

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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July 18, 2022

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Thomas Weinberg President USRC Wailuku, LLC 5851 Legacy Circle, Suite 900 Plano. Texas 75024

Dear Mr. Weinberg:

The State Health Planning and Development Agency (the "Agency") has evaluated Certificate of Need application #21-21A for administrative review from USRC Wailuku, LLC for the establishment of chronic renal dialysis services at 270 Dairy Road, Space Nos. 152, 154, 156 and 158, Kahului, HI, at a capital cost of \$9,186,678 (the "Proposal").

- A. The Agency makes the following findings of fact with respect to Title 11, Chapter 186 of the Hawaii Administrative Rules (HAR). The Agency finds each of the following statements to be true and accurate.
- The applicant states¹ that "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")."
- 2. The applicant states that "The Additional Location will offer a full range of dialysis services and modalities including 18 hemodialysis stations. USRC Wailuku, 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."

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.

- 3. The applicant states 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 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 application will support the general principles of the Statewide Health Coordinating Council ("SHCC")."

- 4. 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."
- 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 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."

- 6. 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."
- 7. The applicant states that "The Primary Service Area for the Additional Location will include the immediate Maui community of Kahului, the adjacent community of Wailuku, and (particularly since 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.
- 8. The applicant states that "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 Mauilani-Wailuku... and Rainbow Wailuku... [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 service and quality)..."
- 9. In Attachment E of its application, the applicant states that, per the CMS Cost Reports data source, the dialysis treatments per station for Liberty Dialysis Mauilani was 649 and 668 for 2018 and 2019, respectively and 1,045 and 1,111 for Rainbow Wailuku for 2018 and 2019, respectively.
- 10. The applicant states that "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."
- 11. In written testimony received July 1, 2022, Pliny Arenas, Regional Vice President of Operations for US Renal Care states "Maui Memorial Medical Center and other local hospitals have patients in need of specialized dialysis services; however, complex co-occurring medical conditions such as having a tracheostomy, requiring a medical ventilator, or needing intravenous antibiotics, are barriers to patients waiting to receive dialysis

services once they are ready for discharge from an acute care setting. The proposed project will allow for greater capacity to care for higher acuity dialysis patients with co-occurring conditions and medically complex needs."

- 12. In his written testimony received July 1, 2022, Mr. Arenas states "By establishing dialysis services for patients with higher acuity, the proposed project meets the criteria for addressing the documented needs of an actual population rather than basing care design on statistical generalizations. The proposed project improves access to care for higher acuity patients by establishing a new dialysis center that will have the capacity to treat these patients."
- 13. The applicant states that "Diabetes is one of the most serious, common, and costly diseases in Hawaii. It is a leading cause of death in Hawaii and the prevalence of adult diabetes has been increasing. The Hawaii Department of Health has found that one of the higher rates of diabetes has been occurring in the Kahului area."
- 14. In written testimony dated April 21, 2022, Mark Mugiishi, President and Chief Executive Officer, Hawaii Medical Service Association states "Kidney disease is a significant problem in Hawaii. Approximately 3.7 percent of Hawaii's population (about 50,000 individuals) have been formally diagnosed with chronic kidney disease ("CKD"), which is a precursor to end stage renal disease ("ESRD"). HMSA estimates that approximately 12,000 individuals are in late-stage CKD and, thus, are one to five years away from developing ESRD and requiring dialysis. In fact, the actual number of individuals in Hawaii suffering from CKD (diagnosed and undiagnosed) is significantly higher. Caring for ESRD patients requires adequate dialysis facilities across the state, preferably geographically close to patients' place of residence for ease of care. HMSA therefore endorses CON approval for outpatient dialysis centers that will deliver quality care and service in the community."
- 15. In written testimony received July 1, 2022, Mr. Arenas, states "...the ESRD population in Kahului and Maui County is growing at increasingly high rates and there is no clinic in Kahului to treat this population needing dialysis. In 2013 there were 130,000 Chronic Kidney Disease (CKD) patients in Hawaii. As of 2021, the number of CKD patients in Hawaii went up to 200,000 according to the collaborative study conducted by the University of Hawaii and the National Kidney Foundation of Hawaii. A great number of patients are living in Maui County. Medicare Costs Report shows that the number of individuals suffering from chronic kidney disease that are residing in Maui County is increasing every year. This excludes people who are suffering from diabetes and hypertension. These groups may eventually end up on ESRD (End Stage Renal Disease) and will be needing dialysis."
- 16. In written testimony dated June 15, 2022, Thomas Chen, MD states "I am the Chief of Nephrology for Hawaii Permanente Medical group, the physician practice providing care for the patients enrolled in the Kaiser Foundation Health Plan... Opening another dialysis unit will also provide more treatment shifts available to patients in the servce [sic] area, as many

units reach capacity during the shifts that patients are able to attend. This will also help in improving patient compliance with the dialysis treatment: a common problem leading to worsening of patient's physical condition, hospitalizations and increased medical cost/ treatments. The patient's quality of life is often improved with providing more reasonable treatment times. There is also a lack of adequate COVID-19 isolation dialysis clinics in Maui, forcing patients to dialyze in Kahana which is over an hour drive."

- 17. The applicant states that "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."
- 18. 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."
- 19. 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."
- 20. 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."
- 21. The applicant projects Net Revenue of \$1,867,788 and Total Facility Expenses of \$1,986,017 for Year 1 of the Proposal, Net Revenue of \$4,622,017 and Total Facility Expenses of \$3,465,948 for Year 2 of the Proposal, and Net Revenue of \$5,314,588 and Total Facility Expenses of \$4,031,981 for Year 3 of the Proposal.
- 22. In his written testimony received July 1, 2022, Mr. Arenas states "USRC Wailuku, LLC will collaborate and engage with other providers in the community to ensure access to care, especially for higher acuity dialysis patients, with co-occurring conditions and medically complex needs."

- 23. The applicant states that "...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."
- 24. 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 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."
- 25. The applicant states that "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."
- 26. 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."
- 27. 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."
- 28. The applicant states "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)... There is an even larger pool of potential patient care technicians both currently and into the foreseeable future."
 - 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 Wailuku, 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 Wailuku, LLC for the Proposal described in Certificate of Need Application #21-21A. The maximum capital expenditure allowed under this approval is \$9,186,678.

Darryl D. Shutter Acting Administrator