



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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January 14, 2021

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Mary Dittrich, MD
Interim CEO
USRC Kalihi, 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 #20-09A from USRC Kalihi, LLC (the "applicant") for the establishment of chronic renal dialysis services at 2055 N. King Street, Suite Nos. 100, 101, 201 and 203, Honolulu, HI, at a capital cost of \$8,378,462 (the "Proposal").

1. Pursuant to Title 11, Chapter 186 of the Hawaii Administrative Rules (HAR), the Agency has determined that the Proposal is eligible for administrative review as it meets the criteria in Subsection 11-186-99.1(b) (5) and (6), HAR, i.e.: "An additional location of an existing service or facility" and "Any proposal which is determined by the agency not to have a significant impact on the health care system."
2. 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-K 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, application will support the general principles of the Statewide Health Coordinating Council ("SHCC")."

3. The applicant states that "The application will advance the Honolulu Subarea Health Planning Council ("HONSAC") priority of increasing the availability of supportive services to help maintain quality of life and controlling escalating costs in the senior care industry and other needed services. 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."
4. The HSFP states that "Capacity (utilization) thresholds...guide the initial determination of need for a service area."
5. The applicant states that "It has long been recognized that dialysis facilities in the Primary Service Area of Honolulu are operating in excess of the HSFP Threshold. Utilization data and information submitted by the applicants in CON Application Nos. 19-21A, 19-16A and 19-03A represented/acknowledged that every facility in the Primary Service Area of Honolulu, except Beretania (which was mentioned in CON Application No. 19-21A, but not CON Application Nos. 19-16A and 19-03A), exceeded the HSFP Threshold. Beretania is actually well on its way to doing so..."
6. In written testimony dated December 29, 2020, Keith A. Lee states that Beretania had a treatment volume of 11,246 as of October 2020.
7. 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."

8. In written testimony dated December 12, 2020, Liza Josue-Cabaccang, Clinical Coordinator for U.S. Renal Care states that "The dialysis population is extremely vulnerable to adverse outcomes related to COVID-19 with a number of comorbidities associated with mortality from the virus. Honolulu has very few dialysis stations relative to the United States in general. As a result, there is limited capacity to isolate infectious patients from the general patient population to limit the virus' spread or to close facilities to deal with disinfection. This lack of supply puts patients at risk in the current environment and needs to be addressed immediately."
9. The applicant states "In Honolulu, there are 3,935 dialysis patients being served by 587 dialysis stations... When one factors in the U.S. average of each dialysis station supporting 6.21 patients, there should be 634 stations in service... This means that there is a current shortfall of 47 dialysis stations in Honolulu. With the ESRD population growing in Honolulu at 5.1% compounded annually, in three years the patient population will be 4,568 meaning that there will be a need for 736 stations... The 149-station shortage (736 stations minus 587 stations) will still be beyond what can be covered by the applicant's 16 station Additional Location, KDH's 16 station facility and Hawaii Dialysis' 24 station center."
10. In written testimony dated December 14, 2020, Pliny Arenas, Vice President of Operations, U.S. Renal Care, states that "The establishment of the proposed facility will enable USRC to expand its provision of life-saving renal dialysis services primarily to the Kalihi corridor of urban Honolulu on the Island of Oahu and make them more accessible to those in need. This area is heavily impacted by the surge of COVID-19. Patients diagnosed as PUI and COVID positive are being dialyzed in Ko'Olau-Kaneohe (USRC) and in Leeward-Ewa Beach (Liberty)."
11. The applicant states "Although Kalihi Dialysis Hawaii, LLC ("KDH") obtained approval of its CON Application No. 19-16A to establish a 16 station facility at a portion of the same location as the Additional Location, USRC does not believe that the establishment of that facility in any location in the Primary Service Area of Honolulu will significantly reduce the utilization rates of existing facilities in the Primary Service Area. As KDH stated in its application: "there continues to be a high demand for dialysis services and expects such demand to climb for the foreseeable future ... [and] that its opening will not affect the utilization levels of any existing dialysis facility on Oahu."
12. In written testimony dated December 14, 2020, Mark Mugiishi, MD, President and Chief Executive Officer, HMSA, 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."

13. In written testimony dated December 16, 2020, Jason C. Chang, President, The Queen's Medical Center and Executive VP and Chief Operating Officer, The Queen's Health Systems, states that "End-stage renal disease, or ESRD, is a chronic illness that requires patients to undergo regular, long-term dialysis or receive a kidney transplant to maintain life. With the high occurrence of ESRD in the community and the finite number of kidneys available for transplant, the result has been a critical need for access to additional dialysis treatment services... We believe that access to additional dialysis services is necessary to meet the growing needs of the community. QHS respectfully request that the State Health Planning and Development Agency approve CON application #20-09A."
14. The applicant states that "Although the Additional Location primarily is intended to serve the dialysis needs of residents residing in the Primary Service Area of Honolulu, USRC-K will make its services available to all individuals with ESRD Oahu Island-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. In his written testimony dated December 14, 2020, Mr. Arenas, states that "The new facility will be operated under the same policies and procedures as are USRC's other facilities across the country and on Oahu. USRC is committed to quality care, benefitting patients' quality of life and longevity. The quality outcomes of our clinics on Oahu are some of the best in our company. This is validated by numerous commendations from regulatory agencies such as ESRD Network 17-Healthcare Services Advisory Group, Hawaii Department of Health and from the Hawaii Department of Epidemiology."
17. The applicant projects a year 1 ending census at the Additional Location of 24 (translating into 216 treatments per station) and a year 3 ending census of 90 (translating into 810 treatments per station).
18. The applicant projects Net Revenue of \$597,284 and Total Facility Expenses of \$747,755 for Year 1 of the Proposal, Net Revenue of \$2,783,877 and Total Facility Expenses of \$2,064,158 for Year 2 of the Proposal, and Net Revenue of \$4,572,166 and Total Facility Expenses of \$3,062,144 for Year 3 of the Proposal.

19. In written testimony dated December 11, 2020, 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 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."
20. In his written testimony dated December 14, 2020, Mr. Arenas states that "The world drastically changed because of the COVID-19 virus. It impacted the healthcare delivery system. Dialysis patients diagnosed as PUI or COVID positive do not have to stay in the hospital for a longer period of time if they can be isolated at designated facilities that can dialyze them six feet apart. This approach will help patients recover from the virus quickly and prevent exposure of the community at large. It will also decongest our hospitals and be available to residents that are in need of critical medical services. The establishment of the proposed Kalihi clinic will positively impact the health care system in Honolulu by providing additional dialysis capacity and options for individuals with ESRD."
21. 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-K for its costs and expenses. USRC-K 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-K's lease for the clinic."
22. The applicant states "The Additional Location (with merely 16 stations) will only require one nurse and one patient care technician to launch; once fully ramped up, the Additional Location will just require two nurses and four patient care technicians to operate."
23. 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."

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 Kalihi, 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 Kalihi, LLC for the Proposal described in Certificate of Need Application #20-09A. The maximum capital expenditure allowed under this approval is \$8,378,462.

Please be advised that pursuant to Section 323D-47, HRS, any person may, for good cause shown, request in writing a public hearing for reconsideration of the Agency's decision within ten working days from the date of this decision. Accordingly, if no person makes such a timely request for reconsideration, this decision shall become final immediately after the deadline for making such a request has expired.



Serafin Colmenares, Jr.
Administrator