



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: #14-17A
To be assigned by Agency

Date of Receipt: 12/8/14
STATE HEALTH PLANNING & DEV. AGENCY

APPLICANT PROFILE

Project Title: Expansion of Positron Emission Tomography (PET) services

Project Address: 98-1247 Kaahumanu Street, Aiea, Hawaii 96701, suite 109/111

Applicant Facility/Organization: Hawaii PET Imaging, L.L.C.

Name of CEO or equivalent: Scott Halliday

Title: President, National Medical Development, Inc., Majority Owner, Hawaii PET Imaging, L.L.C.

Address: 5001 N.E. 25th Avenue, Suite 202, Seattle, WA 98105

Phone Number: 206-272-3580 Fax Number: 206-272-3588

Contact Person for this Application: same as above

Title: _____

Address: _____

Phone Number: _____ Fax Number: _____

CERTIFICATION BY APPLICANT

I hereby attest that I reviewed the application and have knowledge of the content and the information contained herein. I declare that the project described and each statement amount and supporting documentation included is true and correct to the best of my knowledge and belief.

Signature

Date

Name (please type or print)

Title (please type or print)

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

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

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: X
- Maui County: _____
- 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)- See Attachment 1
- 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.)-

Building Permit to be received once architectural plans completed

- C. Your governing body: list by names, titles and address/phone numbers – See Attachment 2
- D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:
 - Articles of Incorporation – Attachment 3
 - By-Laws -
 - Partnership Agreements – Attachment 3
 - Tax Key Number (project's location) -TMK: (1) 9- 4-14-14

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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 Service	Change in Beds
Inpatient Facility					
Outpatient Facility				X	
Private Practice					

5. **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
TOTAL			

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6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:	AMOUNT:
1. Land Acquisition	_____
2. Construction Contract	\$__500,000__
3. Fixed Equipment	\$ 1,500,000__
4. Movable Equipment	_____
5. Financing Costs	_____
6. Fair Market Value of assets acquired by lease, rent, donation, etc.	\$__100,000__
7. Other: _____	_____
TOTAL PROJECT COST:	\$2,100,000

B. Source of Funds	
1. Cash	\$2,000,000
2. State Appropriations	_____
3. Other Grants	_____
4. Fund Drive	_____
5. Debt	_____
6. Other: FMV of leased space	\$__100,000__
TOTAL SOURCE OF FUNDS:	\$2,100,000

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7. **CHANGE OF 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 reference the 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.

The PET unit planned is an expansion of our existing PET service located at 1401 S. Beretania Street, Suite 107, Honolulu, HI 96814. The service to be added is an additional outpatient PET to be located at: 98-1247 Kaahumanu Street, Aiea, Suite 109/111, Hawaii 96701

This addition is in response to numerous requests by Central/West Oahu physicians and their patients, for a local, more accessible location of our high level of outpatient PET services for the Central/West Oahu community.

8. **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, - December 5, 2014
 - b) Dates by which other government approvals/permits will be applied for and received, - upon CON approval - approx 10 weeks after application for building permits
 - c) Dates by which financing is assured for the project - n/a
 - d) Date construction will commence, -8 weeks after CON approval
 - e) Length of construction period, - 6 months
 - f) Date of completion of the project, -est. August 1, 2015
 - g) Date of commencement of operation - September 1, 2015

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.

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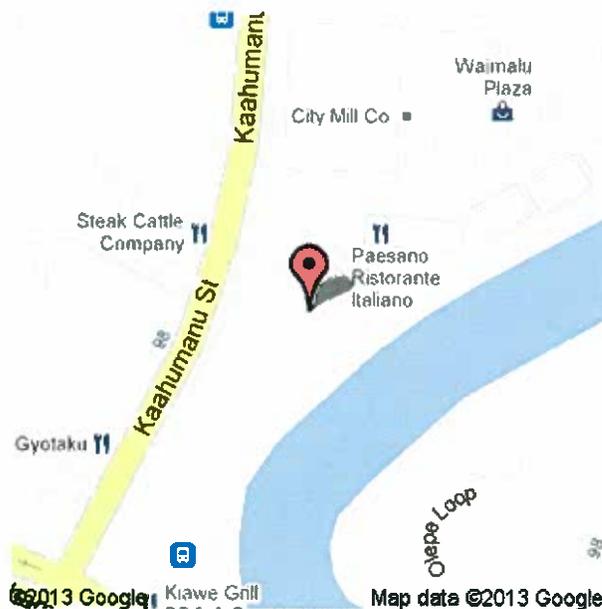
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9. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the certificate of need criteria listed below. If a new location is proposed, please attach an easy to read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

Hawaii PET Imaging, L.L.C. ("HPI") seeks approval to add an additional Central/West Oahu outpatient PET facility location to our existing service located in downtown Honolulu. This new outpatient PET Facility will improve needed access to PET for Central/West Oahu residents and healthcare providers.

This additional outpatient PET is in response to local requests to provide the same level of PET services that we currently provide in Honolulu. This will be the only PET in Central/West Oahu, providing the highest quality outpatient PET access to all types of patients, especially those that require less traveling time due to illness, disability, or other factors that often complicate their ability to travel to downtown Honolulu for this needed care.

LOCATION



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a) Relationship to the State of Hawai'i Health Services and Facilities Plan.

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Regarding thresholds for additional locations:

HSFP states:

Positron Emission Tomography (PET) Unit

For a new unit/service, the minimum annual utilization for each provider in the service area is 600 procedures per unit, and the utilization of the new service is projected to meet the minimum utilization rate by the third year of operation.

For expansion of existing units/services, the provider's utilization is an average of at least 720 procedures per year per unit

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HPI's PET is performing procedures in excess of 720 per year (HPI performed more than 1,000 PET exams in 2013), therefore qualifying this application for the expansion of PET services.

HPI receives many patients from the Central/ West Oahu area, so there should be minimal affect upon the other PET facilities business.

Regarding Goals of HSFP;

HSFP states as one of its Goals; "Promote regionalization of services where appropriate". This application does meet this Goal by providing a needed service in the "Central/West Oahu region", that currently is not locally served, and therefore, underserved, by the PET units located exclusively in Honolulu. A PET facility in Central/West Oahu, will promote regionalization of this service, while also promoting associated healthcare services growth in the region. It will expedite the regions' locally based treatment of disease associated with PET diagnosis/identification, and the modalities used in this pursuit.

Regarding the Statewide Health Coordinating Council Priorities ("SHCC"), (in bold below);

1. Promote and support the long-term viability of the health care delivery system

Placement of an increasingly needed diagnostic modality in an area that is not locally served, yet has the fastest growing population in the state of Hawaii, is promoting and supporting the long term viability of health care delivery system. This new location is making these important tests more readily, locally, available to patients and therefore the results for diagnosis and treatment purposes more readily available to physicians, at no increase in costs to the healthcare delivery system, patients, or payors. In fact, the placement of this new PET in this area will serve to Reduce overall costs of PET to these residents. Timely access to PET services is integral to facilitating efficient diagnosis and treatment protocols. Therefore, this does extend and truly promote at no actual cost to the public, the healthcare delivery system.

2. Expand and retain the health care workforce to enable access to the appropriate level of care in a timely manner

3. Ensure that any proposed service will at least maintain overall access to quality health care at a reasonable cost

This expansion will provide new training and additional jobs to the Hawaii healthcare workforce, while also providing increased access to a needed service, at the same costs as current providers, supporting these SHCC priorities. By having a new PET located in the region,

patients will have increased access to needed quality healthcare at the same prices as all other PET services in Hawaii, yet at reduced travel and other associated costs.

4. **Strive for equitable access to health care services**
6. **Encourage and support health education, promotion, and prevention initiatives**

The addition of this needed service to the Central/West Oahu area will assist in the providing equitable access thru the reduction of the increasing costs of access to these region residents (travel costs, time costs, scheduling difficulties at such distances, traffic, etc) to healthcare services, located in Honolulu.

This new facility will utilize our existing HPI management and education to support, increase awareness and communication, on healthcare education and prevention initiatives to the local residents.

Regarding the WEST OAHU SAC PRIORITIES

1. IMPROVE AND INCREASE ACCESS

- Specialty care
- Routine outpatient diagnostic services (i.e., blood pressure, urinalysis)
- Services for uninsured and underinsured

HPI is fully supporting these priorities by providing more convenient local access to PET as a component of "specialty care" in Radiology, and more specifically in this case, "cancer diagnostics". PET services have now also grown to be part of "routine diagnostic services" with the addition of the Kuakini PET unit and the increased usage of the Queens-Hamamatsu and HPI PET units. This new facility will improve and Increase needed Access for local area residents to this needed service.

HPI has a long standing, open, and community supportive policy for those patients that are uninsured and underinsured. We will continue this policy at the new location.

b) Need and Accessibility

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The need for local, more accessible PET services already exists, and will continue to increase with the current expansion of the Central/West Oahu region population. According to the State of Hawaii Department of Business, Economic Development and Tourism, "2011 State of Hawaii Date Book" the area that this facility will provide services to was by far the fastest growing in the State;

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**Table 1.15-- RESIDENT POPULATION FOR OAHU NEIGHBORHOODS:
2000 AND 2010**

Neighborhood Area 1/ (see maps)	2000	2010	Percent change
Oahu total	876,156	911,841	4.1
21 Pearl City	49,345	47,879	-3.0
22 Waipahu	59,284	61,879	4.4
23 Ewa	43,794	59,877	36.7

and is projected to continue high levels of growth in the near future.

If this application isn't approved, the need to transport patients away from the convenience of their homes and likely also the local physicians' offices in the area, for these time sensitive procedures, will continue to negatively impact patient care, by delaying diagnosis, possible immediate treatments, and through the additional stress that travel imposes on patients that are already in acute distress.

HPI currently is far in excess of threshold requirements to add a new location; there is No PET Service in this area, clearly demonstrating that according to HSFP standards, (and local patients and physicians) there is a real need for this additional outpatient PET service.

The area population is one of the fastest growing in Hawaii and the fastest growing on Oahu. This location is virtually equidistant from downtown Honolulu and Ewa making it ideal to service the area.

As is our policy at HPI, the proposed PET services will be available to all on a non-discriminatory basis, with a physician's order, without regard to ability to pay, including low income people, racial and ethnic minorities, women, people with disabilities, the elderly and other underserved groups.

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c) Quality of Service/Care

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This investment is in an additional PET, continuing our commitment to provide the best in imaging services to Hawaii's population.

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Regarding the Quality of the new PET;

From the manufacturer:

The Discovery 610 PET/CT is the most sensitive scanner on the market which means that it is the industry leader in radiation dose efficiency for PET. In fact the scanner is up to twice as dose efficient as compared to many of the products from our competition. This allows you to reduce the amount of FDG you inject per scan and thereby decrease the radiation burden for the patient. In addition the D610 was just recently launched and supports the new QSuite features. These features dramatically improve the quantitative accuracy of the final PET image. This is important in expanding the role of PET into increased utilization for mid treatment therapy response. Determining if the treatment is working has potential implications for both overall health economics and improved outcomes. This system also supports ASiR CT dose reduction.

Regarding Quality of Service/Care today and in the future with HPI facilities and staff;

HPI facilities were one of first to seek and receive accreditation by the American College of Radiology and all HPI facilities are licensed by the State of Hawaii. This new outpatient facility will again seek the same accreditation, continuing our commitment to quality. Our radiologists are **all certified by the American Board of Radiology** and are licensed physicians in Hawaii. They all are members of a wide variety of professional organizations. Our technologists are **each certified by the American Registry of Radiologic Technologists, and licensed by the State of Hawaii**. As HPI currently operates, the physicians and technologists are continually expected to meet or exceed all state and national registry requirements for continuing medical education ("CME"). Currently, radiologists are required to obtain 50 CME credits annually and technologists are required to obtain 12 CME credits annually, and this facility will follow this requirement.

HPI shall utilize our existing, experienced, high quality PET staff, and radiologists to provide the staffing at the new location. HPI has provided staffing and training on PET over 10 years now, and our staff has been integral in HPI receiving ACR accreditation, as a clear verification of the quality of operations and staff.

We staff each location with a qualified physician to comply with Medicare regulations and standards of medical care.

The facility will operate, as all HPI facilities, in accordance with all applicable state and federal guidelines and the standards of the American College of Radiology, which require adherence to extensive policies and procedures to insure the quality and safety of patient care.

The technical staff-to-patient ratio is 2 to 1. The technologists are with each patient at all times while a procedure is being performed. We also will employ a **"technologist assistant"** to assist in patient comfort, placement, and understanding of the procedures involved.

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

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Three year revenue and cost projections are below:

(Assuming a \$1,900 per PET average reimbursement, debt payments of \$35,000/mo., supplies, rent, utilities, and added staffing)

	Volume	Revenue	Costs	NET
Year one	400	\$760,000	\$1,000,000	\$- 240,000
Year two	500	\$950,000	\$1,050,000	\$- 100,000
Year three	600	\$1,140,000	\$1,100,000	\$ 140,000

HPI projects to lose money in the early years, however we feel this is truly a needed service for the area and that the projected conservative, eventual growth, will suffice to bring this unit to profitability.

e) Relationship to the existing health care system

The addition of this outpatient PET unit is in response to current capacity issues at our facility in Honolulu, and increasing demand issues we are receiving from Central/West Oahu residents and physicians. As this is a transfer of a portion of our current business, some normal increases in demand/usage due to availability/reduced travel and other costs, and the continued expansion of PET usage (see below, there are increasing usages of PET in oncology, Neuro, and other areas), this addition will not have any significant impact on the existing healthcare system or any other PET provider.

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10. Eligibility to file for Administrative Review. This project is eligible to file for Administrative review because: (Check all applicable)

- It involves bed changes, which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.
- It involves service changes which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.
- It is an acquisition of a health care facility or service, which will result in lower annual operating expenses for that facility, or service.
- It is a change of ownership, where the change is from one entity to another substantially related entity.
- It is an additional location of an existing service or facility.
- The applicant believes it will not have a significant impact on the health care system.