



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

NEIL ABERCROMBIE
GOVERNOR OF HAWAII

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March 19, 2013

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Mark Caputo
Manager
Liberty Dialysis - Hawaii, LLC
7650 Southeast 27th Street, Suite 200
Mercer Island, WA 98040

Dear Mr. Caputo:

The State Health Planning and Development Agency (the "Agency") has evaluated Certificate of Need application #12-28A from Liberty Dialysis-Hawaii, LLC (the "applicant") for the establishment of Chronic Renal Dialysis services at TMK No. (1) 9-5-049-085 (space adjacent to 95-1091 Aina Makua Drive, Mililani, HI), at a capital cost of \$3,361,451 (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 criterion in Subsection 11-186-99.1(b) (5), HAR, i.e.: "An additional location of an existing service or facility."
2. The applicant states that "This project will advance the State Health Coordinating Council's ("SHCC") priority of ensuring maintenance of overall access to quality health care at a reasonable cost by providing improved access to dialysis services. There are few medical facilities of any type conveniently available to residents of Oahu's North Shore... The improved safety of travel on roads into Mililani, as compared to Kamehameha Highway, would provide a separate intangible benefit to North Shore residents seeking dialysis services at the Proposed Dialysis Center."
3. In written testimony received by the Agency March 7, 2013, Margery S. Bronster, attorney for the applicant, states that "...the State Health Coordinating Council's priority of ensuring access to quality health care at a reasonable cost by providing improved access to dialysis services is satisfied. Currently, in order to reach existing clinics, residents of the North Shore must travel a two-lane road to Kaneohe or Kailua or take the freeway to central Honolulu and south Oahu. This must be done at least three times a week. By allowing Liberty to establish the Mililani facility, patients from the North Shore, Mililani, and Wahiawa will substantially reduce their commute times."
4. The applicant states that "This proposal will also advance the West Oahu Subarea Councils' ("SAC") priorities by improving education and increasing preventive health efforts for persons suffering from end stage renal disease through Liberty Dialysis' initiatives to education (sic) its patients about how to better manage their disease and thereby prevent or delay the onset of more serious health problems."

5. Chapter 2 of The State of Hawaii Health Services and Facilities Plan (the "HSFP") states that "Capacity (utilization) thresholds for certain standard categories of health care services are established to guide the initial determination of need for a service area."
6. The HSFP provides that the capacity threshold for Chronic Renal Dialysis services is as follows:

"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."
7. The HSFP further provides that:

"It is recognized that some service areas may not meet the required threshold for a health care service. Sub-optimum utilization may be proposed if the benefits clearly outweigh the costs to the community of duplicate or under-utilized services, facilities, or technologies. Benefits are defined as the form of improved access for the service area(s) population combined with significant improvement in quality and/or significant reduction in cost to the public.

In addition, 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 on statistical generalizations;
 - Create opportunities for cost 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. The applicant states that its Primary Service Areas are O'ahu-wide and West O'ahu.
9. The applicant states that "The primary service area ("PSA") will include Central Oahu and the North Shore communities of Mililani (zip 96789), Wahiawa (zip 96786), Haleiwa (96712), Waialua (96791), and Kahuku (96731)."
10. The applicant states that "Island wide, only two dialysis centers are not performing at or above the HSFP threshold utilization level. Liberty Dialysis' clinic in Kailua currently performs 433 treatments per station per year, or at 72% of the threshold. DSI's Koolau dialysis center performs 533 treatments per station per year, or at about 89% of the HSFP threshold. However, these facilities are too far distant from the PSA to be effectively accessible to its residents because patients typically must receive dialysis treatments ranging from 3 to 5 hours in length at least 3 three times each week. Travel is also difficult for dialysis patients because many are unable to drive and must arrange other transportation for their treatments. Accordingly, lengthy travel between their homes and dialysis facilities sometimes discourage dialysis patients from complying with their treatment regimens."

11. In written testimony received by the Agency March 13, 2013, Jay Yalowitz, Executive Vice-President of DSI Renal, states that the utilization at DSI Honolulu (zip code 96817) is 557 treatments per station per year and DSI Kapahulu (zip code 96816) is 527 treatments per station per year.
12. In written testimony received by the Agency March 7, 2013, Dr. James Ireland states "Factors like long commutes, limited availability of treatment times, and other access issues substantially exacerbate the burden of dialysis treatment and, in my experience, can lead to patients who are less likely to comply with dialysis prescriptions, either through cutting treatment short, missing treatments or discontinuing dialysis treatments entirely resulting in poorly managed ESRD. Poorly managed ESRD leads to a number of complications, resulting in costly hospitalizations, loss of productivity and, in some cases, death. Ensuring access to local, high quality dialysis care is the best and most cost effective way, to guard against unnecessary complications that lead to expensive and avoidable interventions and diminished quality of life."
13. In written testimony received by the Agency March 7, 2013, Glen Hayashida, CEO of the National Kidney Foundation of Hawaii states "While we take no position on the merits of the application, I would like to emphasize the needs of the patient and what a difference a dialysis center in a closer proximity means... While there is little that can be done to shorten the time on dialysis without impacting the quality of treatment, if we can reduce the travel time for patients then it will relieve driving time, time in traffic, or waiting time for a Handivan... With convenience, there is less likelihood of skipping treatments. If treatment is skipped then the body can feel like a blown up balloon. However, we all know how we sometimes plan our lives to avoid traffic concerns. Patients on dialysis machines are no different. I ask that you consider how much time and convenience having a closer dialysis facility means to people."
14. In his written testimony, Mr. Hayashida further states "...the combination of our aging population, diabetes, and incidence of chronic kidney disease in our community (sic) that the need for dialysis centers will only increase in a short period of time. Currently, it is estimated that 1 out of 7 adults or 156,000 of our residents in Hawaii have chronic kidney disease. Nationally, one out of every three people is at risk of chronic kidney disease."
15. The applicant states that "Data developed by the City & County of Honolulu Department of Planning & Permitting shows that the PSA is expected to experience significant growth in its senior population between now and 2025."
16. In written testimony dated March 8, 2013, Arthur A. Ushijima, President and Chief Executive Officer of The Queen's Health Systems states that "According to the 2012 U.S. Census, West O'ahu is the fastest growing region on the island and is home to 356,000 (42%) of O'ahu's residents. While the overall population on O'ahu is expected to grow at an average of less than 1% per year, West O'ahu's population is projected to grow at an annual rate of 2-3%. By 2030, it is expected to grow to 50% of O'ahu's population with over 600,000 residents. Housing growth is expected to be strongest in Kapolei/Ewa, followed by moderate growth in Mililani/Waipio and Waianae."

17. In his written testimony, Mr. Ushijima states “The West O’ahu region is home to the largest concentration of Native Hawaiians in the State. According to the State of Hawaii Department of Health, Native Hawaiians have the poorest health status and lowest life expectancy among Hawaii’s major ethnic groups. According to the State of Hawaii Department of Health’s Behavioral Risk Factor Surveillance System (BRFSS), Native Hawaiians had the highest incidence of diabetes among Hawaii’s major ethnic groups in 2010, followed closely by Filipinos. Many diabetes patients can digress towards kidney failure, thereby requiring hemodialysis.”
18. In his testimony, Mr. Ushijima further states “This project increases access to care for all patients in the West O’ahu primary service area. As an inpatient hospital, The Queen’s Medical Center (QMC) experiences significant delays in the discharge processing, especially new patients, for dialysis treatment in a clinic... A patient remains hospitalized until outpatient services are secured, unnecessarily utilizing critical bed space and adding to the overall cost of healthcare. For example, in recent past, two leeward patients remained hospitalized at QMC for two weeks while waiting for an outpatient slot. Both had to accept Honolulu slots, while being waitlisted for a hemodialysis slot closer to home. Another patient remained hospitalized for three months at QMC while awaiting a care home near an existing facility with an open slot.”
19. In written testimony dated March 5, 2013, Brigitte McKale, Vice-President & Chief Nurse Executive of Pali Momi Medical Center, states that “This project is a much needed expansion to meet the dialysis needs for residents of Central O’ahu and the North Shore. On any given day at Pali Momi Medical Center (PMMC) there are patients who have been treated and are waiting to be discharged but who must remain “waitlisted” because they do not have access to outpatient dialysis services. This represents a poor quality of life option for the patient, presents an often insurmountable dilemma for providers and patients, and creates a serious financial drain on acute care hospitals with ripple effects felt throughout other healthcare service sectors”
20. The applicant states that “Liberty Dialysis projects that the utilization of the new facility will reach the threshold level of 600 treatments per dialysis station by the third year of the center’s operation...”
21. In her written testimony, Ms. Bronster states that “We recognize that DSI has approval for a 24 station clinic in Waipahu. However, while approval for that facility was granted by SHPDA in 2008, we understand that there are currently no patients dialyzing at that clinic and the Department of Health will need to do a certification survey before the clinic can be fully functional... even factoring in the use of those 24 *de novo* stations, there would still be a need for 54 more stations in the West Oahu PSA... Plus, these numbers do not take into account the projected demand growth that we anticipate in the Central Oahu/North Shore communities. Thus, even under conservative estimates that are most favorable to DSI, there still exists a demand for Liberty’s proposed Mililani facility.”

22. The applicant states that "While the Proposed Dialysis Center is intended primarily to meet the needs of individuals residing within the PSA, Liberty Dialysis will make its services available to all Oahu residents, including low-income individuals, racial and ethnic minorities, women, individuals with disabilities, other underserved groups, and the elderly. As always, Liberty Dialysis will maintain its commitment to provide charity care to those otherwise unable to afford dialysis treatment."
23. The applicant states that "Liberty Dialysis provides the highest quality of dialysis services to its patients and is in full compliance with all federal and state regulations at all of its dialysis centers in Hawaii."
24. The applicant states that "All Liberty Dialysis centers are CMS certified, and observes the standards set by both the CDC and CMS in its centers' operations. Liberty Dialysis' quality improvement program was developed in accordance with CMS and the National Kidney Foundation's Disease Outcomes Quality Initiative ("KDOQI") guidelines. In keeping with the Liberty Dialysis Quality Improvement Program, each facility monitors the quality of care in the following areas: anemia management, bone management, adequacy of dialysis, patient satisfaction, and technical management."
25. The applicant states that "All Liberty Dialysis nurses are licensed in Hawaii and all patient care technicians are nationally certified as required by CMS. All nurses and hemodialysis technicians must complete the Liberty Dialysis training program prior to assignment to patient care duties. All Liberty Dialysis patient care staff will participate in regular in-service training in order to assure maintenance of the highest level of competency."
26. The applicant states that "The total cost of the project is estimated at approximately \$3,361,451.00 which includes \$1,250,000.00 for construction costs, \$200,000.00 for fixed equipment, \$425,000.00 for movable equipment, and \$1,486,451.00 for the site lease. The project will be financed with cash or a committed working capital line."
27. The applicant projects that for the first full year of the Proposal, total operating revenue will be \$1,500,000 and net income from operations will be \$10,000. The applicant projects that for year three of the Proposal, total operating revenue will be \$2,150,000 and net income from operations will be \$370,000.
28. In his written testimony, Mr. Ushijima states "The proposed project will have a positive impact on the State's existing health care system because it will help fill the gap between the current availability of hemodialysis services and the increasing need for more services. As QHS anticipates the opening of The Queen's Medical Center - West O'ahu in 2014, this proposed project will also have positive impact to the capacity to discharge patients from that hospital facility, as well."

29. The applicant states that "There are no financial obstacles to this project. The Proposed Project will be paid for with cash reserves or a committed working capital line, which Liberty has dedicated for the project."
30. The applicant states that "Liberty Dialysis expects to assign staffing for the proposed facility from its current pool of employees in addition to seeking new employees through local and national advertisements. Liberty Dialysis engages in extensive local recruitment and conducts in-house nurse and technician training programs to insure that its personnel are qualified to provide high quality care to its dialysis patients."

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, Liberty Dialysis-Hawaii, 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), HRS, the Agency finds 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 the and ISSUES a Certificate of Need to Liberty Dialysis-Hawaii, LLC for the Proposal described in Certificate of Need Application #12-28A. The maximum capital expenditure allowed under this approval is \$3,361,451.

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.


Romala Sue Radcliffe
Administrator