



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

RECEIVED

20 JAN 21 P 1:05

ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: #20-01A
To be assigned by Agency

Date of Receipt: ST HLTH PLNG & DEV. AGENCY

APPLICANT PROFILE

Project Title: Establishment of additional chronic renal dialysis location and services in Wailuku, HI

Project Address: 58 Maui Lani Pkwy (Building B), Wailuku, HI 96732

Applicant Facility/Organization: USRC Wailuku, LLC

Name of CEO or equivalent: Stephen M. Pirri

Title: President

Address: 5851 Legacy Circle, Suite 900, Plano, Texas 75024

Phone Number: 214-736-2704 Fax Number: 214-736-2701

Contact Person for this Application: Thomas Weinberg

Title: Chairman

Address: 5851 Legacy Circle, Suite 900, Plano, Texas 75024

Phone Number: 214-736-2730 Fax Number: 214-736-2731

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: [Handwritten Signature]

Date: December 31, 2019

Name (please type or print): Thomas Weinberg

Title (please type or print): Chairman

RECEIVED

20 JAN 21 P1 05

ST HLTH PLNG & DEV. AGENCY

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: _____
- Windward O'ahu: _____
- West O'ahu: _____
- Maui County: _____ X
- 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 – Letter of Intent to Lease Space at 58 Maui Lani Pkwy (Building B), Wailuku, HI 96732

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 County of Maui, Department of Public Works Development Services Administration
 Certificate of occupancy from County of Maui, Department of Public Works Development Services Administration
 Fire Marshall's Approval from County of Maui, Fire Prevention Bureau
 Certification from the Centers for Medicare and Medicaid Services

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

USRC Wailuku, LLC is a manager-managed limited liability company with one manager: Thomas L. Weinberg, 5851 Legacy Circle, Suite #900, Plano, Texas 75024, 214-736-2730

RECEIVED

USRC Wailuku, LLC's officers include:

20 JAN 21 P1 06

Thomas Weinberg, Chairman
5851 Legacy Circle, Suite #900
Plano, Texas 75024
214-736-2730

ST HLTH PLNG
& DEV. AGENCY

Steve Pirri, President
5851 Legacy Circle, Suite #900
Plano, Texas 75024
214-736-2704

James D. Shelton, Vice President and Treasurer
5851 Legacy Circle, Suite #900
Plano, Texas 75024
214-736-2740

David Eldridge, Secretary
5851 Legacy Circle, Suite #900
Plano, Texas 75024
214-736-2742

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 – See "Certificate of Formation" Attachment B
- By-Laws – See "Company Agreement" Attachment C
- Partnership Agreements – N/A
- Tax Key Number (project's location) – (2)-3-8-007: 121

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					

RECEIVED

20 JAN 21 P1:06

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			

RECEIVED

6. PROJECT COSTS AND SOURCES OF FUNDS

20 JAN 21 P 1 06

A. List All Project Costs:

1	Land		
2	Construction Contract	\$	4,420,881
3	Fixed Equipment	\$	463,719
4	Moveable Equipment	\$	584,562
5	Financing Costs (Interest Expense years 1-5)	\$	1,075,025
6	FMV of assets, Rent (PV 10 years)	\$	5,016,000
7	Other (Impact fees)	\$	10,000
	Total Project Costs	\$	11,570,187

B. Source of Funds

1.	Cash		
2.	State Appropriations		
3.	Other Grants		
4.	Fund Drive		
5.	Debt and financing cost		\$6,554,187
6.	Other: Fair market value of lease payments (10 year lease)		\$5,016,000

TOTAL SOURCE OF FUNDS: \$11,570,187

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 24 station chronic renal dialysis location and services (HAR § 11-186-5(4)(A)).

RECEIVED

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:

20 FEB 18 P 1:17

- a) Date of site control for the proposed project: January 6, 2020
- b) Dates by which other government approvals/permits will be applied for and received:
 - 1. Building permits applied – February 28, 2020
 - 2. Building permits received – August 28, 2020
- c) Dates by which financing is assured for the project: December 2019
- d) Date construction will commence: September 2020
- e) Length of construction period: 160 days
- f) Date of completion of the project: April 2021
- g) Date of commencement of operation: June 2021

STATE HEALTH PLAN
DEVELOPMENT AGENCY

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

USRC Wailuku, LLC ("USRC Wailuku") seeks approval to establish an additional location for its dialysis services, located in the Wailuku community at 58 Maui Lani Pkwy (Building B), Wailuku, HI 96732 (the "Additional Location"). The Additional Location will offer a full range of dialysis services and modalities, including 24 hemodialysis stations and a 6-training room, home dialysis program. USRC Wailuku is a wholly owned

RECEIVED

20 FEB 18 01:17
STATE HEALTH PLAN
MAUI AGENCY

subsidiary of Dialysis Newco, Inc. ("DSI") and DSI is a wholly owned subsidiary of U.S. Renal Care, Inc. ("USRC"). USRC, through DSI will be the owner of USRC Wailuku and will manage the clinic's day to day operations under a Management Agreement between USRC and USRC Wailuku. The establishment and operation of the Additional Location will enhance USRC's ability to continue to provide high quality and accessible dialysis services to individuals with End Stage Renal Disease ("ESRD") on Maui, especially in Wailuku.

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 Hawaii'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 the HSFP, USRC (hereinafter refers to USRC and USRC Wailuku collectively) will strive to maintain a high standard of quality care while also being focused on cost-effective measures.

The services provided by the clinic will include health education, nutrition education and care education for patients and their families. By maintaining and 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 application will support the general principles of the Statewide Health Coordinating Council ("SHCC").²

The application, including with respect to the home dialysis program, will advance the MAUI COUNTY/TRI-ISLE SAC priorities of (i) establishing health promotion and disease prevention as a primary focus while promoting personal responsibility for optimal health, (ii) increasing home and community-based services and (iii) promote the paradigm shift of long term care -- the notion that home and community-based services encompasses more than nursing facilities.³

¹ HSFP at page 15 (<http://health.hawaii.gov/shpda/files/2013/07/shhsfp09.pdf>).

² See HSFP at page 33.

³ See HSFP at page 36.

RECEIVED

Patient counts and prevalence rates for ESRD are highest among those individuals age 65 and older.⁴ 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 ensuring continued 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.

USRC 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 USRC's nutrition guidelines and support to patients are all based on industry standards and scientifically-based knowledge.
- USRC aims 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, and the National Renal Administrators Association.
- A vital part of USRC's 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.

Hawaii Revised Statute §323D-12 mandates that HSFP must include standards for utilization of health care facilities. Capacity (utilization) thresholds for certain standard categories of health care services are established to guide the initial determination of need for a service area. 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 600 treatments per unit 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.⁵ In addition, 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.⁶

The Primary Service Area for the Additional Location includes the Maui communities of Wailuku, Kihei, and Pukalani. Currently there are only two dialysis facilities in that area: FMC/Liberty Maulani-Wailuku (2018 232 patient census times 150 treatments per station divided by 53 stations = 657 treatments per station) and Rainbow Wailuku (2018 77 patient census times 150 treatments per station divided by 11 stations

⁴ See United States Renal Data System at Figure 1.12 Prevalence by age - https://www.usrds.org/2016/view/v2_01.aspx.

⁵ See HSFP at page 29.

⁶ See HSFP at pages 31-32.

= 1,050 treatments per station). Both of those facilities are providing treatments in excess of the utilization threshold established by HSFP.

The Additional Location will provide another 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 Area. In addition, the added stations in the Primary Service Area will allow residents in the Primary Service Area to obtain dialysis closer to their homes without having to travel to Kahana (FMC/Liberty Kahana: 2017 50 patient census times 150 treatments per station divided by 12 stations = 625 treatments per station; 2018 49 patient census times 150 treatments per station divided by 24 stations = 306 treatments per station) or Lahaina (Rainbow Lahaina: 2018 20 patient census times 150 treatments per station divided by 6 stations = 500 treatments per station).⁷ As dialysis patients receive treatment three times per week, having a close, updated and convenient dialysis facility is beneficial to the lives of these patients.

In approving CON Application No. 15-07A, SHPDA referenced testimony that "The HSFP states that utilization thresholds may be modified to allow for suboptimum utilization if a proposal's benefits clearly outweigh [sic] the costs to the community of duplicating or under-using services, facilities or technologies. The HSFP further states 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. Best practice requires minimizing the distance that a dialysis patient must travel for treatment in order to reduce the incentive to miss treatment sessions."⁸

SHPDA has further indicated that, irrespective of the actual number and location of dialysis facilities outside of the immediate area of the proposed location which may be operating below the 600 treatments per station per year threshold, sub-optimum utilization outside of the immediate area 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.⁹ Simply put, no responsible physician would willingly refer a Wailuku patient for treatment three times per week outside of Wailuku and its adjacent communities.

USRC projects that the utilization of the Additional Location will meet HSFP's minimum utilization of 600 treatments per station by the third year of operation. Even if USRC's projection does not achieve such utilization, as discussed above, suboptimum utilization is acceptable, where, as here, the proposal's benefits clearly outweigh the costs to the community. Moreover, as discussed below, the population growth in the Primary

⁷ Based on CMS cost report that dialysis facilities file before May annually. See raw data at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Renal-Facility-265-2011-form>.

⁸ See letter dated August 3, 2015 from SHPDA to Liberty at sections 4 and 5, page 1 - <http://health.hawaii.gov/shpda/files/2015/08/shd1507a.pdf>.

⁹ See letter dated March 19, 2013 from SHPDA to Liberty at sections 10, 12-13 and 18-19, pages 2-4 - <http://hawaii.gov/shpda/certificate-of-need/applications-and-decisions/decisions/shd1228a>.

RECEIVED

20 FEB 20 10 33 51

Service Area and the prevalence of diabetes in that population are expected to lead to a significant increase in the need for dialysis services. USRC projects a year 1 ending census at the Additional Location of 49 (translating into 306 treatments per station) and a year 3 ending census of 96 (translating into 600 treatments per station). As such, HSFP utilization threshold levels are met by this project.

ST HLTH PLNG
& DEV. AGENCY

b) Need and Accessibility

As discussed above, the Additional Location will meet the utilization thresholds as required by HSFP. In addition, as evidenced by the utilization of the other facilities in the Primary Service Area, there is need for the Additional Location. Further, upon commencement of operations, patient access to dialysis services in the Primary Service Area will be improved. The clinic will provide crucial services for ESRD patients who would die without dialysis or successful kidney transplants.

Although the Additional Location primarily is intended to serve the dialysis needs of residents residing in Wailuku and its adjacent communities, USRC will make its services available to all individuals with ESRD Maui County-wide, including low-income persons, racial and ethnic minorities, women, persons with disabilities, and the elderly.

Diabetes is one of the most serious, common, and costly diseases in Hawaii. It is a leading cause of death in Hawaii¹⁰ and the prevalence of adult diabetes has been increasing.¹¹ The Hawaii Department of Health has found that one of the higher rates of diabetes has been occurring in the Wailuku area.¹²

c) Quality of Service/Care

USRC is a leading dialysis provider in the United States. USRC is the third largest for profit dialysis provider and owns and operates over 300 dialysis facilities in 33 states and the U.S. Territory of Guam. USRC also provides dialysis services to over 24,000 individuals with End Stage Renal Disease. USRC's standards of patient care are established through medical protocol guidelines developed and monitored by USRC's Medical Advisory Board. These protocols are established using the best practices across our network of affiliated nephrologists. USRC is committed to quality care, benefitting patients' quality of life and longevity which results in higher survival rates and reduced hospital stays.

Mary Dittrich, MD, USRC Chief Medical Officer, is actively involved in the training and protocol development of USRC's dialysis facilities. The involvement of Dr. Dittrich and other nephrology members of the USRC Medical Advisory Board have been a significant factor in: (1) attracting new medical directors and (2) maintaining strong

¹⁰ See <http://health.hawaii.gov/diabetes/>.

¹¹ See <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/HI?edition-year=2016>.

¹² See Hawaii Diabetes Report 2010 - <http://health.hawaii.gov/diabetes/files/2013/10/2010diabetesreport.pdf> at page 15.

RECEIVED

relationships with existing physicians. USRC'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 our facilities. USRC measures clinical outcomes using industry standards developed by the National Kidney Foundation and the ESRD Network.

20 FEB 20 10 33 51

ST HLTH PLNG

USRC provides training for all members of its clinical care team and nurses and patient care technicians must be licensed or certified, as applicable. USRC maintains a robust education department which offers continual educational and training opportunities for employees. USRC 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

USRC 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 Hawaii. All USRC Hawaii dialysis facilities are CMS certified, and observe the standards set by both the CDC and CMS in their operations. USRC's quality improvement program was developed in accordance with CMS and the National Kidney Foundation's Disease Outcomes Quality Initiative guidelines.

All USRC nurses are licensed in Hawaii and all patient care technicians are nationally certified as required by CMS.

d) Cost and Finances

RECEIVED

The total cost of developing the Additional Location will be approximately \$11,570,187. Of this amount, \$4,420,881 is pegged for leasehold improvements on the site, \$463,719 for fixed equipment, \$584,562 is for movable equipment, \$1,075,025 for financing costs, \$5,016,000 for 10 year lease payments, and \$10,000 for impact fees.

The estimated revenue and cost projections for the first and third full years of operation are set forth below. The 3,768 and 12,600 treatment numbers (and therefore all related numbers in the rest of those columns) are accurate even given that (in the last paragraph of section a beginning on the bottom of page 9) USRC states that "USRC projects a year 1 ending census at the Additional Location of 49 (translating into 306 treatments per station) and . . . a year 3 ending census of 96 (translating into 600 treatments per station)." USRC notes that multiplying the treatments per station numbers by 24 stations generates treatments of 7,344 (versus 3,768) and 14,400 (versus 12,600). The seeming discrepancy is due to the timing of providing dialysis services in each of the given years as the patient census increases from the 1st month through the 12th month of each respective operational year.

	Year 0	Year 1	Year 2	Year 3
			Total \$	
HD Treatments	0	3,768	9,480	12,600
PD Treatments	0	1,788	5,268	7,728
Total Treatments	0	5,556	14,748	20,328
<i>Commercial Mix</i>	<i>NM</i>	<i>36%</i>	<i>27%</i>	<i>25%</i>
HD Revenue Before Bad Debt Expense	\$0	\$1,639,944	\$3,872,635	\$5,103,980
PD Revenue Before Bad Debt Expense	\$0	\$757,476	\$2,113,310	\$3,103,912
Bad Debt Expense	0	74,320	185,564	254,445
Net Revenue	\$0	\$2,323,100	\$5,800,381	\$7,953,447
HD Salaries and Wages	\$18,337	\$505,811	\$1,037,073	\$1,339,247
HD Benefits	3,667	101,162	207,415	267,849
HD Medical Supplies	0	67,233	174,228	238,516
HD Medications	0	137,474	356,251	487,703
HD Other Exp	0	203,245	526,690	721,031
PD Salaries and Wages	0	155,921	363,998	509,986
PD Benefits	0	31,184	72,800	101,997
PD Medical Supplies	0	209,726	636,454	961,670
PD Medications	0	60,267	182,892	276,346
PD Other Exp	0	80,761	245,085	370,318
Medical Director Fees	0	87,500	100,000	100,000
Rent	0	501,600	501,600	501,600
Total Facility Expenses	\$47,254	\$2,141,885	\$4,404,486	\$5,876,264
Facility EBITDAM	(\$47,254)	\$181,215	\$1,395,895	\$2,077,183
<i>% Margin</i>	<i>NM</i>	<i>8%</i>	<i>24%</i>	<i>26%</i>

RECEIVED

e) Relationship to the Existing Health Care System 20 JAN 21 P1 06

As many of the existing dialysis facilities in the Primary Service Area are operating in excess of the thresholds established by HSFP, the establishment of the Additional Location will positively impact the health care system in Maui County by providing additional dialysis capacity and options for individuals with ESRD. USRC will collaborate with other providers, community groups and government organizations in the Primary Service Area to ensure quality care for our mutual patients and support for our shared health goals.

f) Availability of Resources

USRC will initially fund the Additional Location with cash on hand. The net working capital is required to cover the initial expenses during the beginning month of operations. USRC will then lend necessary amounts to USRC Wailuku for its costs and expenses. USRC Wailuku will agree to repay the principal together with interest and loan charges on the aggregate unpaid principal balance of the loan and assume the remaining obligations under USRC Wailuku's lease for the clinic.

As USRC already operates dialysis facilities in Hawaii, USRC anticipates filling a portion of the staffing positions for the Additional Location from its existing labor force, and the remainder through recruiting efforts in Hawaii through job fairs, advertising and open houses. If necessary, USRC has access to national recruiting firms that will help identify and/or supply nurses, patient care technicians and other personnel for the facility.

RECEIVED

10. **Eligibility to file for Administrative Review.** This project is eligible to file for Administrative review because: (Check all applicable) 20 JAN 21 P1 06

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. ST. CLAIR COUNTY
& DEV. AGENCY

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.