



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

NEIL ABERCROMBIE
GOVERNOR OF HAWAII

LORETTA J. FUDDY, A.C.S.W., M.P.H.
DIRECTOR OF HEALTH

ROMALA SUE RADCLIFFE, B.A., M.A.
ADMINISTRATOR

1177 Alakea St., #402, Honolulu, HI 96813 Phone: 587-0788 Fax: 587-0783 www.shpda.org

February 17, 2012

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Rice Powell
Chief Executive Officer
Fresenius Medical Care Holdings, Inc.
920 Winter Street
Waltham, MA 02451

Dear Mr. Powell:

Re: Second Amended Administrative Review Decision CON Application No. 11-20A

The State Health Planning and Development Agency (the "Agency") has reevaluated Certificate of Need application #11-20A from Bio-Medical Applications Management Company, Inc. (BMAMC) (the "applicant") for the acquisition of Liberty Dialysis Holdings, Inc., at a capital cost of \$16,260,743 (the "proposal").

1. Pursuant to Title 11, Chapter 186 of the Hawaii Administrative Rules (HAR), the Agency has determined that this proposal is eligible for administrative review as it meets the criterion in Section 11-186-99.1(b)(6).
2. The applicant states that "This project will advance the Statewide Health Coordinating Council ("SHCC") priorities of promoting the long-term viability of the health care delivery system and of ensuring maintenance of overall access to quality health care at a reasonable cost by ensuring that Hawai'i residents have continued access to cost-effective dialysis services. The anticipated reduction in the clinics' operating expenses will not only ensure their long-term financial viability, but will also help to slow the rising cost of providing dialysis services to Hawaii's ESRD [End Stage Renal Disease] patients."
3. The applicant states that "In addition, this Project will advance the goals of the Honolulu Subarea Council ("SAC"), the Kauai SAC and the Maui County/Tri-Isles SAC by maintaining the availability of support services and reducing the cost of senior care. ESRD frequently develops secondary to diabetes mellitus, which is prevalent among individuals between 45 - 64 years of age, with the median age of onset over the age of 55. The costs associated with dialysis are minimal compared to the costs of emergency medical care and/or hospitalization due to complications from ESRD that can result from noncompliance with prescribed dialysis treatment regimens. Additionally complications of ESRD not infrequently make it impossible for

seniors to continue living in their homes and necessitate costly nursing home care. By maintaining access to dialysis centers in their communities and near their homes, this proposal will assist seniors with ESRD to comply with their dialysis treatment regimens, thereby helping them to avoid nursing home care and reducing the financial and social costs of ESRD for patients, their families, and the community.”

4. The applicant states that "The need for these services is evidenced and established in the already approved certificates of need ("CONS") held by Liberty for these dialysis clinics. Access to dialysis services in the current service areas will be maintained."
5. The applicant states that "The centers will continue to provide service for all of their approximately 2000 ESRD patients throughout Hawai'i, who would die without dialysis or a successful kidney transplant. Charity care will continue to be provided to those who are otherwise unable to afford dialysis treatment."
6. The applicant states that "The centers will continue to serve all Hawai'i residents including low income persons, racial and ethnic minorities, women, persons with disabilities and other underserved groups, and the elderly."
7. The applicant states that "The centers are, and will continue to be Medicare certified. The merger is not intended to alter the scope of services provided at the centers, nor change the clinical staff and attending physicians, thereby ensuring the continuity and quality of care."
8. The applicant states that "FMCH [Fresenius Medical Care Holdings, Inc.] will incorporate its UltraCare® program into the centers' quality assurance protocols. UltraCare and certain innovative technology are exclusively available to patients at FMCH facilities. UltraCare represents FMC's [Fresenius Medical Care's] commitment to deliver excellent care to patients, through innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service. UltraCare is delivered by highly trained staff and demonstrated through dedication, leadership and compassion by every team member, every day."
9. The applicant states that "Clinical outcomes will be measured using industry standards developed by the National Kidney Foundation and the ESRD Network."
10. The applicant states that the estimated revenue for LDNH [Liberty Dialysis-North Hawaii, LLC] for the first and third full years of operation following the merger are projected to be \$1,819,274 and \$1,948,049 respectively and total expenses for the first and third full years of operation following the merger are projected to be \$1,859,373 and \$2,005,875, respectively.

11. The applicant states that the estimated revenue for LDH [Liberty Dialysis-Hawaii, LLC] for the first and third full years of operation following the merger are projected to be \$79,283,131 and \$84,895,108 respectively and total expenses for the first and third full years of operation following the merger are projected to be \$72,524,634 and \$78,776,712, respectively.
12. The applicant states that “The improved operating efficiencies that are expected from the integration of the LDH and LDNH dialysis centers into the Fresenius network will augment their ability to provide life-sustaining dialysis treatment to residents of their respective service areas and maintain high quality patient care in the most efficacious way possible.”
13. The applicant states that “LDH and LDNH will continue their collaboration with other health care providers, community and government organizations, such as the National Kidney Foundation, Hawaii Health Systems Corporation, Transpacific Renal Network; the GFR Alliance, HMSA, Kaiser Permanente; University of Hawai’i at Manoa, Hilo, Maui and Kauai; Kapi’olani Community College; and the National Renal Administrators Association, and work with these partners to help enhance (i) patient education, (ii) interaction with the Hawai’i medical community, and (iii) advanced treatment of CKD [Chronic Kidney Disease] patients to forestall the onset of ESRD and better prepare them to begin dialysis.”
14. The applicant states that “The total value of the Hawai’i-based assets that will be transferred as the result of the merger transaction is estimated at \$16,260,743, which includes fixed equipment valued at \$848,690, movable equipment valued at \$4,039,419, and clinic site leases valued at \$11,372,634. BMAMC will purchase all of the outstanding stock of Liberty Dialysis Holdings in a cash transaction.”
15. The applicant states that “Because this merger is not intended to result in any change in the staff currently employed by the clinics, no additional employees will be required to continue serving the existing patient base.”
16. The applicant states that “The centers will continue to provide chronic outpatient and acute dialysis services as they are currently provided by Liberty. Because the centers will continue an existing service, with no anticipated change in scope of service or staffing, the merger is not expected to have any effect on other providers or patients.”

17. In testimony dated January 5, 2012, Ellen Godbey Carson, Esq., writing on behalf of Kaiser Foundation Health Plan ("Kaiser") and its affiliate, Rainbow Dialysis, LLC ("Rainbow") states:

"This [applicant's expectation that the transaction will not change the manner in which Liberty manages its dialysis clinics] raises severe concerns because Liberty has been very harmful to the healthcare system in places like Maui, where Liberty has obtained a monopoly and mis-used its power as a sole provider, as was shown in the prior Rainbow CON proceedings... In the three years after Liberty took over from St. Francis, total charges to Kaiser for dialysis increased over 350%... Liberty's charges for basic dialysis rates and Epogen increased 250% to 450% higher on neighbor islands where it had no competition, than on Oahu (where it had competition)... For iron sucrose (a drug needed by most dialysis patients to prevent anemia), Liberty's charges to Kaiser escalated from under \$15,000 in 2010 to over \$2 million in 2011... Based on the Application... Liberty apparently plans to continue its harmful pricing practices and anti-competitive activities, thus threatening further harm to our healthcare system."

18. In her testimony dated January 5, 2012, Ms. Godbey Carson states that "Liberty and Fresenius should not be permitted to merge into an even more dominant presence in Hawai'i without close evaluation, inquiry, and imposition of conditions that will control abusive practices and detrimental impact in areas where the new company will have a monopoly."
19. In a letter to the Agency dated January 12, 2012, J. George Hetherington, Esq., representing Bio-Medical Applications Management Company, Inc., and its parent, Fresenius Medical Care Holdings, Inc. states "As disclosed in the application, Fresenius made a Hart-Scott-Rodino filing for this transaction with the Federal Trade Commission ("FTC") and the Antitrust Division of the United States Department of Justice ("DOJ") on August 1, 2011. In response to concerns raised by the FTC, Fresenius has agreed to divest *all* of it (sic) dialysis clinics on Oahu to a buyer approved by the FTC. Accordingly, the competitive status quo in regards to dialysis services in Hawaii will be maintained."
20. In her testimony dated January 5, 2012, Ms. Godbey Carson states that "Even if the Federal Trade Commission (FTC) orders a divestiture of some of the clinics, the new proposed merger will likely result in a monopoly in Hawaii for outpatient dialysis services for certain islands and geographic areas... The evidence is clear that monopolistic abuse of life-saving dialysis services is detrimental to the existing healthcare system and imposes unsustainable costs to the community and other providers."

21. In Ms. Godbey Carson's testimony dated January 5, 2012, she states "There is already a monopoly on dialysis services on Maui, the Big Island, Kauai, Molokai and Lanai. While Rainbow has an approved CON for Maui, it has not been able to open yet due to delays caused by Liberty's efforts to shut down Rainbow, which are ongoing." Ms. Godbey Carson's testimony establishes that the Rainbow CON proceedings (CON No. 09-13, 10-SHPDA Recon-01) by which Rainbow was granted a conditional CON to develop and operate two dialysis clinics on Maui, are now on appeal. Liberty appealed against SHPDA and Rainbow first to the Circuit Court of the First Circuit, State of Hawaii, pursuant to section 91-14, Hawaii Revised Statutes (HRS), in Civil No. 11-1-0532-03 KKS. That agency appeal ended in a final judgment in favor of Rainbow on December 13, 2011. Liberty now challenges the final judgment of the Circuit Court in a secondary appeal to the Intermediate Court of Appeals, pursuant to section 91-15, HRS and other relevant authority, in CAAP-12-0000018, and seeks an injunction pending appeal. On January 31, 2012 the Court denied Liberty's request for an injunction pending appeal.
22. The Agency's record of the its proceedings in CON application 09-13 establishes that Rainbow, a wholly owned subsidiary of Kaiser, filed its standard form application for certificate of need to establish chronic renal dialysis services ("CRDS") at two sites in Maui County on September 28, 2009 (CON application No. 09-13). On May 3, 2010, the Agency issued its Decision on the Merits granting a conditional CON to Rainbow. Thereafter, LDH requested reconsideration, which was granted (10-SHPDA Recon-01). LDH also moved to intervene in the reconsideration, which motion was granted. Following four pre-hearing conferences on Oahu, the combined public hearing and contested case hearing on the reconsideration took place on Maui from January 3, 2011 through January 5, 2011. The Agency's Decision on the Reconsideration was issued on February 17, 2011, granting a conditional CON to Rainbow.
23. On March 17, 2011, LDH filed its appeal of the Decision on the Reconsideration in the Circuit Court of the First Circuit, as allowed by section 91-14, HRS. LDH raised and briefed eight issues as the basis for its appeal, as set forth in its Opening Brief filed July 25, 2011. Following review of the appellate briefs and other submissions of the parties, including supplemental briefing; and after hearing oral argument on September 27, 2011 on the appellate briefs and further oral argument on November 29, 2011 on the supplemental briefing requested by the Court pursuant to its minute order dated November 1, 2011, the Court issued its December 13, 2011 Order Affirming the February 17, 2010 Decision on the Reconsideration Issued by Appellee State Health Planning and Development Agency. LDH filed its secondary appeal to the Hawaii Intermediate Court of Appeals pursuant to section 91-15, HRS and other relevant authority on January 10, 2012.

Conclusions

The Agency finds that the proposal meets the certificate of need criteria in Hawaii Administrative Rules (HAR) 11-186-15(a)(1), (3) - (9) inclusive, and HAR 11-186-15(a)(11-12). The criterion in HAR 11-186-15(a)(2) is not applicable to this proposal.

Given that Fresenius has agreed to divest all of its dialysis clinics on Oahu to a buyer approved by the FTC, the Agency finds that the proposal meets the criterion in HAR 11-186-15(a)(10) (the relationship of the proposal to the existing health care system of the area) for the City and County of Honolulu.

However, the Agency finds that the proposal would have a detrimental impact on the health care system in areas where the applicant, its subsidiaries, and its affiliates will be the sole provider of chronic renal dialysis services and therefore does not meet the criterion in HAR 11-186-15(a)(10) for the areas of Hawaii County, Maui County and Kauai County (the "Neighbor Island Counties"). The Agency expects that the denial of the injunction that Liberty sought pending its secondary appeal involving CON #09-13 will improve the relationship of the proposal to the existing health care system for Maui County, at least temporarily. The Agency finds that the proposal, if modified in accordance with the condition below, would not have a detrimental impact in the Neighbor Island Counties, and would meet the criterion in HAR 11-186-15(a)(10) in the Neighbor Island Counties.

Order and Conditional Certification

The State Health Planning and Development Agency hereby APPROVES and ISSUES a CONDITIONAL Certificate of Need to Bio-Medical Applications Management Company, Inc. for the proposal described in Certificate of Need application #11-20A. The condition is that on or before Noon, March 22, 2012, the applicant shall submit to the Agency, for Agency approval:

A plan to take effect after the acquisition and merger for providing dialysis services at reasonable cost for Hawaii County, Maui County and Kauai County consistent with the statutory purpose in 323D-1, HRS "...to promote accessibility for all the people of the State to quality health care services at reasonable cost." (Emphasis added.)

This modification is required for the application to successfully meet the criteria for the issuance of a certificate of need.

As provided under Section 323D-46, HRS and Section 11-186-77 HAR, the Agency establishes Noon, March 22, 2012 as the date and time by which the applicant must certify, in writing, that it accepts this condition otherwise this application shall be deemed to be DENIED as provided under Section 11-186-77 HAR.

There is no compelling public interest which will be served by requiring the application to go through the standard review process.

As required under Section 323D-43(b), HRS, the Agency determines that, if modified as specified in the above Order,

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

The maximum capital expenditure allowed under this approval is \$16,260,743.

Please be advised that pursuant to Section 323D-47, HRS and Section 11-186-99.1(g) HAR, 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 second amended decision. Accordingly, if no person makes such a timely request for reconsideration, this second amended decision shall become final immediately after the deadline for making such a request has expired.



Romala Sue Radcliffe
Romala Sue Radcliffe
Administrator