



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

LINDA LINGLE
GOVERNOR OF HAWAII
CHIYOME L. FUKINO, M.D.
DIRECTOR OF HEALTH
RONALD E. TERRY
ADMINISTRATOR

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

December 18, 2007

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 07-11
Maui Cancer Center PET/CT)	
Company, 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. 07-11 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons and the recommendations of the Tri-Isle Subarea Health Planning 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. 07-11.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of Positron Emission Tomography and Computed Tomography (PET/CT) services at 59 Hookele Street, Kahului, Hawaii, at a capital cost of \$880,000.
2. The applicant, Maui Cancer Center PET/CT Company, 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 27, 2007, the applicant filed with the Agency a Certificate of Need application for the for the establishment of Positron Emission Tomography and Computed Tomography (PET/CT) services at 59 Hookele Street, Kahului, Hawaii, at a capital cost of \$880,000 (the "Proposal"). On July 18, 2007 and August 10, 2007, the applicant submitted additional information. On August 20, 2007, the application was determined to be complete. On August 22, 2007, the applicant requested in writing that its application be scheduled by the Agency for October 2007 reviews. For administrative purposes, the Agency designated the application as Cert. #07-11.

5. The period for Agency review of the application commenced on September 30, 2007, the day notice was provided to the public pursuant to 11-186-39 HAR.

6. The application was reviewed by the Tri-Isle Subarea Health Planning Council at a public meeting held October 4, 2007. The Council voted 4 to 0 in favor of recommending approval of the application.

7. The Certificate of Need Review Panel and Statewide Health Coordinating Council reviews of the application were waived pursuant to Section 323D-44.6 HRS.

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

9. 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."

10. 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"**

11. With respect to the goals and objectives of H2P2, the applicant states that "In 2005, cancer was the second leading cause of death among men and women in Hawai'i and the nation... PET/CT scanning is a widely accepted imaging procedure used in the detection and staging of a variety of cancer related conditions."

12. The applicant states that "Cancer care is also identified as priority in Chapter V with the following goals:

- Provide access to cost effective diagnostic work-up, medical and surgical interventions in treatment of cancer, and support programs that promote continuity of comprehensive services and follow-up, especially for neighbor island residents.

The proposed PET/CT will provide enhanced care for patients diagnosed with cancer, the proposed project addresses this priority for the Maui County area and the State of Hawaii."

13. The applicant states that "In Section II, Vision and Guiding Principles, Part G, the H2P2 guidelines for a new PET unit: (a) minimum average annual utilization for all other providers in the service area needs to be 1,000 procedures; and (b) utilization of the new unit/service is projected to meet the minimum utilization rate of 1,000 procedures by the third year of operation. Since there are no other PET/CT operators in Maui County, criteria (a) does not apply. With respect to criteria (b), Maui PET/CT relies on the criteria outlined in Section G, Pages II-4 to II-5 (sub-optimization utilization).

'In cases where sub-optimum utilization' is proposed, the benefits in the form of improved access for the service area(s) population combined with significant improvement in quality and/or significant reduction in price to the public - clearly outweigh the costs to the community pf (sic) duplicating or under-using services, facilities, or technology. This provision of sub-optimum utilization is not intended to be applied to conditions that (1) address convenience for the provider and patients of the service(s);

and (2) service areas that have existing excess capacity for that service(s), including existing beds, facilities and services.

Examples of situations where sub-optimum utilization is allowed by the Agency include:

CT for Molokai General Hospital: The population size of Molokai is too small to ever meet the threshold standard to justify a CT. However, concerns about access and quality of care (CT is a standard of care for hospitals) outweighed the sub-optimum utilization data. Therefore, the Agency approved the certificate of need application for a CT from Molokai General Hospital.' (Section G, Page II-5)

Sub Optimization Utilization

We believe that the thresholds should be modified for this project for the following reasons as the project:

- Incorporates current and best clinical practices for cancer care, management and detection.
- Is a cost-effective introduction of modern technology.
- Addresses the documented needs of an actual population - Maui County patients needing to travel to Oahu to receive optimal cancer care & management - rather than a statistical generalization.
- Creates an opportunity for price reduction through competition in PET/CT services statewide through introduction of a service to a regional population.
- Encourages innovation in improving health care services that contribute to enhancing Maui County's healthcare status.

As these services will (sic) the only one of its kind for the community, the project provides benefits without the potential of negative side effects of providing excess capacity."

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

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

15. The applicant states that "The demand for PET/CT services for the projected service area of Maui County can conservatively include cancer patients newly diagnosed 409..., 5 year survivors 1,386 ..., and CT based simulations 321. This yields a potential pool of 2,116 cancer patients that may require at least one PET/CT scan in any given year."

16. The applicant states that "There are currently no other providers of PET/CT services in Maui County. Current access to this technology is limited to patients that can be transported to the island of Oahu. The proposed provision of PET/CT services on Maui , in conjunction with all other comprehensive cancer service available on Maui makes it possible for the target population to receive complete cancer care services without leaving Maui."

17. The applicant states that "The demand for PET/CT services is not currently being met to the extent patients must choose between traveling to Oahu or the mainland for PET/CT services and foregoing the use of this useful tool."

18. The applicant states that "Maui Cancer Center PET/CT Company, LLC will accept all patients, regardless of ability to pay including low income persons, racial and ethnic minorities, women, persons with disabilities and other underserved groups, and the elderly."

19. The Agency finds that the proposal meets the need and accessibility criteria.

C. REGARDING QUALITY AND LICENSURE CRITERIA

20. The applicant states that "The inclusion of the proposed PET/CT service in the comprehensive cancer facility being developed on Maui makes possible access to state-of-the-art imaging both anatomic and molecular. The fusion of these two technologies has clearly advanced the quality of healthcare and the residents of Maui will have available the highest quality cancer care in the State of Hawaii."

21. The applicant states that "The proposed PET/CT service will be conducted in accordance with all state and federal regulations related to the operation of a radiation facility. The facility will operate under license from the Hawaii State Department of Health and shall maintain safety and quality assurance standards pursuant to the requirements of H.A.R. Chapter 11-45."

22. The applicant states that "Medical Direction will be provided by a Radiation Oncologist licensed by the State of Hawaii... Medical Physics and radiation safety oversight will be provided through a contractual agreement with a licensed, Board Certified Medical Physicist."

23. The applicant states that the Radiology Technologist will be registered by the American Registry of Radiological Technologists (ARRT) and will have additional certification as a PET technologist.

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

D. REGARDING THE COST AND FINANCIAL CRITERIA

25. The applicant states that "In the first year of operations, Maui PET/CT projects a total of 528 patients for a net income of \$220,260. By the third year of operation, Maui PET/CT projects a total of 639 patients, resulting in net income of \$134,749."

26. The applicant states that "Clinically, not all patients in the potential pool (2116) will require PET/CT services on an annual basis but those that are newly diagnosed (409) alone will meet over 75% of the projected procedures in the first year of operation. The financial projections are very conservative in evaluating the financial viability of the venture and the identified need for services easily supports the financial requirements of the venture."

27. The applicant states that "Maui patients who require tumor imaging by a PET/CT will incur less expense since they will not have to pay for travel and lodging costs associated with a trip to Oahu or the mainland."

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

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

29. The applicant states that "Current access to this technology is limited to patients that can be transported to the island of Oahu. The proposed provision of PET/CT services on Maui, in conjunction with all other comprehensive cancer service available on Maui makes it possible for the target population to receive complete cancer care services without leaving Maui."

30. The applicant states that since there are currently no other PET/CT services in Maui, this project will have no adverse impact on other healthcare services in the community.

31. The Agency finds that the applicant has met these criteria.

F. REGARDING THE AVAILABILITY OF RESOURCES

32. The applicant states that the "The proposed Maui PET/CT will rely upon existing human resources that already exist within Maui County. A qualified applicant for the Radiation Technologist position currently residing on Maui has been identified and will be available to fill the position. Due to the limited number of staff required it is not anticipated that there will be difficulty in recruiting qualified applicants for all positions."

33. The applicant states that "As a participating member, Hawaii Pacific Health Partners, Inc., has the financial resources to secure all equipment and staffing resources required for this proposed project."

34. 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. 07-11 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 Tri-Isle Subarea Health Planning 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 Maui Cancer Center PET/CT Company, LLC for the proposal described in Certificate Application No. 07-11. The maximum capital expenditure allowed under this approval is \$880,000.

WRITTEN NOTICE

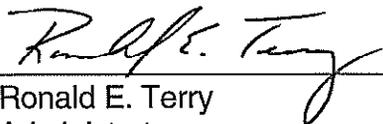
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

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: December 18, 2007
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



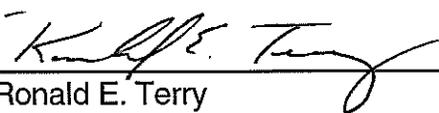
Ronald E. Terry
Administrator

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 December 18, 2007.

Bobby C. Baker, M.D.
President
Maui Cancer Center PET/CT Company, LLC
227 Mahalani Street
Wailuku, Maui 96793

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



Ronald E. Terry
Administrator