



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

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Application Number: # 21-21A
To be assigned by Agency

Date of Receipt: SI HEALTH PLANNING & DEV. AGENCY

APPLICANT PROFILE

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

Project Address: 270 Dairy Road, Space Nos. 152, 154, 156 and 158, Kahului, HI 96732

Applicant Facility/Organization: USRC Wailuku, LLC

Name of CEO or equivalent: Thomas Weinberg

Title: President

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

Phone Number: 214-736-2700 Fax Number: 214-736-2701

Contact Person for this Application: Thomas L. Weinberg

Title: Chairman and President

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.

DocuSigned by:
Thomas L. Weinberg
Signature

April 20, 2022
Date

Thomas L. Weinberg
Name (please type or print)

Chairman and President
Title (please type or print)

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

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- 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: 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 270 Dairy Road, Space Nos. 152, 154, 156 and 158, Kahului, 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

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USRC Wailuku, LLC's officers include:

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

Mary Dittrich, Vice President
5851 Legacy Circle, Suite #900
Plano, Texas 75024
214-736-2700

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

Steve Nottingham, 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)-3-8-080: 023

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 involves 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

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A. List All Project Costs:

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1	Land		
2	Construction Contract	\$	4,462,100
3	Fixed Equipment	\$	276,077
4	Moveable Equipment	\$	478,416
5	Financing Costs (Interest Expense years 1-5)	\$	489,308
6	FMV of assets - rent (10 years)	\$	3,470,777
7	Other (Impact fees)	\$	10,000
	Total Project Costs	\$	9,186,678

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B. Source of Funds

1.	Cash	\$2,606,471
2.	State Appropriations	
3.	Other Grants	
4.	Fund Drive	
5.	Debt and financing cost	\$3,109,430
6.	Other: Fair market value of lease payments (10 year lease)	\$3,470,777

TOTAL SOURCE OF FUNDS: \$9,186,678

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 18 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:

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- a) Date of site control for the proposed project: April 2022
- b) Dates by which other government approvals/permits will be applied for and received:
 - 1. Building permits applied -- September 2022
 - 2. Building permits received -- March 2023
- c) Dates by which financing is assured for the project: April 2022
- d) Date construction will commence: April 2023
- e) Length of construction period: 150 calendar days
- f) Date of completion of the project: November 2023
- g) Date of commencement of operation: November 2023

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 Kahului") seeks approval to establish an additional location for its dialysis services, located in the Kahului community at 270 Dairy Road, Space Nos. 152, 154, 156 and 158, Kahului, HI 96732 (the "Additional Location"). The Additional Location constitutes a change of location from the original site proposed for this Application. USRC believes relocation of the proposed site from the original

location at 58 Maui Lani Pkwy (Building B), Wailuku, HI to the Maui Marketplace Shopping Center at 270 Dairy Road, Space Nos. 152, 154, 156 and 158, Kahului, HI will provide even greater accessibility and acceptability of the new location to the target group. The new location has ample parking, including conveniently located handicapped accessible stalls. The new site is directly within Kahului (home to Maui's largest population), adjacent to Wailuku (Maui's second largest population base), and an even closer facility for residents of east Maui. The distance from the prior location to the new location is about 3 miles (USRC notes that SHPDA previously approved a change in location of the Waianae facility of Liberty Dialysis-Hawaii, LLC ("Liberty") to a site 5 miles away).

The Additional Location will offer a full range of dialysis services and modalities including 18 hemodialysis stations. USRC Wailuku, LLC (may be eventually renamed, or do business, as USRC Kahului, LLC) is a wholly owned subsidiary of Dialysis Newco, LLC ("DSI") and DSI is a wholly owned subsidiary of U.S. Renal Care, Inc. ("USRC"). USRC, through DSI will be the owner of USRC Kahului and will manage the clinic's day to day operations under a Management Agreement between USRC and USRC Kahului. The establishment and operation of the Additional Location will enable U.S. Renal Care, Inc. to provide high quality and accessible dialysis services to individuals with End Stage Renal Disease ("ESRD") in Maui County, especially in Kahului.

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 the HSFP, USRC (hereinafter refers to USRC and USRC Kahului 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

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

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

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

² See HSFP at page 33.

³ See HSFP at page 36.

⁴ See United States Renal Data System at Figure 1.5 - <https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population>.

dialysis unit/service should be projected to meet the minimum utilization rate by the third year of operation (the "HSFP Threshold").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

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The Primary Service Area for the Additional Location will include the immediate Maui community of Kahului, the adjacent community of Wailuku, and (particularly since there are no existing or planned stand-alone dialysis facilities east of Kahului) the communities of east Maui including Haiku-Pauwela, Makawao, Kula and Pukalani. Kahului is a necessary area for additional services since it is the largest census-designated place on the island of Maui with a population of 26,337 as of 2010 and it is the closest central Maui transportation hub for East Maui communities. See <https://en.wikipedia.org/wiki/Maui> including footnote 5.

USRC further notes:

Largest cities in Maui

The largest cities and towns in Maui are (all data from 2010 census):

City Population	(2010)
Kahului	26,337
Kihei	20,881
Wailuku	15,313
Lahaina	11,704
Waihee-Waiehu	8,841
Haiku-Pauwela	8,118
Pukalani	7,574
Napili-Honokowai	7,261
Makawao	7,184
Kula	6,452

Maui's population is growing more quickly than the population of Hawaii and the rest of the United States. Between 2010 and 2016, the number of people living in Maui increased by 6.8%, compared to an increase of 5.0% across Hawaii, and 4.7% across the United States as a whole. <https://countrydigest.org/maui-population/>.

Currently, there are only two dialysis facilities in that immediate service area and those two centers are providing treatments in excess of the utilization threshold established by HSFP: FMC/Liberty Mauiani-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 = 1,050 treatments per station) [There are two other dialysis facilities in Maui County, but neither of those are reasonably accessible to patients residing in Kahului/Wailuku/east Maui Island (the distance and drive times are too prohibitive to sufficiently address patient

⁵ See HSFP at page 29.
⁶ See HSFP at pages 31-32.

service and quality): FMC/Liberty Kahana (2017 50 patient census times 60 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); and Rainbow Lahaina (2018 20 patient census times 150 treatments per station divided by 6 stations = 500 treatments per station)].⁷ The Additional Location will provide an additional dialysis option to patients residing in the Primary Service Area.

Although SHPDA approved USRC Kihei, LLC's CON Application No. 21-15A to establish an additional 13 station facility in Kihei, Maui, USRC does not believe that the establishment of that facility in any location in the Primary Service Area of Maui County will significantly reduce the utilization rates of existing facilities in the Primary Service Area. Moreover, since USRC Kihei, LLC's has yet to commence operations, it is technically not currently a provider which should be accounted for in determining the applicant's relationship to the HSFP.⁸

Whether or not USRC Kihei, LLC's facility is included for purposes of the Applicant's HSFP calculation, as shown in Attachment E, the Additional Location will satisfy the 600 treatments per station HSFP utilization threshold.

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."⁹

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

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 HSFP at pages 29-30 provides "For a new unit/service, the minimum annual utilization for each provider in the service area is 600 treatments per unit, and the utilization of the new unit/service is projected to meet the minimum utilization rate by the third year of operation. For expansion of existing units/services, the provider's utilization is an average of at least 720 treatments per year per unit." The reference to "existing" and lack of specificity as to an approved application without commencement of operations indicates that USRC Kihei, LLC's impact on the Maui market should be excluded from consideration of utilization for this Application.

⁹ 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>.

and cost-reduction are so significant.¹⁰ Simply put, no responsible physician would willingly refer a Kahului patient for treatment three times per week outside of Kahului and its adjacent communities. Indeed, it is at least 3 miles and, controlling for traffic, an 11-minute one-way drive between the proposed Kahului location and the next closest facility (FMC/Liberty MauiLani-Wailuku) at 105 Maui Lani Parkway, Wailuku, Hawaii 96793. That facility is already above the HSFP 600 station threshold and has at best non-desirable third shift availability requiring Saturday evening treatment. When one adds in the scheduling and waiting issues related to any Maui Handivan and/or bus service, a Kahului location would make a material difference in the lives of Kahului and east Maui dialysis patients both clinically and emotionally.

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USRC 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'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 ESRD patient population growth in the Primary Service Area is 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 60 (translating into 500 treatments per station) and a year 3 ending census of 94 (translating into 784 treatments per station). As such, the HSFP Threshold utilization 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 other facilities in the immediate Kahului 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.

Per Attachment D — Report dated June 8, 2020 by J. Douglas Zona, Ph.D.:

In Maui County, there are 668 dialysis patients being served by 94 dialysis stations. See Zona page 7. When one factors in the U.S. average of each dialysis station supporting 6.21 patients, there should be 108 stations in service. See Zona page 5. This means that there is a current shortfall of 14 dialysis stations in Maui County. With the ESRD population growing in Maui County at 5.4% compounded annually, in three years the patient population will be 783 meaning that there will be a need for 126 stations. See Zona page 5. The 32-station shortage (126 stations minus 94 stations) will still be beyond what can be covered by the applicant's 18-station Additional Location.

Additional data, information and analysis is provided at Attachment E.

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

The proposed project will address an outpatient dialysis service provider monopoly/oligopoly currently existing on Maui. Accordingly, there would be a significant improvement to the health care system with the opening of the proposed facility and services.

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There are special characteristics and long-term needs of Maui County's dialysis care system. The delivery of dialysis services should be considered from a countywide and prospective perspective so that resources can be assured, and quality may be maintained and elevated.

The Maui community and its patients should have a network of providers analogous to that operating on Oahu that ensures patient choice of providers and payor health plans. The manner any need is met is extremely important to the viability and quality of the health care delivery system. The danger of monopolies and the importance of a diversified provider base to ensure resiliency of the health care system should not be dismissed. Efforts should be made to add additional providers to the market that can act as a failsafe in the event of an emergency or an unanticipated circumstance.

Maui County, like all of Hawaii, is severely impacted by the surge of COVID-19. The pandemic heightens the need for more dialysis providers. This would help control the spread of viruses. The lack of available dialysis spots puts Maui residents at risk if existing providers have operational issues or are not in compliance with legal requirements and health regulations. Maui patients would have nowhere to go to dialyze.

Although the Additional Location primarily is intended to serve the dialysis needs of residents residing in Kahului 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.

The current health system on Maui lacks the proper medical infrastructure to serve all its residents suffering from kidney related complications in a timely manner. The lack of access to care, travel distance to available resources and the insufficient number of practicing physicians are a few of the major contributing factors.

Accordingly, USRC has developed a Mobile CKD Program which it is rolling out in the State of Hawaii (including in Maui County to service residents of Lanai, Molokai and rural areas outside of existing and planned dialysis facilities in concert with an approval of this proposal. This program is designed to conduct health screenings and treatment options education in both the urban and rural areas of Maui, Molokai, Lanai, Kauai, Big Island, and Oahu. The establishment of the Mobile CKD Program will enable residents living in areas with limited access to healthcare services to obtain screenings for diabetes and hypertension, the two leading causes of kidney failure. The Mobile CKD Program will not be treating patients with mobile dialysis machines.

In addition to health screening services, USRC's Mobile CKD Program plans to have its Kidney Care Options Educator conduct regular information sessions across the

state to educate participating residents about the various treatment options and resources available to them. Looking at the historical home adoptions percentage, Maui County has averaged a mere 10.9% home penetration rate between the years 2016-2019 (see Figure 1). This can be in part attributable to the lack of awareness by County residents of the various treatment options available. As one of the industry's leading providers in both home and in-center dialysis, US Renal Care is committed to ensuring that patients are properly informed and receive the appropriate modality of care that best suits their circumstances.

Figure 1.

Historical Patient Census (CMS)				
County	2016	2017	2018	2019
Maui County In-center Patient Count	392	411	432	440
Maui County Home Patient Count	43	50	54	58
<i>Home Penetration (%)</i>	9.9%	10.8%	11.1%	11.6%

The projected costs to operate the Mobile CKD Program can be seen in Figure 2.

Figure 2.

Projected Cost of Mobile CKD Program			
	Year 1	Year 2	Year 3
Labor	163,000	167,890	172,927
Supplies	20,000	20,600	21,218
Lease Expense	20,000	20,000	20,000
Marketing and Community Events	50,000	51,500	53,045
Other Expenses	62,000	63,860	65,776
Total	\$ 315,000	\$ 323,850	\$ 332,966

The Mobile CKD Program for Maui County will work part and parcel with USRC building partnerships with a wide array of stakeholders throughout Maui County including on Lanai and Molokai and in Hana and the eastern end of the island of Maui. USRC intends to create a County-wide backup network, creating critical redundancy for the health care system. In fact, USRC is willing to guarantee sustaining services for any withdrawal by FMC/Liberty of services to underserved areas.

Moreover, USRC has developed a Transitional Care Unit (TCU) Program which it will soon launch for the first time in the State of Hawaii in Maui County with the opening of USRC's approved Kihei, Maui location. The TCU Program will be extended to Maui County in concert with an approval of this Application.

Approval of this Application with the TCU Program will benefit, enhance, and positively impact the existing health care system in Maui County. This is a Program which is not available elsewhere in the State of Hawaii; would help revolutionize care in Maui

County; is a novel, intensive and up-front costly intervention (but with cost savings over time); and will improve access to care, quality of care, service and affordability.

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Benefits include:

- Better patient experience: More frequent, slower, gentler dialysis allows the patient to feel better. A smoother start designed to provide time, support, and robust education elevates the patient's psychological adjustment and ability to address fears. Thorough explanation of treatment options without pressure to make an immediate or premature decision is a patient benefit.
- Enhanced Clinical Outcomes: Reduced missed treatments. Additional benefits are generated from more frequent dialysis, including managed fluid fluctuations, reduced cardiac stress, BP control with fewer meds, and shorter recovery time. This contributes to lower hospitalization rates during the first 90-day transitional period.

Another Hawaii dialysis provider may claim that components and features of USRC's TCU Program are already a feature of their process and procedures, but there is no other program which meaningfully matches what USRC's TCU Program will provide. What exists in the State has already been a baseline within USRC's care offerings. The TCU program qualitatively transcends currently available services. TCU is utilized when the patient has already started incenter dialysis and provides a soft landing and gentle start to dialysis. USRC will offer a four-week program with a built-out educational curriculum delivered by interdisciplinary teams chairside. This, in fact, is not provided by anyone else. This is a material service upgrade.

An in-center home is foundational to the introduction and viability of the TCU Program. While the TCU Program would drive more patients to a home modality, it would not lessen the need for incenter stations. Incenter stations are needed to provide TCU treatments and a program. In addition, with the increasing demand for dialysis due to many comorbidities and now long COVID, the need for incenter stations will not diminish.

Approval of this proposal will benefit, enhance, and positively impact the existing health care system and in Maui County's underserved areas by adding unique and transformative services.

Diabetes is one of the most serious, common, and costly diseases in Hawaii. It is a leading cause of death in Hawaii¹¹ and the prevalence of adult diabetes has been increasing.¹² The Hawaii Department of Health has found that one of the higher rates of diabetes has been occurring in the Kahului area.¹³ Hawaii's CKD population has continued to embark on an uptrend in recent years. In 2013, the National Kidney Foundation of Hawaii estimated that a total of 156,000 residents suffered from chronic

¹¹ See <http://health.hawaii.gov/diabetes/>.

¹² See <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/HI?edition-year=2016>.

¹³ See Hawaii Diabetes Report 2010 - <http://health.hawaii.gov/diabetes/files/2013/10/2010diabetesreport.pdf> at page 16.

kidney disease. These estimates are now closer to 200,000 this year and put Hawaii at continued risk for the highest prevalence of ESRD compared to the nation's average.

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c) Quality of Service/Care

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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 USRC's 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 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 USRC's 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 Technicians	1 per 4 patients
Dieticians	1 per 100 patients
Social Workers	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

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The total cost of developing the Additional Location will be approximately \$9,186,678. Of this amount, \$4,462,100 is pegged for leasehold improvements for the site, \$276,077 for fixed equipment, \$478,416 is for movable equipment, \$489,308 for financing costs, \$3,470,777 for 10-year lease payments, and \$10,000 for impact fees.

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	Year 0	Year 1	Year 2	Year 3
	Total \$			
HD Treatments	0	4,913	11,850	13,675
PD Treatments	0	0	0	0
Total Treatments	0	4,913	11,850	13,675
<i>Commercial Mix</i>	<i>NM</i>	<i>18%</i>	<i>17%</i>	<i>15%</i>
HD Revenue Before Bad Debt Expense	\$0	\$1,927,541	\$4,769,883	\$5,484,611
PD Revenue Before Bad Debt Expense	\$0	\$0	\$0	\$0
Bad Debt Expense	0	59,754	147,866	170,023
Net Revenue	\$0	\$1,867,788	\$4,622,017	\$5,314,588
HD Salaries and Wages	\$0	\$560,620	\$1,151,803	\$1,438,965
HD Benefits	0	112,124	230,361	287,793
HD Medical Supplies	0	88,081	212,471	245,193
HD Medications	0	127,725	308,100	355,550
HD Calcimimetics	0	983	2,370	2,735
HD Other Exp	0	300,000	658,268	767,243
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 Calcimimetics	0	0	0	0
PD Other Exp	0	0	0	0
Medical Director Fees	0	108,000	120,000	120,000
Fixed Labor Expenses	74,255	306,755	391,328	413,446
Common Area Maintenance (CAM)	16,094	64,377	64,377	64,377
Rent	79,338	317,352	326,873	336,679
Total Facility Expenses	\$169,687	\$1,986,017	\$3,465,948	\$4,031,981
Facility EBITDAM	(\$169,687)	(\$118,229)	\$1,156,069	\$1,282,607
<i>% Margin</i>	<i>NM</i>	<i>(6%)</i>	<i>25%</i>	<i>24%</i>

The estimated revenue and cost projections for the first and third full years of operation are set forth above. The 4,913 and 13,675 treatment numbers (and therefore all related numbers in the rest of those columns) are accurate even given that USRC

states in section 9.a above that "USRC projects a year 1 ending census of 60 (translating into 500 treatments per station) and . . . a year 3 ending census of 94 (translating into 784 treatments per station)." USRC notes that multiplying the treatments per station numbers by 18 stations generates treatments of 900 (versus 4,913) and 14,112 (versus 13,675). 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

As the existing dialysis facilities in the adjacent area of Wailuku (as well as most of the existing dialysis stations in the Primary Service Area) are operating in excess of the thresholds established by HSFP, and given the need described above in section 9.b, 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. The addition by USRC of new dialysis facilities in Hawaii (including the Additional Location) will not detrimentally impact the existing health care system and workforce in any Hawaii service area as well as the quality of service/care delivered to patients of approved facilities. New facilities and services by USRC (including the Additional Location) will generate additional jobs throughout Hawaii's health care sector as well as increased access, quality of services and perhaps even affordability for Hawaii's communities. See Attachment D — Report dated June 8, 2020 by J. Douglas Zona, Ph.D. at pages 2-3:

- i. Supply-demand analysis suggests that new USRC dialysis centers throughout the State of Hawaii including anywhere in the Counties of Hawai'i, Maui, Kaua'i, and O'ahu (and specifically but not limited to Hilo, Kona, Wailuku, Kihei, Kalihi, and urban and rural Honolulu, Windward O'ahu, and West O'ahu) will serve an unmet need and can be staffed without negative impact;
- ii. There is substantial and growing patient demand for new dialysis centers in Hawaii;
- iii. There is an adequate supply pool of clinician labor. There is significant reason to believe USRC can effectively recruit clinicians into Hawaii without undermining the quality of healthcare services statewide and in local communities; and
- iv. Increased competition can bring improvements in quality and innovation in the provision of dialysis services in Hawaii.

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.

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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. U.S. Renal Care, Inc. will then lend necessary amounts to USRC Kahului for its costs and expenses. USRC Kahului 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 Kahului'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 Hawaii-based and national recruiting firms that will help identify and/or supply nurses, patient care technicians and other personnel for the facility.

As discussed above in sections 9.b and 9.e, the Additional Location by USRC of new dialysis facilities in Hawaii (including the Additional Location) will not detrimentally impact the existing health care system and workforce in any Hawaii service area as well as the quality of service/care delivered to patients of approved facilities. New facilities and services by USRC (including the Additional Location) will generate additional jobs throughout Hawaii's health care sector as well as increased access, quality of services and perhaps even affordability for Hawaii's communities.

The Additional Location will only require two nurses and three patient care technicians to launch; once fully ramped up, the Additional Location will require five nurses and twelve patient care technicians to operate. The required staff is small relative to the total supply of nurses and patient care technicians from which to draw.

The demand for nurses in Hawaii is expected to grow 2.6 percent from 2014 to 2030 (a growth of about 5,600 nursing positions). See Attachment D — Report dated June 8, 2020 by J. Douglas Zona, Ph.D. at page 10. At the same time, the supply of nurses in Hawaii are expected to increase at a faster rate of about 3.8 percent. See Zona page 10. This pipeline of nurses into Hawaii will cause an expected surplus of about 20 percent more nurses (about 3,000 nursing positions) than required to meet patient demand. See Zona page 10.

There is currently a surplus of 24 patient care technicians in Maui County relative to the national average (52 identifiable PCTs which represent an available pool of almost twice the national average). See Zona page 13. There is an even larger pool of potential patient care technicians both currently and into the foreseeable future. See Zona page 14.

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

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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.

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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.