



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: # 19-18A Date of Receipt:
To be assigned by Agency

APPLICANT PROFILE

Project Title: Establishment of additional chronic renal dialysis location and services in Hilo, Hawaii

Project Address: 111 E. Puainako Street, Suite No. 655, Hilo, HI 96720

Applicant Facility/Organization: USRC Hilo, LLC

Name of CEO or equivalent: Steven 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

October 22, 2019
Date

Thomas Weinberg
Name (please type or print)

Chairman
Title (please type or print)

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

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

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2. PROJECT LOCATION INFORMATION

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

- Statewide: _____
- O`ahu-wide: _____
- Honolulu: _____
- Windward O`ahu: _____
- West O`ahu: _____
- Maui County: _____
- Kaua`i County: _____
- Hawai`i County: X

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 – New Lease Proposal dated October 17, 2019 signed by Brookfield Properties Retail with reference to Dialysis Newco, Inc. as tenant (parent entity of applicant USRC Hilo, LLC and with various "U.S. Renal Care" Hawaii trade name dbas)

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 Hawaii County
Certificate of occupancy
Certification from the Centers for Medicare and Medicaid Services

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

USRC Hilo, 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

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USRC Hilo, LLC's officers include:

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

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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) (3) 2-2-047:001 and 006

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.

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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

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A. List All Project Costs:

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1	Land		
2	Construction Contract	\$	4,986,040
3	Fixed Equipment	\$	227,985
4	Moveable Equipment	\$	779,975
5	Financing Costs (Interest Expense years 1-5)	\$	1,714,824
6	FMV of assets, Rent (PV 10 years)	\$	7,488,000
7	Other (Impact fees)	\$	10,000
	Total Project Costs	\$	15,406,824

B. Source of Funds

1.	Cash	
2.	State Appropriations	
3.	Other Grants	
4.	Fund Drive	
5.	Debt and financing cost	\$7,918,824
6.	Other: Fair market value of lease payments (10 year lease)	\$7,488,000

TOTAL SOURCE OF FUNDS: \$15,406,824

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

8. **IMPLEMENTATION SCHEDULE** RECEIVED 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:

- 19 OCT 22 AM 51
- a) Date of site control for the proposed project: October 2019
- b) Dates by which other government approvals/permits will be applied for and received. AGENCY
- Building permits applied January 2020
 - Building permits received July 2020
 - 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: October 2019
- d) Date construction will commence: August 2020
- e) Length of construction period: 120 calendar days
- f) Date of completion of the project: February 2021
- g) Date of commencement of operation: July 2021

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

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.

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- 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.

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Executive Summary

USRC Hilo, LLC ("USRC-H") seeks approval to establish an additional location for its dialysis services, located in the Hilo community at 111 E. Puainako Street, Suite No. 655, Hilo, HI 96720 (the "Additional Location"). The Additional Location will offer a full range of dialysis services and modalities, including 36 hemodialysis stations and a home dialysis program. USRC-H 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-H and will manage the clinic's day to day operations under a Management Agreement between USRC and USRC-H. 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 the Big Island, especially in Hilo.

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 and USRC-H will strive to maintain a high standard of quality care while also being focused on cost-effective measures.

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

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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 will advance the HSAC priority of increasing the number of, improving access to, and bolstering the quality of health care facilities.³ 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 and USRC-H acknowledge and represent:

- 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 and USRC-H 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, and the National Renal Administrators Association.
- A vital part of USRC and USRC-H'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

² See HSFP at page 33.

³ See HSFP at pages 33-34.

⁴ 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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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 will include the Big Island communities of Hilo, Pepeekeo, and Keaau. Currently there is only one dialysis facility in that immediate area: Liberty Dialysis Hawaii's "Hilo Dialysis" Center (1384 Kinooole Street, Hilo, HI 96720). The Additional Location will provide an additional dialysis option to patients residing in the Primary Service Area.

Liberty Dialysis-Hawaii LLC recently represented that "the Hilo Dialysis Center operates at a high capacity, offering six shifts per day [which] equals more than 799 treatments per station annually, well above the utilization threshold established by the HSFP."⁷ SHPDA has since approved a separate Liberty Dialysis outpatient dialysis facility in the area (85 Lanikaula and 85 West Lanikaula Streets, Hilo, HI 96720)⁸ which is scheduled to commence operation in 2022.⁹

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."¹⁰

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.¹¹ Simply put, no responsible physician would willingly refer a Hilo patient for treatment three times per week outside of Hilo and its adjacent communities.

⁵ See HSFP at page 29.

⁶ See HSFP at pages 31-32.

⁷ See page 6 of <https://health.hawaii.gov/shpda/files/2019/04/sh1906a.pdf>.

⁸ See <https://health.hawaii.gov/shpda/files/2019/05/shd1906a.pdf>.

⁹ See page 5 of <https://health.hawaii.gov/shpda/files/2019/04/sh1906a.pdf>.

¹⁰ 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>.

¹¹ See letter dated March 19, 2013 from SHPDA to Liberty at sections 10, 12-13 and 18-19, pages 2-4 - <http://health.hawaii.gov/shpda/files/2014/09/shd1228a.pdf>.

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USRC-H projects that the utilization at the Additional Location will meet HSFP's minimum utilization of 600 treatments per station by the third year of operation. Even if USRC-H'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 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-H projects a year 1 ending census at the Additional Location of 92 (translating into 383 treatments per station) and (even if Liberty does commence operation at 85 Lanikaula and 85 West Lanikaula Streets, Hilo, HI 96720 in or about 2022) a year 3 ending census of 145 (translating into 604 treatments per station). As such, HSFP utilization threshold levels are met by this project.

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 existing Hilo facility 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 Hilo and its adjacent communities, USRC-H will make its services available to all individuals with ESRD Big Island-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 Hawaii¹² and the prevalence of adult diabetes has been increasing.¹³ The Hawaii Department of Health has found that one of the highest rate of diabetes has been occurring in Hawaii County and particularly the Hilo area.¹⁴

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

¹² See <http://health.hawaii.gov/diabetes/>.

¹³ See <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/HI?edition-year=2016>.

¹⁴ See Hawaii Diabetes Report 2010 - <http://health.hawaii.gov/diabetes/files/2013/10/2010diabetesreport.pdf> at page 15.

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care, benefitting patients' quality of life and longevity which results in higher survival rates and reduced hospital stays.

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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 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 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 \$15,406,824. Of this amount, \$4,986,040 is pegged for leasehold improvements to the site, \$427,985 for fixed equipment, \$779,975 for movable equipment, \$1,714,824 for financing costs, \$7,488,000 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:

	Year 0	Year 1	Year 2	Year 3
			Total \$	
HD Treatments	0	7,176	16,692	19,968
PD Treatments	0	0	0	0
Total Treatments	0	7,176	16,692	19,968
<i>Commercial Mix</i>	<i>NM</i>	<i>49%</i>	<i>28%</i>	<i>25%</i>
				554.6666667
HD Revenue Before Bad Debt Expense	\$0	\$3,355,704	\$6,854,048	\$8,054,085
PD Revenue Before Bad Debt Expense	\$0	\$0	\$0	\$0
Bad Debt Expense	0	104,027	212,475	249,677
Net Revenue	\$0	\$3,251,677	\$6,641,572	\$7,804,408
HD Salaries and Wages	\$18,337	\$911,294	\$1,786,480	\$2,111,067
HD Benefits	3,667	182,259	357,296	422,213
HD Medical Supplies	0	128,043	306,774	377,991
HD Medications	0	261,814	627,272	772,893
HD Other Exp	0	425,779	1,020,111	1,256,929
PD Salaries and Wages	0	0	0	0
PD Benefits	0	0	0	0
PD Medical Supplies	0	0	0	0
PD Medications	0	0	0	0
PD Other Exp	0	0	0	0
Medical Director Fees	0	87,500	100,000	100,000
Rent	0	864,000	864,000	864,000
Total Facility Expenses	\$47,255	\$2,860,688	\$5,061,933	\$5,905,095
Facility EBITDAM	(\$47,255)	\$390,989	\$1,579,639	\$1,899,313
<i>% Margin</i>	<i>NM</i>	<i>12%</i>	<i>24%</i>	<i>24%</i>

The 7,176 and 19,968 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 on page 10) USRC-H states that "USRC-H projects a year 1 ending census at the Additional Location of 92 (translating into 383 treatments per station) and . . . a year 3 ending census of 145 (translating into 604 treatments per station)." USRC-H notes that multiplying the treatments per station numbers by 36 stations generates treatments of 13,788 (versus 7,176) and 21,750 (versus 19,968). 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.

e) Relationship to the Existing Health Care System

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As all 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 on the Big Island by providing additional dialysis capacity and options for individuals with ESRD. USRC and USRC-H 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-H for its costs and expenses. USRC-H 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-H'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.

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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.