

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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February 19, 2009

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 08-17
Kuakini Medical Center)	
)	
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. 08-17 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 Oahuwide Certificate of Need Review Committee 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. 08-17.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of Positron Emission Tomography/Computed Tomography (PET/CT) services at 347 N. Kuakini Street, Honolulu, Hawaii, at a capital cost of \$2,154,100.
2. The applicant, Kuakini Medical Center, is a non profit 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 September 5, 2008, the applicant filed with the Agency a Certificate of Need application for the for the establishment of Positron Emission Tomography/ Computed Tomography (PET/CT) services at 347 N. Kuakini Street, Honolulu, Hawaii, at a capital cost of \$2,154,100 (the "Proposal"). On November 5, 2008, the applicant submitted additional information. On December 5, 2008, the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #08-17.
5. The period for Agency review of the application commenced on December 8, 2008, the day notice was provided to the public pursuant to 11-186-39 HAR.
6. The application was reviewed by the Oahuwide Certificate of Need Review Committee at a public meeting held December 15, 2008. The Committee voted 5 to 0 in favor of recommending approval of the application.
7. The application was reviewed by the Statewide Health Coordinating Council at a public meeting held January 22, 2009. The Council voted 12 to 0 in favor of recommending approval of the application.
8. The Certificate of Need Review Panel review was waived pursuant to Section 323D-44.6 HRS.
9. This application was reviewed in accordance with Section 11-186-15, HAR.
10. 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.”
11. 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"

12. The applicant states that "Positron emission tomography (PET) imaging has become the standard of care for much of oncology...and the use of PET imaging has resulted in earlier detection, more timely treatment, and in many cases, improved outcomes (H2P2 Chapter II, Part C, 2. Objectives 'Early Detecting and Diagnosing of Treatable Diseases' and Reducing Morbidity and Pain Through Timely and Appropriate Treatment')."

13. The applicant states that "Kuakini provides a coordinated, comprehensive cancer program, responsive to community and regional needs (H2P2 Chapter II, Part D)."

14. The applicant states that "In considering the critical elements of a well-functioning health care delivery system, Kuakini believes its proposed project to establish a PET/CT scanner service through the acquisition of a combined PET/CT scanner will complete the spectrum of imaging modalities that Kuakini Medical Center should provide to its patient population, especially its cancer patients."

15. The applicant states that "According to Kuakini's independent data gathering, the total number of PET imaging procedures performed on the two existing PET/CT scanners is approximately 10 to 12 procedures per day (based on 6 to 7 procedures per day performed by QMC and 4 to 5 procedures performed by Hawaii PET Imaging). Assuming 5-day week operations for both existing PET/CT scanners, the minimum annual utilization for The Queen's Medical Center is approximately 1,560 procedures and the minimum annual utilization for the Hawaii PET Imaging is approximately 1,040 procedures. Both existing PET/CT scanners exceed the H2P2 established annual capacity threshold for a PET Unit which is a minimum average annual utilization of 1,000 procedures for all existing providers in the service area...."

16. The applicant states that "Kuakini projects that the utilization of its proposed PET/CT scanner service will be at the annual capacity threshold of a minimum average annual utilization of 1,000 PET procedures per year (as indicated in H2P2) by the third year of operations of Kuakini's new service."

17. The applicant states that "... Kuakini's establishment of the PET/CT scanner service will address the statewide values of Comprehensiveness and Community (Chapter III, Subpart A.2) through the integration and coordination of the new service as part of Kuakini's continuum of health care services, and Kuakini's recognition of the cultural diversity and similarities of its patients."

18. The applicant states that "Under the specific priorities of the Honolulu subarea (Subpart C.2), the priority of increasing geriatric care services for the growing elderly population is addressed by Kuakini's proposal... "

19. The applicant states that "Kuakini's proposed project also supports the H2P2 focus and concern on cancer as noted in Chapter V of the H2P2."

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

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

21. The applicant states that "Applying the projections and utilization data from Bio-Tech Systems Inc., Kuakini has determined that the utilization rate for PET imaging procedures per 1000 population in the U.S. was 2.23 procedures/1,000 population ...in 2003, and 3.06 procedures/1,000 population ...in 2004; and the projected utilization rate in 2010 is 6.68 procedures/1,000 population... "

22. The applicant states that "Conservatively applying the 2004 U.S. utilization rate of 3.06 PET imaging procedures/1,000 population to the estimated population of the Island of Oahu in 2006 and the projected population of the Island of Oahu in 2008 and 2010, the projected annual utilization for the Island of Oahu is 2,781 PET imaging procedures for 2006...4,300 PET imaging procedures for 2008...and 4,429 PET imaging procedures for 2010..."

23. The applicant states that "According to Kuakini's independent data gathering, the total number of PET imaging procedures performed on the two existing PET/CT scanners is approximately 10 to 12 procedures per day (based on 6 to 7 procedures per day performed by QMC and 4 to 5 procedures performed by Hawaii PET Imaging). Assuming 5-day week operations for both existing PET/CT scanners, the minimum annual utilization for The Queen's Medical Center is approximately 1,560 procedures and the minimum annual utilization for the Hawaii PET Imaging is approximately 1,040 procedures. Both existing PET/CT scanners exceed the H2P2 established annual capacity threshold for a PET Unit which is a minimum average annual utilization of 1,000 procedures for all existing providers in the service area...."

24. The applicant states that "Based on the projected growth of the elderly population (persons age 65 and older) on the Island of Oahu which is the primary target population for Kuakini and the projected increase in the incidence of cancer in the elderly population, Kuakini is projecting that the need for PET/CT scanner service will continue to increase on Oahu."

25. The applicant states that "Kuakini's proposed establishment of a PET/CT scanner service will be available and accessible to all residents of the community. Kuakini provides services to those persons who are in need of health care and this is regardless of a person's race, ethnicity, gender, physical disability, ability to pay, and age."

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

C. REGARDING QUALITY AND LICENSURE CRITERIA

27. The applicant states that "The combined PET/CT scanner will enhance Kuakini's cancer program through the improvements that the modality will provide (1) in the detection, diagnosis, and staging of tumors, (2) in the determination of the extent of the disease and localization of disseminated tumors which will reduce unnecessary biopsies and surgeries, and (3) in the determination of optimal treatment planning for patients and in monitoring the patients on their response to the treatment protocols."

28. The applicant states that "Kuakini Medical Center is fully accredited by the Joint Commission... and licensed as an acute care hospital through the State of Hawaii Department of Health. Kuakini's Imaging Department adheres to the licensing standards and guidelines developed by the Society of Nuclear Medicine, the Nuclear Regulatory Commission, Food and Drug Administration, and American College of Radiology."

29. The applicant states that "The Nuclear Medicine technologists are licensed by the State of Hawaii. Also, the Nuclear Medicine technologists are registered with either the Nuclear Medicine Technology Certification Board (NMTCB) or American Registry of Radiological Technologists (ARRT). The Nuclear Medicine technologists who will be assigned to operate the PET/CT scanner have received or will be scheduled to receive additional training on this equipment."

30. The applicant states that "Kuakini's Imaging Department and the Nuclear Medicine section are required to comply with the organization-wide Performance Improvement Plan and to relate the initiatives in providing quality care to the patients served by the Imaging Department and the Nuclear Medicine section. The Imaging Department conducts quarterly assessments of the quality of care provided to the patients, and uses best practice guidelines from the American College of Radiology and the Society of Nuclear Medicine."

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

D. REGARDING THE COST AND FINANCIAL CRITERIA

32. The applicant states that "The total project cost is \$2,154,100 which includes \$1,954,100 for the purchase of the combined PET/CT scanner and \$200,000 for the renovation an existing room in Kuakini's Imaging Department. for the installation of the equipment...Kuakini has sufficient cash reserves for the financing and implementation of the proposed project."

33. The applicant states that "Kuakini's proposed establishment of a PET/CT scanner service will have a minimal impact on the overall costs of health care services for the Hawaii community as it will be funded by Kuakini's available capital resources... Kuakini's proposed project will be cost-effective as it will (1) utilize existing facility space currently occupied the CT simulator for radiation therapy; (2) utilize current imaging staff in Kuakini's Imaging Department, and (3) utilize radioactive isotopes which will be purchased from The Queen's Medical Center as Kuakini has no plans to duplicate the cyclotron services already provided by Queen's."

34. The applicant projects excess funds from operations from the proposal as follows: \$153,397 in Year 1, \$122,773 in Year 2, and \$407,299 in Year 3 of the proposal.

35. 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

36. The applicant states that "The predominant patient population served by Kuakini is the elderly population (persons 65 and older); this population is the most rapid growing segment of Hawaii's population and is the segment of the population that has an increasing incidence of cancer. The proposed new PET/CT scanner service will fill a gap in services that Kuakini provides to its target patient population and will enhance the comprehensiveness of Kuakini's cancer program."

37. The applicant states that "Also, this new PET/CT scanner service will strengthen the research capabilities for Kuakini as it continues to conduct its sponsored research initiatives in the area of longitudinal studies, multi-generational studies, and the area of aging."

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

F. REGARDING THE AVAILABILITY OF RESOURCES

39. The applicant states that "The total project cost is \$2,154,100 which includes \$1,954,100 for the purchase of the combined PET/CT scanner and \$200,000 for the renovation an existing room in Kuakini's Imaging Department. for the installation of the equipment...Kuakini has sufficient cash reserves for the financing and implementation of the proposed project."

40. The applicant states that the "The existing imaging staff of Kuakini's Imaging Department will be utilized for the operations of the proposed PET/CT scanner service."

41. 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. 08-17 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 Oahuwide Certificate of Need Review Committee 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 Kuakini Medical Center for the proposal described in Certificate Application No. 08-17. The maximum capital expenditure allowed under this approval is \$2,154,100.

WRITTEN NOTICE

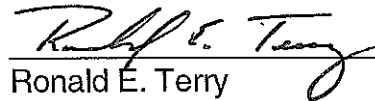
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

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: February 19, 2009
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



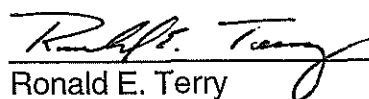
Ronald E. Terry
Administrator

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 February 19, 2009.

Gary K. Kajiwara
President and Chief Executive Officer
Kuakini Medical Center
347 N. Kuakini Street
Honolulu, Hawaii 96817

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



Ronald E. Terry
Administrator