



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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October 20, 2008

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 08-15
Kauai Oncology, LLC)	
)	
Applicant)	
_____		DECISION ON THE MERITS

DECISION ON THE MERITS

The State Health Planning and Development Agency (hereinafter "Agency"), having taken into consideration all of the records pertaining to Certificate of Need Application No. 08-15 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Kauai Subarea Health Planning Council, the Certificate of Need Review Panel and the Statewide Health Coordinating Council, the Agency hereby makes its Decision on the Merits, including findings of fact, conclusions of law, order, and written notice on Certificate of Need Application No. 08-15.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of radiation therapy services at 4388 Pahe'e Street, Lihue, Hawaii, at a capital cost of \$4,036,000.
2. The applicant, Kauai Oncology, LLC is a limited liability corporation.

3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).
4. On April 25, 2008, the applicant filed with the Agency a Certificate of Need application for the establishment of radiation therapy services at 4388 Pahe'e Street, Lihue, Hawaii, at a capital cost of \$4,036,000 (the "Proposal"). On July 9, 2008, August 5, 2008, and August 20, 2008 the applicant filed additional information. On September 2, 2008 application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #08-15.
5. The period for Agency review of the application commenced on September 3, 2008, the day notice was provided to the public pursuant to 11-186-39 HAR.
6. The application was reviewed by the Kauai Subarea Health Planning Council at a public meeting on September 10, 2008. The Council voted 4 to 0 in favor of recommending conditional approval of the application. The conditions were:
 - a. The applicant provides copies of current licensure and certifications for its physicians.
 - b. The applicant enters into memorandum of understanding (MOU) with Wilcox Hospital to ensure that CT services are accessible and available at the hospital for the applicant's oncology patients.
 - c. The applicant enters into memorandum(s) of understanding with alternate provider(s) of oncology services in the State of Hawaii to ensure that its patients can continue their treatments in the event of a breakdown of equipment at the applicant's facility.
 - d. If possible, the applicant obtains fee schedule agreement(s) with commercial health care insurers with the objective being to minimize its patients' out of pocket payments or co-payments for oncology services.
7. On September 16, 2008, September 23, 2008, and October 14, 2008, the applicant filed additional information in response to the Kauai Subarea Health Planning Council's recommendation for conditional approval.
8. The application was reviewed by the Certificate of Need Review Panel at a public meeting on September 18, 2008. The Council voted 6 to 1 in favor of recommending approval of this application.
9. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on September 25, 2008. The Council voted 14 to 0 in favor of recommending approval of this application

10. This application was reviewed in accordance with Section 11-186-15, HAR.

11. Pursuant to Section 323D-43(b), HRS:

“(b) No Certificate shall be issued unless the Agency has determined that:

- (1) There is a public need for the facility or service; and
- (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs.”

12. Burden of proof. Section 11-186-42, HAR, provides:

“The applicant for a certificate of need or for an exemption from certificate of need requirements shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence.”

II

FINDINGS OF FACT

A. REGARDING THE RELATION OF THE PROPOSAL TO THE STATE HEALTH SERVICES AND FACILITIES PLAN (HAWAII HEALTH PERFORMANCE PLAN) OR “H2P2”

13. The applicant states that the Proposal will "...contribute to the goal of increasing the span of healthy life for Hawai'i's residents. Radiation therapy is curative and can definitely increase the span of healthy life of residents. At the present time, radiation therapy is not available on the island of Kauai. As such, residents of Kauai must go to neighboring islands for treatment. The proposed project will eliminate this disparity."

14. With respect to the H2P2 utilization thresholds for radiation therapy, the applicant states that "For a new unit of service to be offered, all other providers in the services area should have a minimum utilization of 8000 procedures and 320 patients per year. New facilities should be projected to achieve a minimum utilization of 6000 procedures by the third year of operation. As previously stated, there are no radiation therapy units in operation on the island of Kauai. Given the present population estimate of approximately 63,000 people, coupled with a cancer incident rate of 416 patients per 100,000 population for lung cancer, 416 patients per 100,000 for breast cancer and 583 patients per 100,000 population for prostate cancer, it appears that a radiation therapy center on the island of

Kauai would initially treat approximately 120-150 patients per year. Depending upon the stage and mix of cancer patients referred to Kauai Oncology Institute, it is estimated that 4160 to 5000 patient treatments would be provided in the third year of operation... However, the applicants certainly believe that the capacity thresholds to offer radiation therapy services on the island of Kauai could be met after three years of operation, given the population growth on the island of Kauai, the aging of the population on Kauai, and the growth of linear accelerator stereotactic radiosurgery."

15. The applicant states that "The proposed project would meet the Kauai County subarea values and priorities by helping improve the distribution of services to patients in the Kauai subarea. Specifically, Priority 2G mentions that certain services need to be provided on the island or better distributed geographically. 'Currently, these include cancer care (specifically radiation therapy)'"

16. The applicant states that "The proposed project will address the accessibility issue to residents in the Kauai subarea and being centrally located on the island should minimize the transportation costs that cancer patients face in receiving numerous radiation therapy treatments for those cancer patients who would benefit from radiation therapy."

17. The Agency finds that this criterion has been met.

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

18. The applicant states that "The proposed project will fill a gap that currently exists in the healthcare delivery pattern since radiation therapy is not available on the island of Kauai. It is stated in the Kauai Subarea Council Plan as well as in the Hawaii Health Performance Plan that radiation therapy should be available on the island of Kauai."

19. The applicant states that "At the current time, approximately 250 patients a year are diagnosed with cancer on Kauai. Of those 250 patients, it is estimated that approximately 60% will require some type of radiation therapy... It is estimated that one treatment vault may serve the needs of 350 patients per year. The proposed project to establish a single radiation therapy vault meets the need for the present time as well as the foreseeable future."

20. The applicant states that "Radiation therapy will be accessible to all the residents on the island of Kauai... In the applicant's financial projections, it is estimated that the applicant will provide 5% charity care to patients who do not have the resources necessary to pay for cancer treatment."

21. The Agency finds that the need and accessibility criteria have been met.

C. REGARDING QUALITY AND LICENSURE CRITERIA

22. The applicant states that "The proposed project will improve the quality of care being delivered to the target population by being delivered on state-of-the-art equipment, utilizing 120-leaf collimator. In addition, three-dimensional computerized treatment plans as well as IMRT radiation therapy will ensure that patients receiving services at the facility have the maximum dose accurately delivered to a tumor with a minimal radiation dose delivered to the surrounding tissue. In addition, the proposed project will allow patients to be taken care of without leaving the island, which should improve the quality of life to the patient being treated associated with those providing adjunctive care to the patient."

23. The applicant states that "Each radiation therapy facility has internal policies and procedures that are utilized to monitor the quality of care being provided."

24. The applicant states that "The principals comprising Kauai Oncology, LLC, have operated facilities on the mainland... All these facilities have maintained Medicare certification throughout their operation and none of the three principals have ever been reprimanded or sanctioned by Medicare. All physicians are applicants in good standing at the respective hospitals where they have medical staff privileges. All applicants are board certified by the American Board of Medical Specialties."

25. The applicant states that "The special qualifications of the staff include registry as a radiation therapy technologist and board certification as a physician as well as licensure as a medical physicist by the applicable state in which the physicist is licensed."

26. The Agency finds that quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

27. The applicant states that "The operating entity, Kauai Oncology, LLC will be entering into a long-term lease with a related entity Kauai Oncology Institute, LLC. Kauai Oncology Institute, LLC has obtained financing from the Bank of Edwardsville to borrow \$4,011,000 to purchase land in the amount of \$375,000, construct a building and related sitework in the amount of \$2,100,000, pay construction interest in the amount of \$134,700 and purchase capital equipment in the amount of \$1,401,300. The land, building and capital equipment is to be leased to Kauai Oncology, for approximately \$38,000 per month. The principals of Kauai Oncology and Kauai Oncology Institute are the same."

28. The applicant states that "The projections show that a small operating margin will exist in all three years. As a result, it appears that the proposed project will be able to be supported through the utilization of the services by patients in Kauai County."

29. The applicant states that "The proposed project should decrease the cost that cancer patients on the island of Kauai incur as a result of seeking radiation therapy treatments. Residents will not have costs associated transportation and lodging as well as food costs, which may be significant when obtaining services on another island."

30. The Agency finds that cost and financial criteria have been met.

E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA

31. The applicant states that "The proposed project will fill a gap that currently exists in the healthcare delivery pattern since radiation therapy is not available on the island of Kauai. It is stated in the Kauai Subarea Council Plan as well as in the Hawaii Health Performance Plan that radiation therapy should be available on the island of Kauai."

32. The applicant states that "The proposed project does not intend to duplicate any services that are presently available at Wilcox Memorial Hospital and should, indeed, increase the utilization of laboratory services and diagnostic services that cancer patients require during their course of treatment as well as post treatment. It is the position of the applicant that the proposed project will improve the existing healthcare system."

33. The Agency finds that this criterion has been met.

F. REGARDING THE AVAILABILITY OF RESOURCES

34. The applicant states that "The operating entity, Kauai Oncology, LLC will be entering into a long-term lease with a related entity Kauai Oncology Institute, LLC. Kauai Oncology Institute, LLC has obtained financing from the Bank of Edwardsville to borrow \$4,011,000 to purchase land in the amount of \$375,000, construct a building and related sitework in the amount of \$2,100,000, pay construction interest in the amount of \$134,700 and purchase capital equipment in the amount of \$1,401,300. The land, building and capital equipment is to be leased to Kauai Oncology, for approximately \$38,000 per month. The principals of Kauai Oncology and Kauai Oncology Institute are the same."

35. The applicant states that "It is the applicant's preference to hire local individuals, if they are available, for the positions of medical secretary, radiation therapy technologist, medical physicist. However, if local personnel are unavailable, several existing personnel employed by the principals have already requested consideration for the positions that will be available if the proposed project is approved."

36. The Agency finds that the applicant has met this criterion.

III

CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 08-15 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Kauai Subarea Health Planning Council, the Certificate of Need Review Panel and the Statewide Health Coordinating Council and based upon the findings of fact contained herein, the Agency concludes as follows:

The applicant has met the requisite burden of proof and has shown by a preponderance of the evidence that the Proposal meets the criteria established in Section 11-186-15, HAR.

Accordingly, the Agency hereby determines that, pursuant to Chapter 323D-43(b):

- (1) There is a public need for this proposal; and
- (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.

ORDER

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a certificate of need to Kauai Oncology, LLC for the proposal described in Certificate Application No. 08-15. The maximum capital expenditure allowed under this approval is \$4,036,000.

WRITTEN NOTICE

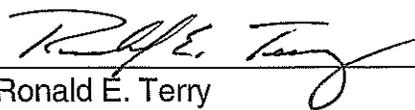
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 HAR. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

(Note, pursuant to Chapter 323D-47, Hawaii Revised Statutes, a request for reconsideration shall be received by the Agency within ten working days of the state agency decision.)

DATED: October 20, 2008
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



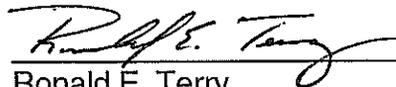
Ronald E. Terry
Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Decision on the Merits, including findings of fact, conclusions of law, order, and written notice, was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on October 20, 2008

David Horace
Project Manager
Kauai Oncology, LLC
332 Country Club Acres
Belleville, IL 62223

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



Ronald E. Terry
Administrator