



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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February 12, 2021

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Mary Dittrich, MD
Interim CEO
USRC Kona, 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 #20-14A from USRC Kona, LLC (the "applicant") for the establishment of chronic renal dialysis services at 74-5586 Palani Road, Suite No. 29, Kailua-Kona, HI, at a capital cost of \$9,738,805 (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 Hawaii County/Hawaii Subarea Planning Council (HSAC) priority of increasing the number of, improving access to, and bolstering the quality of health care facilities. 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 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.”
6. In written testimony dated December 28, 2020, Liza Josue-Cabaccang, 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.”
7. In written testimony received by the Agency January 12, 2021, Senator Dru Mamo Kanuha states “As Hawai'i Island has very limited resources for chronic kidney disease and end-stage renal disease (ESRD) patients, the only treatment option for residents is operated by Fresenius Clinic which is operating at four shifts per day to accommodate new patients and reaches max capacity at every shift. With the lack of dialysis stations available, Fresenius is unable to meet the dialysis needs of the community while providing appropriate social distancing for staff and patients.”

8. In her written testimony dated December 28, 2020, Liza Josue-Cabaccang, states "... 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. In written testimony dated January 13, 2021, Pliny Arenas, Vice President of Operations, U.S. Renal Care, states "An article published in October by the American Legion shares the devastating effect of this global pandemic to the residents of Hawaii County – 'A COVID-19 outbreak that struck a state veterans home in Hilo, Hawaii, in late August has infected a majority of the residents and led to the deaths of at least 27 veterans and spouses. It's a stark reminder that the pandemic, now entering its ninth month, continues to devastate long-term care centers.' It also mentioned 'A few residents of the state veterans home also may have been exposed to the novel coronavirus at an off-site dialysis center, according to the state report.' ...this pandemic heightens the need for more dialysis clinics to control the spread of the virus. The lack of another provider and facility puts the residents at risk if the current provider has operational issues or is not in compliance with Department of Health regulations. Residents would have nowhere to go to properly dialyze."
10. The applicant states "In Hawaii County, there are 809 dialysis patients being served by 81 dialysis stations... When one factors in the U.S. average of each dialysis station supporting 6.21 patients, there should be 131 stations in service... This means that there is a current shortfall of 50 dialysis stations in Hawaii County. With the ESRD population growing in Hawaii County at 5.9% compounded annually, in three years the patient population will be 960 meaning that there will be a need for 155 stations... The 74-station shortage (155 stations minus 81 stations) will still be beyond what can be covered by the applicant's 21 station Additional Location and Liberty Dialysis' additional 24 station facility."
11. In written testimony dated January 20, 2021, Mark Mugliishi, 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."
12. In written testimony dated January 29, 2021, 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."

13. In written testimony dated December 22, 2020, Malia Alcain-Galiza states "I am a CCHT, currently employed by Fresenius Kidney Care/Liberty Dialysis Kona... this past year I lost my Aunt due to ESRD. She was going to begin dialysis, but was unable to because of her taxi situation, on top of that, the time availability that Kona Clinic had available."
14. The applicant states that "Although the Additional Location primarily is intended to serve the dialysis needs of residents residing in Kailua-Kona and its adjacent communities, USRC 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."
15. In his written testimony dated January 13, 2021, 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 in Hawaii 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."
16. 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."
17. The applicant projects a year 1 ending census at the Additional Location of 36 (translating into 258 treatments per station) and a year 3 ending census of 107 (translating into 765 treatments per station).
18. The applicant projects Net Revenue of \$1,189,370 and Total Facility Expenses of \$1,283,473 for Year 1 of the Proposal, Net Revenue of \$3,197,971 and Total Facility Expenses of \$2,495,879 for Year 2 of the Proposal, and Net Revenue of \$5,236,904 and Total Facility Expenses of \$3,693,882 for Year 3 of the Proposal.
19. In his written testimony dated January 13, 2021, 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 Kailua-Kona clinic will positively impact the health care system in Hawaii County by providing additional dialysis capacity and options for individuals with ESRD."

20. 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."
21. The applicant states "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 ten 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."
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. In his written testimony dated January 13, 2021, Mr. Arenas states that "We recently had taken over the acute dialysis services of Hilo Medical Center. They currently have 40 new graduate nurses in their Residency Program. They informed us that they will only hire 20 of them on a temporary basis. There will be 20 trained nurses that will be looking for a job on the Big Island, Oahu or the mainland. There are a lot of Nurses in Hawaii, especially on the Big Island, that are unemployed or underemployed, because of the pandemic. This will create a surplus of nurses that we need to keep in Hawaii to keep our healthcare system stable."
24. In the Expert Report of J. Douglas Zona, Ph.D. dated June 8, 2020, Dr. Zona states "Hawaii enacted strict travel restrictions to quarantine itself during the Covid-19 pandemic. These policies have effectively slowed the spread of the disease, but at the expense of tremendous job loss (given Hawaii's heavy reliance on tourism). Healthcare workers are among those filing for unemployment – while some healthcare professionals are actively treating Covid patients, many have been furloughed or laid off as non-essential healthcare services grind to a halt."
25. In his report, Dr. Zona states "Hawaii went from having one of the lowest unemployment rates in March (2.6 percent) to having the highest unemployment rate of any U.S. state in April (37 percent), increasing by a factor of about 13 times."
26. In written testimony dated October 22, 2020, Rob Machado, Managing Director, Kahu Malama Nurses, states "There is no strain on the health care workforce that adding another center to an existing or proposed facility might cause given the current coronavirus pandemic. Any stress on Hawaii's health care resources, including the availability of qualified personnel, is limited to hospital acute and ER services. Hospitals are struggling

because not all RNs are willing to work in the hospital due to high workload and high exposure to COVID-19. Outpatient health care jobs have actually increased due to COVID-19. USRC will be able to recruit the clinicians needed to launch new centers throughout the State of Hawaii without undermining the quality of healthcare services in any county or community.”

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 25 patient care technicians in Hawaii County relative to the national average (49 identifiable PCTs which represent an available pool of more than twice the national average)... There is an even larger pool of potential patient care technicians both currently and into the foreseeable future.”

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 Kona, 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 Kona, LLC for the Proposal described in Certificate of Need Application #20-14A. The maximum capital expenditure allowed under this approval is \$9,738,805.

#20-14A, Administrative Review Decision
February 12, 2021
Page 7

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