



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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November 30, 2021

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Mary Dittrich, MD
Interim CEO
USRC Kihei, LLC
5851 Legacy Circle, Suite 900
Plano, Texas 75024

Dear Dr. Dittrich:

The State Health Planning and Development Agency (the "Agency") has evaluated Certificate of Need application #20-15A from USRC Kihei, LLC (the applicant) for the establishment of chronic renal dialysis services at 281 Piikea Avenue, Kihei, HI, at a capital cost of \$8,924,714 (the "Proposal").

A. The Agency makes the following findings of fact with respect to Title 11, Chapter 186 of the Hawaii Administrative Rules (HAR) 11-186-15(a). The Agency finds each of the following statements to be true and accurate.

1. The applicant states¹ that "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.

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 Kihei 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

¹ For clarity, when the Agency quotes statements from the applicant or from witnesses in this section, it does so because the Agency finds such testimony to be persuasive and because the Agency has incorporated the referenced testimony as a finding of fact.

to assist patients and their families in better understanding and managing their chronic disease, application will support the general principles of the Statewide Health Coordinating Council ("SHCC")."

2. The applicant states that "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. The applicant states that "Patient counts and prevalence rates for ESRD are highest among those individuals age 65 and older. 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 continuing 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."
4. The applicant states "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."
5. The HSFP states that "Capacity (utilization) thresholds...guide the initial determination of need for a service area."

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

7. The applicant states that "In approving CON Application No. 15-07A (Liberty Dialysis – Hawaii, LLC for the establishment of a 2 station chronic renal dialysis facility at 500 Ala Moana Boulevard, Suite 7-302, Honolulu, Hawaii), SHPDA referenced testimony that '*... 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.*'" [Emphasis added]

8. The applicant states that "... it is at least 12 miles and a 22-minute one-way drive between the proposed Kihei location and the next closest facility (FMC/Liberty Mauilani-Wailuku) at 105 Maui Lani Parkway, Wailuku, Hawaii."

9. The applicant states that "When one adds in the scheduling and waiting issues related to any Maui Handi Van service, a Kihei location would make a material difference in the life of a Kihei area dialysis patient both clinically and emotionally."

10. In written testimony received October 28, 2021, Kristen P. Tamura, MD states "Opening an additional dialysis center in Kihei will provide needed options for patients in the service area. This will foster patient compliance with dialysis treatment—a common problem leading to worsening of patients' physical condition, hospitalizations and increased medical cost/treatments."

11. In written testimony dated October 27, 2021, Scott J. Sivik, Plan President & CEO, Ohana Health Plan, states "When patients adhere to dialysis treatment schedules, they can avoid costly complications from ESRD such as needing nursing home care and avoiding unnecessary emergency medical care or hospitalizations. Access to these critical services in Kihei will not only benefit Maui's healthcare system and kupuna population as a whole, but will also address the growing need for more outpatient dialysis centers in Hawaii."

12. The applicant states "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."
13. The applicant states that "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."
14. The applicant states that "Although the Additional Location primarily is intended to serve the dialysis needs of residents residing in Kihei 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."
15. The applicant states that "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."
16. The applicant states that "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."
17. The applicant states that "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."
18. The applicant projects Net Revenue of \$1,144,195 and Total Facility Expenses of \$1,302,212 for Year 1 of the Proposal, Net Revenue of \$3,019,582 and Total Facility Expenses of \$2,338,775 for Year 2 of the Proposal, and Net Revenue of \$3,878,586 and Total Facility Expenses of \$2,834,839 for Year 3 of the Proposal.
19. The applicant states that "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 Kihei for its costs and expenses. USRC Kihei 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 Kihei's lease for the clinic."

20. The applicant states that "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."
 21. The applicant states that "The Additional Location will only require two nurses and two patient care technicians to launch; once fully ramped up, the Additional Location will require four nurses and sixpatient [sic] care technicians to operate. The required staff is small relative to the total supply of nurses and patient care technicians from which to draw."
 22. The applicant states that "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."
 23. The applicant states "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)... At the same time, the supply of nurses in Hawaii are expected to increase at a faster rate of about 3.8 percent... 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."
 24. The applicant states "There is currently a surplus of 24 patient care technicians in Maui County relative to the national average (49 identifiable PCTs which represent an available pool of almost twice the national average)."
- B. Pursuant to Title 11, Chapter 186 of the Hawaii Administrative Rules (HAR), the Agency finds that this proposal is eligible for administrative review as it meets the criterion in HAR Subsection 11-186-99.1(b) (5), i.e.: "An additional location of an existing service or facility".

Conclusions and Order

Pursuant to Title 11, Chapter 186, HAR, the Agency has determined that:

- (a) The Proposal is eligible for administrative review as it meets one or more of the criteria in HAR 11-186-99.1(b).
- (b) The applicant, USRC Kihei, LLC has proven by a preponderance of the evidence that the Proposal meets the Certificate of Need criteria in HAR 11-186-15 (a).
- (c) There is no compelling public interest which will be served by requiring the application to go through the standard review process.

As required under Subsection 323D-43(b), Hawaii Revised Statutes, the Agency has determined that:

- 1. There is a public need for the Proposal.
- 2. The cost of the Proposal will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

Accordingly, the State Health Planning and Development Agency hereby APPROVES and ISSUES a Certificate of Need to USRC Kihei, LLC for the Proposal described in Certificate of Need Application #20-15A. The maximum capital expenditure allowed under this approval is \$8,924,714.



Serafin Colmenares, Jr.
Administrator