's residents.¹¹ The resident population of the City and County of Honolulu is projected to

¹⁰ See http://www.esrdnet17.org/Annual%20Report/2012/Annual_Report_Table1_ESRD_Incidence.pdf, http://www.esrdnet17.org/Annual%20Report/2011/Annual_Report_Tables_2011.pdf, and <http://www.esrdnet17.org/Annual%20Report/2010/2010%20Annual%20Report%20Tables.pdf>.

¹¹ See http://factfinder2.census.gov/faces/nav/jsf/pages/community_facts.xhtml and http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2013_PEPANR_ES.

increase at an annual rate of 0.4% from 2010 to 2040.¹² The aging of the population is one of the most prominent features of Hawai'i's population trend. The share of the population sixty-five (65) years of age and over increased from 8.0% in 1980 to 14.5% in 2010. This trend will continue in the future, increasing this share of the total population to 23.6% in 2040.¹³ The population of zip code 96826 (in which the Additional Location is situated) was recorded as thirty thousand eight hundred forty-two (30,842).¹⁴ Urban Honolulu is home to a significant—twenty-seven thousand (27,000) plus—Native Hawaiian population.¹⁵

Diabetes is one of the most serious, common, and costly diseases in Hawai'i and diabetes mellitus is the most common cause of ESRD. Diabetes is a significant leading cause of death in Hawai'i and the prevalence of adult diabetes has been increasing.¹⁶ Per an article from earlier this year quoting the National Kidney Foundation of Hawaii, one hundred sixty thousand (160,000) people in Hawai'i have chronic kidney disease ("CKD"), translating into a prevalence rate which is 30% higher than the national average. Native Hawaiians and Polynesians are at the highest risk, but CKD also strikes Filipinos and Japanese in high numbers. All of those ethnic groups are well-represented in the population of Hawai'i. The article is available at <http://www.kitv.com/news/hawaii/two-hawaii-men-raise-awareness-about-kidney-disease/24706772>. Furthermore, while Hawai'i's kidney failure rate is high, awareness is low. See http://www.staradvertiser.com/newspremium/20130315_Isle_kidney_failure_rate_high_awareness_low.html?id=198421971.

CKD 5 and CKD 4 are the latter stages of kidney disease before ESRD, and a high percentage of CKD 5 patients and many of the CKD 4 patients can be expected to develop ESRD in the next two (2) years. The physician groups that account for approximately 52% of the current admissions to DSI's Aloha, Kapahulu and Honolulu facilities collectively have fifty-three (53) patients with CKD 5 and one hundred and twenty-seven (127) patients with CKD 4 who reside in the zip code in which the Additional Location will be located (96826) as well as in the zip codes contiguous to 96826 (96850, 96823 and 96830 - Capitol District/Kakaako, 96822 - Tantalus, and 96814 - Ala Moana). The other physicians and practices who currently admit patients to DSI's Aloha, Kapahulu and Honolulu facilities can be expected to have similar or larger CKD 5 and CKD 4 patient populations residing in those zip codes. The significant number of individuals with CKD 5 and CKD 4 in the area can be expected to drive the census growth of the Additional Location.

¹² See Population and Economic Projections for the State of Hawaii to 2040 at page 1 - http://files.hawaii.gov/dbedt/economic/data_reports/2040-long-range-forecast/2040-long-range-forecast.pdf.

¹³ See Population and Economic Projections for the State of Hawaii to 2040 at pages 4 and 6.

¹⁴ http://factfinder2.census.gov/faces/nav/jsf/pages/community_facts.xhtml#none

¹⁵ See "Native Hawaiian and Other Pacific Islander alone" at http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_DP_DPDP1

¹⁶ See Hawaii Diabetes Data at <http://health.hawaii.gov/diabetes/home/hawaii-data/>.

2. Existing Facilities in the Primary Service Area Are Operating In Excess of HSFP Utilization Thresholds

As discussed above, there are currently only six (6) dialysis facilities servicing the wider Primary Service Area, DSI's Aloha (1520 Liliha Street, Honolulu, 96817), Honolulu (226 North Kuakini Street, Honolulu, 96817) and Kapahulu (750 Palani Avenue, Honolulu, 96816) facilities and Liberty Dialysis' Kaimuki (3625 Harding Avenue, Honolulu, 96816), Siemens (2226 Liliha Street, Honolulu, 96817) and Sullivan (2230 Liliha Street, Honolulu, 96817) facilities. All of these facilities are providing treatments in excess of the utilization threshold established by HSFP.

The annualized treatments for DSI's dialysis facilities in the Primary Service Area are set forth below:

<u>Facility</u>	<u>Current Census</u>	<u>Stations</u>	<u>Annualized Tx</u>	<u>Tx/station</u>
Aloha	118	20	17,700	885
Honolulu	229	48	34,350	716
Kapahulu	115	24	17,250	719

Based on information provided by Liberty Dialysis in support of its recent CON Application No. 12-28A, the Liberty Dialysis' dialysis facilities in or near the Primary Service Area are also operating at in excess of six hundred (600) treatments per station per year. Although Liberty Dialysis has obtained CON approval (CON Application No. 12-34A) to establish a twenty-four (24) station facility at 4380 Lawehana Street in the Salt Lake/Radford area at the outer fringe of Honolulu, DSI does not believe that the establishment of that facility will significantly reduce the utilization rates of existing facilities in the Primary Service Area. Statements made by Liberty Dialysis in seeking approval of CON Application No. 12-34A acknowledged that the need for dialysis services exceeded that which would be provided by its Salt Lake facility when completed, and that its own capacity calculations undercounted the total projected need for dialysis services in the near future.¹⁸

3. The Additional Location Will Provide a Significant Benefit to ESRD Patients in the Primary Service Area

The Additional Location will provide an additional dialysis option to patients residing in the Primary Service Area. This will result in a reduction in the high utilization of the existing facilities in the Primary Service Area. However, even if there may be Oahu dialysis facilities which are operating below the six hundred (600) treatments per station per year threshold, SHPDA has recognized that sub-optimum utilization is particularly appropriate with respect to dialysis facilities and services since the benefits of improved access, patient compliance with treatment regimen, quality of care, best

¹⁸ See Liberty Dialysis-Hawaii, LLC's Testimony in Opposition to Dialysis Newco Inc.'s Request for Reconsideration of Approval of Certificate of Need Application No. 12-34 A, May 31, 2013.

clinical practice, hospital discharge to outpatient modalities and cost-reduction are so significant.

As dialysis patients receive treatment three (3) times per week, having a close, updated and convenient dialysis facility is beneficial to the lives of these patients. Studies have shown that after only fifteen (15) minutes of travel time to receive dialysis services, morbidity and mortality rates increase, and health related quality of life and treatment adherence decrease. One such study reported in the American Journal of Kidney Disease in 2008 used a sample of twenty thousand nine hundred ninety-four (20,994) hemodialysis patients from the Dialysis Outcomes and Practices Patterns Study ("DOPPS"). Data was collected between 1996 and 2001 covering ten thousand seven hundred seventy-five (10,775) patients, and from 2002 to 2004 including ten thousand two hundred nineteen (10,219) patients. See "Travel Time to Dialysis as a Predictor of Health-Related Quality of Life, Adherence, and Mortality: The Dialysis Outcomes and Practice Patterns Study (DOPPS)," *American Journal of Kidney Diseases*, Vol. 51, No. 4 (April), 2008: pp. 641-650 ("Longer travel time is associated significantly with greater mortality risk and decreased [Health Related Quality of Life] HR-QOL. Exploring opportunities to decrease travel time should be incorporated into the dialysis clinical routine.").²⁰

In the DOPPS study, patients answered a question regarding their one-way travel time to reach their dialysis clinic, with the options for response being fifteen (15) minutes or less, from sixteen (16) to thirty (30) minutes, from thirty-one (31) to sixty (60) minutes, and longer than sixty (60) minutes. Table 3 in the study reflects that HR-QOL is decreased even between those patients with a travel time of fifteen (15) minutes or less and those with a travel time of sixteen (16) to thirty (30) minutes.

A longer travel time was also seen to result in increased patient mortality. The crude (unadjusted) mortality rate increased from 12.0/100 patient-years in patients traveling fifteen (15) minutes or less to 15.0/100 patient-years in those traveling longer than sixty (60) minutes.

Traffic in the metro Honolulu area often results in long drive times for patients to and from their dialysis facility. In addition, many patients rely on private services such as Handivan for their transportation. Patients utilizing these services must endure significantly longer treatment days because of the ride-share nature of these services with multiple pickup and delivery stops and because the patients are tied to the service's scheduled pickup times. The establishment of the Additional Location will alleviate many of the travel time issues faced by patients residing in the 96826 zip code and those patients who live closer to the proposed Additional Location than to their current facility. Reducing travel time for this not-insignificant pool of patients will avoid many of the adverse consequences associated with travel to and from dialysis.

²⁰ The study is available at:

<http://www.cmkn.nhs.uk/attachments/article/99/Port%20et%20al%20%202008%20reprint.pdf>. Health Related Quality of Life ("HR-QOL") includes factors such as physical functioning, mental health, burden of disease, effects of disease, symptoms of disease, quality of social interactions, sexual functioning, work status, sleep, cognitive function, social support, staff encouragement, and satisfaction with care. See Table 3 in the DOPPS study.

Moreover, according to testimony submitted by The Queen's Health Systems in support of another CON application:

Native Hawaiians have the poorest health status, lowest life expectancy, and highest incidence of diabetes among Hawaii's major ethnic groups. Many patients with diabetes can deteriorate to kidney failure, thereby requiring hemodialysis. The Queen's Medical Center (QMC) experiences delays in discharge processing, especially for new patients, for dialysis treatment in a clinic. The most prominent cause for this delay is that existing facilities are filled to capacity, unable to accommodate new referrals. At QMC, there is an average of four (4) to six (6) new hemodialysis patients per week that need to find placement in an outpatient facility. A patient remains hospitalized until outpatient services are secured, unnecessarily utilizing critical bed space and adding to the overall cost of healthcare.²¹

Given the shortage of facilities and services in the Primary Service Area, the Additional Location will have a very positive impact on the ability of patients to access the services it will provide to the community.

Although the Additional Location primarily is intended to serve the dialysis needs of residents residing in the Primary Service Area, DSI will make its services available to all individuals with ESRD Oahu-wide, including low-income individuals, racial and ethnic minorities, women, individuals with disabilities, other underserved groups and the elderly. DSI has a commitment to providing care to individuals, regardless of their ability to pay.

Based on the foregoing, HSFP utilization threshold levels are met by this project.

c) Quality of Service/Care

DSI is a leading dialysis provider in the United States. DSI is the fifth largest for profit dialysis provider in the U.S. and owns and operates ninety-one (91) dialysis facilities in twenty-two (22) states. DSI provides dialysis services to over six thousand eight hundred (6,800) individuals with ESRD. DSI's standards of patient care are established through medical protocol guidelines developed and monitored by DSI's Medical Advisory Board. These protocols are established using the best practices across DSI's network of affiliated nephrologists.

DSI's parallel priorities are to achieve optimal patient outcomes and ensure patient satisfaction. DSI is committed to quality care, benefitting patients' quality of life and longevity, and contributing to the company's financial strength. This commitment results in higher survival rates and reduced hospital stays.

²¹ Page 2, paragraph 7 - <http://hawaii.gov/shpda/certificate-of-need/applications-and-decisions/decisions/shd1401a>; see Hawaii Diabetes Report 2010 for supportive source information - http://www.hawaiihealthmatters.org/javascript/htmleditor/uploads/DOH_DiabetesReport2010_Lo.pdf

The Chairman of DSI's Medical Advisory Board is actively involved in the operations of DSI's dialysis facilities, from training and protocol development to purchasing and costs management opportunities. The substantial involvement of the Chairman and the other members of the Medical Advisory Board, each of whom is a prominent nephrologist, has been a significant factor in: (1) attracting new medical directors; and (2) maintaining strong relationships with existing attending physicians. DSI's physician leadership also allows it to achieve physician consensus among the facilities, which enhances the ability to achieve a high level of standardization among DSI's facilities. DSI measures clinical outcomes using industry standards developed by the National Kidney Foundation and the CMS ESRD Network Program.

DSI provides training for all members of its clinical care team and nurses and patient care technicians must be licensed or certified, as applicable. DSI maintains a robust education department which offers continual educational and training opportunities for employees. DSI maintains patient/staff ratios consistent with those in the dialysis industry in general.

Registered Nurses	1 per 12 patients
Patient Care Tech	1 per 4 patients
Dietician	1 per 100 patients
Social Worker	1 per 100 patients

DSI provides quality dialysis services to its patients and is in full compliance with all applicable federal and state regulations at all of its dialysis centers in Hawai'i. All DSI Hawai'i dialysis facilities are CMS certified, and observe the standards set by both the CDC and CMS in their operations. DSI's quality improvement program was developed in accordance with CMS and the National Kidney Foundation's Disease Outcomes Quality Initiative guidelines.

All DSI nurses are licensed in Hawai'i and all patient care technicians are nationally certified as required by CMS.

DSI already operates or owns a majority interest in nine (9) dialysis facilities on Oahu. The Additional Location will utilize the same clinical policies, procedures and protocols that are utilized in DSI's other facilities. In addition, the physicians of Nada, Ono & Ka'anehe, LLP will serve as medical directors of the Additional Location. This physician practice group already serves as medical directors for six (6) of DSI's facilities on Oahu, thereby assuring the same level of clinical oversight as is provided in many of DSI's other facilities.

d) Cost and Finances

The total cost of developing the Additional Location will be approximately \$3,714,850. Of this amount, \$1,810,917 will be allocated to the site lease, \$414,661 for movable equipment, \$139,742 for fixed equipment and \$1,349,530 for leasehold improvements to the site. The Additional Location project will be financed with DSI's cash on hand. The estimated revenue and cost projections for the first and third full years of operation are:

	Projected 1st Full Year of Operations	Projected 3rd Full Year of Operations
Revenue	\$957,132	\$3,785,578
Bad Debt	\$44,028	\$189,279
NET REVENUE	\$913,104	\$3,596,299
Labor Expense	\$346,750	\$1,168,290
Drug Expense	\$154,418	\$674,808
Other Operating Expenses	\$572,597	\$597,524
TOTAL EXPENSES	\$1,073,765	\$2,440,622
Depreciation	\$184,099	\$184,099
NET INCOME	(\$344,760)	\$971,578

e) Relationship to the Existing Health Care System

As the existing dialysis facilities in the Primary Service Area are each operating in excess of the thresholds established by HSFP, the establishment of the Additional Location will positively impact the health care system on Oahu by providing additional dialysis capacity and options for individuals with ESRD. The proposed project will have a positive impact on the state's existing healthcare system because it will help fill the gap between the current availability of hemodialysis services and the increasing need for more services. The proposed project will also have a positive impact on the capacity to discharge patients from area hospital facilities as well. DSI will collaborate with other providers, community groups and government organizations in the Primary Service Area to ensure quality care for our mutual patients and in support of our shared health goals.

DSI has been a part of the Oahu community since 2012 and looks forward to continuing to provide services that address the island's current and future needs.

f) Availability of Resources

DSI will fund the Additional Location with cash on hand.

As DSI already operates or owns a majority interest in nine (9) dialysis facilities on Oahu, DSI anticipates filling a portion of the staffing positions for the Additional Location from its existing labor force, and the remainder through recruiting efforts in Hawai'i through job fairs, advertising and open houses. In addition, DSI maintains relationships with several national recruiting firms who help identify and/or supply nurses, patient care technicians and other personnel for DSI's other outpatient dialysis facilities throughout the country.

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.