



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

STANDARD APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number: #07-11

Applicant: Maui Cancer Center PET/CT Company, LLC
227 Mahalani Street
Wailuku, Hawaii
Phone: 808-242-2600

Project Title: Establishment of Positron Emission Tomography and
Computed Tomography (PET/CT) services

Project Address: 59 Hookele Street, Kahului, Maui, Hawaii

1. TYPE OR ORGANIZATION: (Please check all applicable)

- Public _____
- Private _____
- Non-profit _____
- For-profit _____ X _____
- Individual _____
- Corporation _____
- Partnership _____
- Limited Liability Corporation (LLC) _____ X _____
- Limited Liability Partnership (LLP) _____
- Other: _____

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2. PROJECT LOCATION INFORMATION:

A. Primary Service Area(s) of Project: (Please check all applicable)

- Statewide: _____
- O`ahu-wide: _____
- Honolulu: _____
- Windward O`ahu: _____
- West O`ahu: _____
- Maui County: _____ X _____
- Kaua`i County: _____
- Hawai`i County: _____

3. DOCUMENTATION (Please attach the following to your application form):

- A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)
Please refer to space lease attached as Addendum A
- B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)
Department of Health, Building Permit, Medicare Provider Number
- C. Your governing body: list by names, titles and address/phone numbers
Bobby Baker, M.D. (President) & Wayde Burt (Secretary)
227 Mahalani Street, Wailuku, HI 96793
Telephone: (808) 242-2600
Virginia Pressler, M.D. (Vice President) & Terry Long (Treasurer)
55 Merchant Street 27th Floor
Honolulu, HI 96813
Telephone: (808) 535-7837
- D. If you have filed a Certification of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:
 - Articles of Incorporation – **Addendum B**
 - By-Laws: N/A
 - Partnership Agreements – **Addendum C**
 - Tax Key Number (project's location) – **3-8-84-004**

4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "X" in the appropriate box.

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	Used Medical Equipment (over \$400,000)	New/Upgraded Medical Equip. (over \$1 million)	Other Capital Project (over \$4 million)	Change in ownership	Change in service/ establish new service/facility	Change in Beds
Inpatient Facility						
Outpatient Facility					X	
Private Practice						

5. **TOTAL CAPITAL COST:** \$880,000

6. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
	N/A	N/A	N/A
TOTAL	N/A	N/A	N/A

7. **CHANGE IN SERVICE.** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please consult Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

Introduction of PET/CT Scanning Services to Maui County. This service will be one of several cancer diagnosis and treatment services located in the Maui Comprehensive Cancer Center being constructed on this site.

8. **PROJECT COSTS AND SOURCES OF FUNDS (For Capital Items Only)**

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A. List All Project Costs:

AMOUNT:

- | | | | |
|----|---|------------------------------|-----------|
| 1. | Land Acquisition | '07 APR 27 P 3 :14 | _____ |
| 2. | Construction Contract | ST. HELENA CO. & DEV. AGENCY | _____ |
| 3. | Fixed Equipment | | _____ |
| 4. | Movable Equipment | | \$880,000 |
| 5. | Financing Costs | | _____ |
| 6. | Fair Market Value of assets acquired by lease, rent, donation, etc. | | _____ |
| 7. | Other: _____ | | _____ |

TOTAL PROJECT COST: \$880,000

B. Source and Method of Estimation

Describe how the cost estimates in Item "A" were made, including information and methods used:

The estimates are based on information provided by the vendor and comparable costs at other facilities.

C. Source of Funds

AMOUNT:

- | | | |
|----|----------------------|-----------|
| 1. | Cash | \$880,000 |
| 2. | State Appropriations | _____ |
| 3. | Other Grants | _____ |
| 4. | Fund Drive | _____ |
| 5. | Debt | _____ |
| 6. | Other: _____ | _____ |

TOTAL SOURCE OF FUNDS: \$880,000

9. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

- a) Date of site control for the proposed project, **May 01, 2007**
- b) Dates by which other government approvals/permits will be applied for and received, **September 1, 2007**
- c) Dates by which financing is assured for the project, **N/A (cash)**
- d) Date construction will commence, **N/A (leased premises)**
- e) Length of construction period, **N/A**
- f) Date of completion of the project, and **N/A**
- g) Date of commencement of operation. **September 1, 2008**

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Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the Certificate of Need.

10. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

Maui Cancer Center PET/CT Company, (MCCPET) LLC a Hawaii Limited Liability Company, plans to introduce Positron Emission & Tomography scanning services to Maui County. This service will be one of several cancer diagnosis and treatment services located in the Maui Comprehensive Cancer Center being constructed on this site.

The proposed project will save patient lives and improve outcomes by reducing the length of time from when a patient is diagnosed with cancer and receives treatment. There is currently no PET/CT facility in Maui County. Given the projected population growth on Maui and lack of available alternatives for Maui oncology patients, MCCPET believes this service will improve patient outcomes and reduce morbidity.

Positron emission tomography, also called PET imaging or a PET scan, is a diagnostic examination that involves the acquisition of physiologic images based on the detection of radiation from the emission of positrons. Positrons are tiny particles emitted from a radioactive substance administered to the patient. The subsequent images of the human body developed with this technique are used to evaluate a variety of diseases. Sample image obtained using a combination of PET and CT imaging technology.

PET scans provide a variety of uses for cancer care. They are used most often to detect cancer and to examine the effects of cancer therapy by characterizing biochemical changes in the cancer. These scans can be performed on the whole body. PET scans of the brain are used to evaluate patients who have memory disorders of an undetermined cause, suspected or proven brain tumors or seizure disorders that are not responsive to medical therapy and are therefore candidates for surgery.

The proposed PET/CT unit is a fixed site unit. It will be owned and operated by MCCPET whose partners have an extensive history in providing and managing cancer care in Hawaii.

a) Relationship to the Hawai'i Health Performance Plan (H2P2), also known as the State of Hawai'i Health Services and Facilities Plan

The proposed PET/CT at MCCC will address all of these five components of H2P2.

Access, Cost-Effectiveness, and Continuity of Care: Access to PET/CT imaging services is effective in early detection of various types of cancers. The introduction of these services on Maui will improve access, cost-effectiveness and continuity of care by eliminating the need for patients to travel to Honolulu to receive their care. Both time savings and reduced travel time will eliminate access barriers for Maui County residents.

Quality: The impact of early cancer detection and intervention with PET/CT imaging services will result in timelier access to service and more effective treatment. The proposed PET/CT service will be conducted in accordance with all state & Federal regulations related to the operation of a radiation facility. All personnel will be licensed and certified as required for technical operation of the scanner and isotope handling equipment.

Constituent Participation: The provision of these high quality services will allow for greater collaboration between radiologists and oncologists. Support from community leaders, oncology staff, patients, and public healthcare workers have been provided. The proposed project also has the support of existing healthcare providers, specifically Maui Memorial Medical Center. The partners of MCCPET have a long history of working with other regional and tertiary care providers. MCCPET will maintain consultation and transfer arrangements with other health care facilities to ensure that patients are receiving all medically required care. MCCPET will actively participate in the well being of the community through educational community outreach efforts.

b) Need and Accessibility

As discussed above PET/CT imagery is a widely accepted tool in the diagnosis, staging and treatment of cancer. 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. It is anticipated that 100% of Maui residents newly diagnosed with cancer and resident cancer survivors will seek access to the PET/CT services described in this proposal.

The service area includes the islands of Maui, Moloka'i and Lana'i. Access to PET/CT imaging will be greatly enhanced since travel to Oahu will be no longer be necessary for patients that reside in Maui County. The travel time to access services will be reduced from at least an entire day to, in most cases, less than an hour. The expense related to transportation and overnight accommodations for patients and family members will be eliminated due to the proximity of the proposed service location to the target population served.

There are an estimated 2,116 cancer patients that may require at least one PET/CT scan in any given year in Maui County. Assuming 264 operating days per year, the threshold of 528 procedures in the first full year of operation translates to 2.0 procedures per day. The pro-forma analysis projects a daily volume increase of 10 per cent annually yielding 2.2 procedures per operating day in Year 2 and 2.4 procedures per operating day in Year 3. Due to the need calculations expressed in Table B-2 and Table B-3 it is clear that utilization of PET/CT scan services should easily meet the annual procedure projections. Less than one-third of the identified potential pool of patients will have to utilize the proposed services to meet the financial projections as stated.

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c) Quality of Service/Care

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 required by regulation. The PET/CT shall be maintained pursuant to the manufacturer's specifications and a board certified medical physicist shall be employed to conduct quality assurance surveys to verify the accuracy and reliability of the scanner and related equipment. All personnel will be licensed and certified as required for technical operation of the scanner and isotope handling equipment.

d) Cost and Finances (include revenue/cost projections for the first and third year of operation)

Maui residents who require the tumor imaging diagnostic services provided by PET scanning must incur the lost work time and travel expenses to Oahu. This project will provide state-of-the-art tumor diagnostic care to residents on their home island. It will also enhance the effectiveness of cancer treatment by allowing medical and radiation oncologists access to more timely feedback and subsequent treatment modifications.

The proposed project is projected to achieve profitability by the end of year 1. 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.

e) Relationship to the Existing Health Care System

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 or forgoing the use of this useful tool. Physicians on Maui are reluctant to request that patients travel to obtain services unless necessary. The cost of transportation for the patient and their family is usually borne by the patient. This reluctance is especially true if the patient is of advanced age or is infirm. The proposed service is designed to bring the service to the patient where treatment is delivered so as to eliminate the costly and inefficient travel required to obtain this service on Oahu. Access to the proposed PET/CT services will be available to the target population of Maui County at a lower cost and greater efficiency.

f) Availability of Resources

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. All start up costs will be paid for with internal resources. Additionally Bobby C. Baker MD, Inc. already has the labor resources to provide these services and the additional investment capital to cover the professional, administrative and overhead costs to deliver this service.

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