

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

DAVID Y. IGE
GOVERNOR OF HAWAII

VIRGINIA PRESSLER, M.D.
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 18, 2015

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 14-13
Pali Momi Medical Center)	
)	
Applicant)	
)	DECISION ON THE MERITS
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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. 14-13 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, 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. 14-13. Where appropriate, Findings of Fact shall operate as Conclusions of Law, and Conclusions of Law shall operate as Findings of Fact. As many of the criteria for Certificate of Need are interrelated, each of the criteria and subheadings within the Findings of Fact shall be deemed to incorporate and include all other Findings of Fact to the extent relevant.

I

FINDINGS OF FACT

1. This is an application for a Certificate of Need ("Cert.") for the establishment Positron Emission Tomography/Computed Tomography (PET/CT) Scanner services at 98-1005 Moanalua Road, FS4 Space 0001G, Aiea, HI, at a capital cost of \$4,251,351.
2. The applicant, Pali Momi Medical Center is a nonprofit 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 July 31, 2014, the applicant filed with the Agency, a Certificate of Need application for the establishment Positron Emission Tomography/Computed Tomography (PET/CT) Scanner services at 98-1005 Moanalua Road, FS4 Space 0001G, Aiea, HI, at a capital cost of \$4,251,351 (the "Proposal"). On August 29, October 10, October 14, October 22, November 5, and November 14, 2014, the applicant submitted revisions/additional information. On December 1, 2014, the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #14-13.

5. The period for Agency review of the application commenced on December 9, 2014, the day notice was provided to the public pursuant to HAR 11-186-39.

6. The application was reviewed by the Oahuwide Certificate of Need Review Committee at a public meeting on December 16, 2014. The Committee voted 4 to 0, in favor of recommending approval of the application.

7. The application was reviewed by the Certificate of Need Review Panel at a public meeting on December 18, 2014. The Committee voted 5 to 0, with one abstention, in favor of recommending approval of the application.

8. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on January 30, 2015. The Council voted 10 to 0, with one abstention, in favor of recommending approval of the application.

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

10. Section 323D-43(b), HRS states:

"(b) No certificate of need shall be issued unless the state 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
CERTIFICATE OF NEED CRITERIA

A. **REGARDING THE RELATION OF THE PROPOSAL TO THE STATE HEALTH SERVICES AND FACILITIES PLAN CRITERIA**

12. The applicant states that its project meets the following Statewide Health Coordinating Council (SHCC) General Priorities:

Strive for equitable access to health care services: This project will be located in close proximity to some of the most vulnerable populations to cancer incidence on O'ahu. By serving as the only PET/CT in Leeward, Central and West O'ahu, this project will ensure that all populations have equitable access to this service.

Ensure all projects are appropriate for the regional and statewide continuum of care: This project will be the first PET/CT unit to be located in the Leeward, Central and West O'ahu region. The introduction of this service to this region will meet the SHCC goal of providing appropriate regionalized services by ensuring that patients have access to services close to their residence or place of employment.

13. The applicant states that its project will meet the following West O'ahu SAC Priorities:

Improve and Increase Access: Specialty Care: By providing this service, this project will expand access to specialty care in Radiology and oncologic services to residents of Leeward, Central and West Oahu.

Improve and Increase Access: Routine outpatient diagnostic services: PET/CT is a useful outpatient diagnostic procedure for staging or restaging malignant disease and metastases and evaluation of treatment.

Improve and Increase Access: Services for uninsured and underinsured: As a not-for-profit hospital, PMMC (Pali Momi Medical Center) has always provided care for inpatients, outpatients, and emergency patients regardless of a patient's ability to pay. As a hospital based service, the implementation of PET/CT services will also provide additional margin to ensure that PMMC is able to continue to provide much needed services in the community.

14. The applicant states that “There are two capacity thresholds for a new PET/CT unit/service: (1) the utilization of the new unit/service is projected to meet the minimum utilization rate by the third year of operation (2) the minimum annual utilization for each provider in the service area is 600 procedures per unit.”

15. The applicant states that “The proposed project will meet the first capacity threshold for new providers as Pali Momi Medical Center (PMMC) anticipates performing 741 PET/CT procedures by Year 3. This would be in excess of the required 600 procedures per unit required to add a new PET/CT unit/service.”

16. The applicant states that “With respect to the second capacity threshold, PMMC acknowledges that the Kuakini Medical Center (KMC) PET/CT is currently performing below the recommended threshold of 600 scans per year. However, we believe this can be partially attributed to the project's location within a dense concentration of existing providers within the Honolulu urban core and existing physician referral patterns. Our proposed project lies outside the traditional boundaries of the service area of existing providers.”

17. The applicant states that “Per the Hawai'i Services & Facilities Plan (HSFP), it is recognized that some service areas may not meet the required threshold for a health care service. In these cases, sub-optimum utilization may be proposed if the benefits outweigh the costs to the community of duplicating or under-using services, facilities or technologies. Our project meets the sub-optimization utilization criteria as the benefits of our project clearly outweigh the costs to the community by providing the following benefits.

Improved Access for the service area combined with significant improvement in quality

First, this project will improve the quality of care delivered to our patients by making the images available on-site. Currently all PET imaging is done outside of Pali Momi... the Institute of Medicine's (IOM) report *Crossing the Quality Chasm* conceptualized of high-quality care by identifying six aims for the 21st-century health care system. One of the 6 aims is timeliness, as reducing wait times and delays for both those who receive and those who give care can improve patient outcomes. In addition, the IOM recommends the development of systems that enable real-time analysis of data from cancer patients in a variety of care settings to allow for best outcomes (IOM, 2013) Bringing PET to Pali Momi would allow for immediate access to both the report and the source images on PACS through the existing Electronic Health Record at Pali Momi.

Second, this project will significantly improve the quality of care to our patients by improving their coordination of care. PET has the ability to determine if a patient is a candidate for surgery. In other cases chemotherapy and/or radiation is given until the tumor becomes removable by a surgeon. These cases require a constant exchange of information between surgeon, oncologist and radiation therapist. This dialogue is

facilitated by tumor conferences. Informed discussion requires current data; often only source images (not just the written reports) are required for critical decision-making. The Institute of Medicine (IOM) has defined good quality care as 'providing patients with appropriate services in a technically competent manner, with good communication, shared decision making, and cultural sensitivity' (IOM and NRC, 1999, p. 79). The location of this service at our facility will better facilitate this dialogue between clinicians and thereby improving the quality of care delivered to our patients."

18. The applicant states that "With all existing PET/CT providers located in Honolulu and concentrated within approximately 3 miles apart from each another, the proposed project will improve accessibility to PMMC patients seeking to find service closer to home."

19. The applicant states that "Additionally, beyond regional factors, the thresholds may be modified to consider the factors below which our project will incorporate..."

Addresses the documented needs of an actual population rather than basing care design on statistical generalizations;

This project will meet the needs of actual oncology patients seeking care at PMMC and thus patients living in Leeward, Central and West Oahu. We have evidence that on average 87% of oncology patients seeking care at PMMC from the past three years (1,183 patients) are from the primary service area of the hospital, further supporting the need for PMMC to provide this (sic) services to the patients we serve. Most importantly, this technology would expedite the treatment planning process for our patients and the benefits are summarized below:

Importance to have in the community: Patient's benefiting from PET scan are generally those with advanced malignancy (cancer's having begun to spread to other organs) or in patients with tumors requiring multi-modality treatment (a combination of surgery, chemotherapy and radiation). Patients facing these diseases are often debilitated requiring suctioning of bodily secretions, supplemental oxygen or feeding tubes for nutritional support. Others are too fatigued to easily make it into Honolulu for diagnostic studies.

Importance of having the source images available: Currently all PET imaging is done outside of Pali Momi. For practitioners at Pali Momi, these important data is made available is conveyed by fax or US mail. While adequate for written reports, facsimile technology is insufficient to transmit color images needed to make certain treatment decisions. CD copies of the data (in DICOM format) require either patients to hand carry or US mail to deliver the scan results. In the era of electronic health records, obtaining actionable data from existing PET facilities is despairingly slow. Bringing PET to Pali Momi would allow for immediate access to both the report and the source images on PACS through the existing Electronic Health Record at Pali Momi.

Importance of PET at Pali Momi for coordination of care. PET has the ability to determine if a patient is a candidate for surgery. In other cases chemotherapy and/or radiation is given until the tumor becomes removable by a surgeon. These cases require a constant exchange of information between surgeon, oncologist and radiation therapist. This dialogue is facilitated by tumor conferences. Informed discussion requires current data; often only source images (not just the written reports) are required for critical decision-making.

Encourages innovation in improving health care services that contribute to enhancing a community's health status.

In providing PET/CT services at PMMC, all four HPH hospitals will now have reports and images immediately integrated into the patients' electronic medical record and thus results will be able to be reviewed by referring physicians and multidisciplinary teams' real time. Pali Momi Medical Center through Hawai'i Pacific Health is a member of the NCI designated University of Hawai'i Cancer Consortium in partnership with Queens Medical Center, Kuakini Medical Center, UH John A. Burns School of Medicine, and the UH Cancer Center. Our investment in this project demonstrates our commitment to the Consortium's efforts in enhancing the community's health status and the quality of care provided to cancer patients in Hawaii. With the factors noted above, the impact to a particular provider needs to be weighed against the known benefits that our patients will receive as a result of this service."

20. The Agency finds that the Proposal meets the relationship to the state health services and facilities plan criteria.

B. REGARDING THE NEED AND ACCESSIBILITY CRITERIA

21. The applicant states that "The primary service area for PMMC is Leeward, Central and West O'ahu, although patients from across the state including the neighbor islands and Pacific Basin are also served."

22. The applicant states that "As measured by the decennial Census, West Oahu grew by 16.1% between 2000 and 2010. Ewa experienced the fastest growth in the decade, at 18.7%."

23. The applicant states that "Recognizing the ongoing demand for oncology services at PMMC which primarily serves residents of Leeward, Central and West O'ahu, there is a clear need for access to PET/CT services on-site to better support the community we serve. As a part of the integrated care network of Hawai'i Pacific Health (HPH), PMMC currently provides patients with a broad scope of cancer care services. Our current inability to provide PET/CT services on site has the potential to create delays in the treatment planning process. Based upon the Commission on Cancer (CoC) quality standards, care should be

provided close to home. Recognizing this, PPMC has secured an additional 24,260 square feet of clinical space to expand oncology services for the community we serve.”

24. The applicant states that “Oncology services are the key drivers in PET/CT utilization, representing 90% of all service referrals. Lung cancer, breast cancer, colorectal cancer, and lymphoma cases are the primary cancer types driving future growth rates according to Sg2 (Sg2 Analysis, 2011). Breast cancer, lung cancer and colorectal cancer are the top three cancer sites at PPMC making this technology a critical component of patient care. In addition, care of patients with thyroid and pancreatic cancers would be better served. When a patient is diagnosed with cancer, staging is required to accurately diagnose the extent or spread of disease and to appropriately plan treatment therapy. Proper staging is essential in determining the choice of therapy and in assessing overall prognosis.”

25. The applicant states that “All existing PET/CT providers are located in Honolulu and within approximately 3 miles of each other. PPMC is seeking to add service outside of the Honolulu area specifically to serve its patient population as the commute to Honolulu adds additional time, cost, and often serves as an access barrier to many patients and families seeking this service.”

26. The applicant states that “On a national level, PET/CT procedure volume has increased 7.1% per year from 2008 to 2010, and with the National Cancer Institute projecting a 23% increase in newly diagnosed cancer cases within the next ten years; this clearly positions PET/CT in a steep growth pattern.”

27. The applicant states that “Additionally there is national data suggesting that current Hawai'i PET/CT scan utilization is below the expected utilization rate given our population size. According to research conducted by a private firm (IMV Research, Benchmark Report PET Imaging 2012), the national average of PET scans per thousand was 5.90 in 2011 which exceeded Hawai'i's 2013 average of 3.24 scans per thousand. In the same study Hawai'i was ranked 50th with the lowest scans per thousand in the nation (IMV Research, Benchmark Report PET Imaging 2012).”

28. The applicant states that “Given that Hawai'i PET/CT procedures per thousand is less than the national average indicates that there is additional room for PET/CT growth that is potentially constrained by the lack of providers located in West O'ahu.”

29. The applicant states that "As a not-for-profit provider PMMC accepts all patients regardless of their inability to pay. The PET/CT will provide service to all patients who are covered by Medicaid/Quest, Medicare, private insurance, self-pay and uninsured. Specifically, all residents of the area, and in particular low income individuals, racial and ethnic minorities, women, persons with disabilities and other underserved groups, and the elderly will have access to this service... This project will also enhance accessibility to Leeward, Central and West O'ahu patients to receive PET/CT services by eliminating the need to travel into Honolulu for this procedure."

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

C. REGARDING QUALITY AND LICENSURE CRITERIA

31. The applicant states that "Pali Momi Medical Center (PMMC) is a part of the Hawai'i Pacific Health (HPH) integrated health care system. PMMC is a not-for-profit community based hospital committed to providing exceptional cancer care to Hawai'i's families. What makes cancer care unique at PMMC and across HPH is our ability to leverage specialized clinical knowledge, cutting edge technology, a shared electronic medical record, and an integrated multidisciplinary approach to cancer care delivery to patients statewide. The cancer program at PMMC is accredited by the Commission on Cancer (CoC), a multidisciplinary program of the American College of Surgeons. Accreditation requires a program to continually evaluate its performance which reaffirms to the community the commitment of PMMC to provide high-quality cancer care. Applying for and maintaining CoC accreditation is a voluntary commitment by a cancer program that ensures its patients will have access to the full scope of services required to diagnose, treat, rehabilitate, and support patients with cancer and their families."

32. The applicant states that "PMMC will operate in accordance with all applicable state and federal guidelines and the standards for the American College of Radiology (ACR) which require adherence to extensive policies and procedures to insure the quality and safety of patient care. The department is certified/recognized by the American Registry of Radiologic Technologists (ARRT), Nuclear Medicine Technology Certification Board (NMTCB)."

33. The applicant states that "The PET/CT program will be managed by the PMMC Imaging Department. All technologists will be licensed and registered by the American Registry of Radiologic Technologists (ARRT) requiring minimum experience and ongoing continuing education. All staff members are required to be trained on all new equipment and required to pass competency on procedures and equipment annually."

34. The applicant states that "PMMC was most recently accredited by the Joint Commission on October 27, 2012... PMMC will additionally seek American College of Radiology (ACR) PET accreditation."

35. In written testimony dated December 11, 2014, Michael Ling, M.D. and Lynn Madanay, M.D. state "Nuclear Medicine Associates of Hawaii, LLC (NMAH) is a physician group that will be closely involved in the performance, supervision, and interpretation of PET/CT at PMMC. NMAH members are Drs. Michael Ling and Lynn Madanay... Since 2009, Drs. Ling and Madanay have been interpreting PET/CT at Kuakini Medical Center. They have read a combined total of over 1500 PET/CT cases. Appropriate PET/CT cases are also presented at weekly Oncology Conferences at Kuakini. In 2012, Dr. Madanay received the SNM certificate of qualification to perform, supervise, and interpret PET/CT. The certification requires fulfilling education and training recommendations for both PET and CT performed with PET/CT. The requirements include supervised interpretations for 150 PET/CT and 500 CT cases... Dr. Ling has also fulfilled these requirements and is in the process of applying for the SNM certificate."

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

D. REGARDING THE COST AND FINANCIAL CRITERIA

37. The applicant projects that the Total Net Revenue for the Year 1 of the proposed project will be \$719,400 and that the Direct Margin for the Year 1 of the proposed project will be (\$231,704). The applicant projects that the Total Net Revenue for the Year 3 of the proposed project will be \$1,510,400 and that the Direct Margin for the Year 3 of the proposed project will be \$151,774.

38. The applicant states that "The startup costs for the project is \$4,251,351 which will be entirely funded by cash reserves of PMMC parent organization, Hawai'i Pacific Health... the proposed project will generate positive cash flow from Year 3 to cover operational costs on a go forwarded basis."

39. The applicant states that "This project will eliminate the current practice of requiring a PMMC patient to commute to Honolulu and the additional time, cost, and often stress to the patients and families seeking service for this diagnostic procedure."

40. The applicant states that "PMMC participates with all insurance carriers and charges will be competitive with other facilities on O'ahu."

41. 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 CRITERIA

42. The applicant states that “Since there are no current PET/CT services in the Leeward, Central and West O’ahu area, the proposed project will create a positive impact for health care services for our patients and physicians in the community. This project will complement existing cancer services currently provided at PMMC for our patients.”

43. The applicant states that “In providing PET/CT services at PMMC, all four HPH hospitals will now have reports and images immediately integrated into the patients’ electronic medical record and thus results will be able to be reviewed by referring physicians and multidisciplinary teams’ real time. Pali Momi Medical Center through Hawai’i Pacific Health is a member of the NCI designated University of Hawai’i Cancer Consortium in partnership with Queens Medical Center, Kuakini Medical Center, UH John A. Burns School of Medicine, and the UH Cancer Center. Our investment in this project demonstrates our commitment to the Consortium’s efforts in enhancing the community’s health status and the quality of care provided to cancer patients in Hawaii.”

44. The applicant states that “As a not-for-profit hospital, PMMC has always provided care for inpatients, outpatients, and emergency patients regardless of a patient’s ability to pay. As a hospital based service, the implementation of PET/CT services will also provide additional margin to ensure that PMMC is able to continue to provide much needed services in the community.”

45. The Agency finds that the relationship to the existing healthcare system of the area criteria have been met.

F. REGARDING THE AVAILABILITY OF RESOURCES CRITERIA

46. The applicant states that “As an affiliate of Hawai’i Pacific Health, PMMC has the financial resources to secure all equipment and staffing resources required for this proposed project.”

47. The applicant states that “The implementation of this new service will not require hiring of additional staff and will be implemented through the utilization and re-allocation of existing staff.”

48. The Agency finds that the availability of resources criteria have been met.

III

CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 14-13 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, 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), HRS:

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

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 Pali Momi Medical Center for the Proposal described in Certificate of Need application No. 14-13. The maximum capital expenditure allowed under this approval is \$4,251,351.

WRITTEN NOTICE

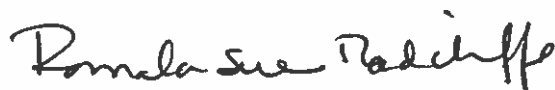
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

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 18, 2015
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



Romala Sue Radcliffe
Administrator