



HAWAI'I STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: # 18-11A Date of Receipt:
To be assigned by Agency

APPLICANT PROFILE

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

Project Address: 86-120 Farrington Hwy, Suite Nos. B211 and B212, Waianae, HI 96792

Applicant Facility/Organization: USRC Waianae, LLC

Name of CEO or equivalent: Steve 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.

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Signature

September 13, 2018
Date

Steve Pirri
Name (please type or print)

President
Title (please type or print)

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

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

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2. PROJECT LOCATION INFORMATION

A. Primary Service Area(s) of Project: (please check all applicable)

- Statewide: _____
- O'ahu-wide: _____
- Honolulu: _____
- Windward O'ahu: _____
- West O'ahu: _____ X
- 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 – Waianae Mall Letter of Intent

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

USRC Waianae, LLC is a manager-managed limited liability company with one (1) manager: Thomas L. Weinberg, 5851 Legacy Circle, Suite #900, Plano, Texas 75024, 214-736-2730

USRC Waianae, LLC's officers include:

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

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

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D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:

- 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) (1) 8-6-001-050

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					

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5. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
TOTAL			

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6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:

1.	Land Acquisition	
2.	Construction Contract	<u>\$2,158,530</u>
3.	Fixed Equipment	<u>\$173,661</u>
4.	Movable Equipment	<u>\$570,990</u>
5.	Financing Costs	<u>\$732,729</u>
6.	Fair Market Value of assets acquired by lease, rent, donation, etc. (present value of 10 year lease payments)	<u>\$2,956,812</u>
7.	Other – Impact Fees	<u>\$50,000</u>

TOTAL PROJECT COST: \$6,642,722

B. Source of Funds

1.	Cash	_____
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt and financing cost	<u>\$3,685,910</u>
6.	Other: Fair market value of lease payments (10 year lease)	<u>\$2,956,812</u>

TOTAL SOURCE OF FUNDS: \$6,642,722

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)).

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: May 10, 2018
- b) Dates by which other government approvals/permits will be applied for and received:
- Building permits applied – November 2018
 - Building permits received – December 2018
 - Upon approval of this CON application, an initial CMS-855A Enrollment Application for Institutional Providers will be submitted to apply for Medicare Certification
- c) Dates by which financing is assured for the project: September, 2018
- Financing has already been secured. Anticipated joint-venture partners will contribute their pro-rata share of the necessary working capital to fund the clinic's operations. USRC Waianae, LLC has secured a loan from U.S. Renal Care, Inc. for the balance of the necessary capital related to the project. The joint-venture partners will be financially responsible for their pro-rata guarantee of the loan amount to U.S. Renal Care, Inc.
- d) Date construction will commence: January/February 2019
- e) Length of construction period: 6 months
- f) Date of completion of the project: July 2019
- g) Date of commencement of operation: August 2019

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Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the certificate of need.

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9. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the certificate of need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

- 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 Waianae, LLC ("USRC-W") seeks approval to establish an additional location for its dialysis services, located in the West Oahu community of Waianae at the Waianae Shopping Mall at 86-120 Farrington Hwy, Waianae, HI 96792 (the "Additional Location"). The Additional Location will offer a full range of dialysis services and modalities, including 24 hemodialysis stations and a home dialysis program. USRC-W is a wholly owned 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-W and will manage the clinic's day to day operations under a Management Agreement between USRC and USRC-W. As a result, the clinic will be operated under the same USRC policies, procedures and protocols as are currently utilized at the other USRC clinics on Oahu. The medical director of the clinic when operational will be Rick Hayashi, MD (Nada, Ono, Ka'anehe, Solomon & Hayashi, LLP). 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 Oahu, particularly in West Oahu.

The clinic will be operated in a manner similar to USRC's other outpatient dialysis clinics on Oahu. Similarly, the clinic will utilize USRC's existing clinical policies, procedures and systems.

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.

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- 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-W 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") and the priorities of the West Oahu Subarea Council ("SAC").²

The application will advance the West Oahu Subarea Health Planning Council priorities to have adequate access and/or improve education and increase preventive medicine. 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 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 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

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

² See HSFP at pages 33, 35-36.

³ See United States Renal Data System at Figure 1.12 Prevalence by age - https://www.usrds.org/2016/view/v2_01.aspx

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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.

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 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.⁴ 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.⁵

The Primary Service Area for the Additional Location will encompass the West Oahu communities of Waianae and Makaha and perhaps Nanakuli and Lualualei/Maili. Currently there are only four dialysis facilities servicing the Primary Service Area, USRC's Kapolei facilities (555 Farrington Highway, Kapolei, 96707 and 889 Kamokila Boulevard, Kapolei, 96707) and Liberty Dialysis' Leeward (91-2137 Fort Weaver Road, Ewa Beach, 96706) and Waianae (86-080 Farrington Highway, Waianae, 96792) facilities. All of these facilities are providing treatments in excess of the utilization threshold established by HSFP. USRC's 555 Farrington Highway facility annualized treatments are currently 23,193, or 725 treatments per station. USRC's 889 Kamokila Boulevard facility annualized treatments are currently 10,450, or 435 treatments per station. Based on information provided by Liberty Dialysis in support of its CON Application No. 12-28A, Liberty Dialysis' Leeward facility is providing approximately 961 treatments per station and Liberty Dialysis' Waianae facility is providing approximately 651 treatments per station.

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. In addition, the additional 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 Kapolei, Waipahu or Honolulu, the next closest areas with facilities. 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. Moreover, the majority of those next closest facilities, including Liberty Dialysis' Waipahu facility (94-450 Mokuola Street, Waipahu, 96797) and USRC's Pearlridge facility (98-1005 Moanalua Road, Aiea, 96701) are operating far in excess of 600 treatments per station.

⁴ See HSFP at page 29.

⁵ See HSFP at pages 31-32.

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In approving CON Application No. 15-07A, SHPDA noted that "Utilization at every facility except USRC's Koolau Dialysis Center exceeds the HSFP threshold."⁶ USRC's Koolau facility is located outside of the Primary Service Area on the Windward side of Oahu. SHPDA further 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."

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SHPDA has further acknowledged that, irrespective of the actual number and locations of Oahu dialysis facilities outside of the Primary Service Area which are operating below the 600 treatments per station per year threshold, sub-optimum utilization outside of the Primary Service 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.⁸ Simply put, no responsible physician would willingly refer a West Oahu Waianae and Makaha patient for treatment three times per week outside of the Primary Service Area.

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. USRC anticipates that some of the individuals currently utilizing USRC's Kapolei facilities will transfer to the Additional Location once it becomes operational. Even if we assume as many as 20 patients transfer, USRC's existing Kapolei facilities will still be operating in excess of HSFP utilization thresholds. The decrease of 20 patients translates into 3,000 fewer treatments than the current 33,643 treatments per year. USRC expects patients to transfer to the Additional Location from other facilities in the Primary Service Area as well, but given the number of treatments per station currently being provided at those other facilities, USRC is confident that none of those other facilities will fall below the minimum utilization threshold, even assuming no additional patients are added. However, as discussed below, the population growth in the Primary 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 30 (translating into 188 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.

b) Need and Accessibility

⁶ See letter dated August 3, 2015 from SHPDA to Liberty ("LETTER") at section 3, page 1 - <http://health.hawaii.gov/shpda/files/2015/08/shd1507a.pdf>.

⁷ LETTER at sections 4 and 5, page 1.

⁸ 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>.

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 transplant.

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

The West Oahu Primary Service Area is expected to experience population growth. The resident population of the City and County of Honolulu is projected to increase at an annual rate of 0.4 percent from 2010 to 2040.⁹

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

c) Quality of Service/Care

USRC is a leading dialysis provider in the United States. USRC is the third (3rd) largest for profit dialysis provider and owns and operates over three-hundred (300) dialysis facilities in thirty-three (33) states and the U.S. Territory of Guam. USRC also provides dialysis services to over twenty-four thousand (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.

Stan Lindenfeld, MD, USRC acting Chief Medical Officer, is actively involved in the training and protocol development of USRC's dialysis facilities. The involvement of Dr. Lindenfeld and other nephrology members of the USRC Medical Advisory Board has been a significant factor in: (1) attracting new medical directors and (2) maintaining strong relationships with existing physicians. USRC's physician leadership also allows it

⁹ 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.

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.

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.

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.

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d) Cost and Finances

The total cost of developing the Additional Location will be approximately \$6,642,722. Of this amount, \$570,990 is pegged for movable equipment, \$732,729 for financing costs, \$173,661 for fixed equipment, \$2,158,530 for leasehold improvements to the site, \$50,000 for impact fees, and \$2,956,812 for 10 year lease payments. 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	906,900	3,932,280
Bad Debt	27,207	117,968
NET REVENUE	879,693	3,814,312
Labor Expense	268,500	1,278,000
Drug Expense	103,104	492,389
Other Operating Expenses	737,089	1,208,728
TOTAL EXPENSES	1,108,693	2,979,117
Depreciation	590,636	605,636
Interest Expense	112,766	177,928
NET INCOME	(932,402)	51,631

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e) Relationship to the Existing Health Care System

As 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 on Oahu 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.

USRC, through DSI, has been a part of Waianae/Makaha/West Oahu since 2012 and looks forward to continuing to provide services that address the community's current and future needs.

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-W for its costs and expenses. USRC-W 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-W's lease for the clinic.

As USRC already operates dialysis facilities on Oahu, 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 who will help identify and/or supply nurses, patient care technicians and other personnel for the facility.

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.

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