



## HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

### ADMINISTRATIVE APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number 05-29A

Applicant: Hawaii PET Imaging, LLC  
1010 S. King Street, #604  
Honolulu, HI  
Phone: (808) 591-1504

Project Title: Change from mobile to fixed-site Positron Emission  
Tomography (PET) Imaging services

Project Address: 500 Ala Moana Blvd., Space 5-B, Honolulu, HI

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: \_\_\_\_\_

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2. PROJECT LOCATION INFORMATION

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

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

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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 see Attachment 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.) **Please see Attachment B**
- C. Your governing body: list by names, titles and address/phone numbers **Please see Attachment C**
- 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
  - By-Laws
  - Partnership Agreements
  - Tax Key Number (project's location) **21029001, 21029002**

**Please see Attachment D**

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.

	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					

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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
<b>TOTAL</b>			

**6. PROJECT COSTS AND SOURCES OF FUNDS (Revised 10/24/05)**

<b>A. List All Project Costs:</b>		<b>AMOUNT:</b>
1.	Land Acquisition	RECEIVED \$0
2.	Construction Contract	'05 NOV 15 A 9:25 \$700,000
3.	Fixed Equipment	\$0
4.	Movable Equipment	ST. HILTH. PLING. & DEV. AGENT \$150,000
5.	Financing Costs	\$152,875
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.— <i>FMV of leased space estimated at \$300/sf.*</i>	\$900,000
7.	Other: _____	<u>\$0</u>
<b>TOTAL PROJECT COST:</b>		<b>\$1,902,875</b>

**B. Source of Funds**

1.	Cash	\$200,000
2.	State Appropriations	\$0
3.	Other Grants	\$0
4.	Fund Drive	\$0
5.	Debt	\$682,875
6.	Other: Monthly lease rent from operations to cover leased space for five year term using schedule found in Attachment A.	\$336,600
	Value held by Landlord	\$563,400
	Tenant improvement allowance (\$40/sf)	<u>\$120,000</u>
<b>TOTAL SOURCE OF FUNDS:</b>		<b>\$1,902,875</b>

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\*Properties in subject area are valued at \$275 - \$500/sf. The \$300/sf for the proposed project site was determined by Craig Neher, Leasing Director of The Shidler Group who manages the Waterfront Plaza property. This was felt to represent the FMV of the property in its current condition. Calculation--\$300/sf x 3000 sf.

**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.

***Hawaii PET Imaging is proposing to change from a mobile PET scanning facility to a fixed-site facility. HPI currently provides mobile services on the St. Francis Medical Center campuses in Honolulu and Ewa Beach. The proposed fixed-site facility is located in Waterfront Plaza, Honolulu.***

**7. 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—  
***August 10, 2005***
- b) Dates by which other government approvals/permits will be applied for and received—  
***September 15, 2005; November 15, 2005***
- c) Dates by which financing is assured for the project—  
***October 14, 2005***
- d) Date construction will commence—  
***November 15, 2005***
- e) Length of construction period—  
***3.5 months***
- f) Date of completion of the project—  
***February 28, 2006***
- g) Date of commencement of operation—  
***March 15, 2006***

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EWA BEACH

## 9. EXECUTIVE SUMMARY

*Please present a brief summary of your project.*

Hawaii PET Imaging, LLC, (HPI) was awarded a certificate of need for mobile PET scanning services in December 2001 and began delivering services July 1, 2002. HPI has two locations from which space is rented and at which PET scanning services are provided: St. Francis Medical Center in Honolulu and St. Francis Medical Center West in Ewa Beach. In addition to the projected growth in PET scan utilization, the premise at the time was that by serving two locations with a mobile venue, we would broaden accessibility to this emerging technology. Prior to this, PET scanning services were only available in Honolulu at the Queen's Medical Center.

PET scanning technology has continued to advance with PET/CT being the modern day equivalent replacement for dedicated PET imaging systems. In keeping with its mission to bring premier PET scanning capabilities to our community, HPI has made the commitment to replace its current dedicated PET scanning system with a state-of-the-art PET/CT system. This has been accepted by SHPDA as the modern day equivalent replacement, thereby not requiring a CON review process.

Over the past months, HPI has reviewed the options for the installation and delivery of this premier service in our community and has concluded that the community will be best served by a fixed site facility rather than a mobile operation. Furthermore, HPI believes that the proposed change in service and location will have minimal impact on service delivery and will, in fact, enhance accessibility to this new technology for years to come. The following is a discussion of the options considered and the data analysis utilized to reach this conclusion. It begins, however, with a description of the PET scanning procedure, the understanding of which serves as a baseline for the analysis.

### Current Scanning Procedures

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The process by which PET scanning is accomplished involves three phases: reception and patient interview, injection of radioisotope (FDG) and uptake period, and scanning.

Reception and patient interview—As in any outpatient clinical facility, the patient is greeted and interview questions are asked which include validation of patient information and a brief assessment specific to the PET scanning process. This requires a degree of privacy to assure confidentiality of patient information.

Injection of radioisotope and uptake (delay) period—After the interview is completed, an intravenous (IV) needle is placed for the purposes of obtaining a small blood sample for blood sugar analysis and to inject the FDG into the patient. Once these processes are completed, the IV is removed and the patient waits quietly in a lounge chair for the FDG to absorb into the body. During this “delay period” the patient is considered radioactive and must be in a shielded area to protect the rest of the environment from unnecessary exposure.

Scanning—At approximately 50 – 60 minutes post injection, the patient is asked to go to the restroom prior to entering the scan room. The reason for this is that FDG is excreted through the urine and an empty bladder facilitates visualization in the pelvic area. The scan itself, with the current CTI scanning system, takes approximately 45 – 60 minutes, depending on the scanning protocol utilized.

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Scanning protocols vary according to patient size and weight, and patient diagnosis. Scans will be lengthened for height and weight, depending on patient dimensions. Additional, or double scans, will be obtained on patients with certain diagnoses. For instance, a patient with a solitary pulmonary nodule will have a lung scan first, followed by a base-of-skull-to-mid-thigh scan in order to obtain a second lung scan with a one hour delay. This assists the interpreting radiologist in determining whether the uptake value changes over one hour which can be more diagnostic for malignancy. In addition, research is demonstrating that PET scan results may be enhanced in certain situations with greater delay times; i.e. take an initial scan after the uptake period and take a second scan one or two hours later. An example of this is in the case of brain scans. This delay, however, requires waiting in an injection suite during both delay periods. Therefore, the scanning facility needs to easily accommodate these various scenarios.

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Other considerations--Accommodation of wheelchair-bound patients and those who are physically challenged is provided in the mobile facility via a hydraulic lift. This has worked moderately well, although not ideal during inclement weather. Restroom facilities are not available in a mobile setting so patients must be directed to restrooms in adjacent buildings. Ambulatory patients can manage but again, the wheelchair-bound and physically challenged patients cannot navigate this and must have assistance.

There is no separate waiting area for patients who arrive early, or for family or companions. HPI accommodates by permitting patients or family to sit in the technologist control area, or permit family to wait in the injection area with the patient. Many times patients and/or family are asked to wait in areas outside the facility.

### **Change in Scanning Procedures with PET/CT**

The components of the scanning process with the PET/CT remain relatively the same with the exception of scanning time and clothing change. Scans will be obtained in half the time as with current PET systems, therefore increasing patient capacity and throughput. Due to the CT component (ionizing radiation), the patient will be required to wear a gown for the scan, adding change room requirements to the facility.

### **Impact on Facility Considerations**

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With the decision to replace the dedicated PET scanning system with the PET/CT system, HPI began to evaluate the options for providing this hybrid service in the community. The goal of this process was to select an option that assured the greatest accessibility to all who need and would benefit from this service. This included

consideration for the change in operations due to faster scan times, patient privacy for gown changing and the interview process, access to restroom facilities, and waiting space for companions/family members. The end result of this evaluation process was the decision to secure a fixed site location for development of a premier PET/CT scanning facility. The following discussion highlights the considerations that led to this decision.

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### **The Mobile Option**

The mobile PET facility has provided a convenient and appreciated option for services to residents living in West and Central Oahu. To continue this option, however, requires that HPI purchase a new medical coach especially designed to accommodate the weight of the PET/CT equipment. The current coach cannot be retrofitted to accept the equipment.

More importantly, however, is the limitation of the mobile facility in the accommodation of the above-mentioned changes related to patient throughput and privacy. This has not been an issue to date, as HPI has been able to accommodate the current throughput with its one patient injection area. The scan times are such that patients are scheduled far enough apart to accommodate one patient at a time in the patient area, thereby assuring privacy.

A new PET/CT coach would provide, at most, two injection areas and, therefore, limit the preparation and uptake capacity to two patients at a time. Given the uptake and advanced protocols described above, HPI would be limited in the number of patients scanned per hour and, therefore, per day. Accommodation for the evolving scanning protocols would also be limited. In addition, given the close physical proximity of the patients in this setting, patient privacy for interviewing and gown changing would be compromised.

Adequate space for companions or family members to wait during the PET scanning procedures could not be accommodated in the mobile facility. In addition, scheduling flexibility is somewhat compromised in that availability at either site is on designated days only. At times, this has been an issue for coordination and scheduling around patient and/or family schedules.

### **Fixed Site Option**

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The limitations of the mobile option are the strengths of a fixed site facility. Provided that an appropriate site with adequate square footage can be secured (3000 sf), patient/family reception and waiting, patient preparation and throughput, privacy, patient restrooms, physical accessibility for wheelchair-bound patients, and scheduling flexibility could all be accommodated.

In addition, HPI would be able to consolidate its decentralized administrative and clinical operations into one location.



It is for the above reasons that a fixed site facility is proposed.

## Site Selection

The criteria utilized in selecting a potential site included an open footprint of 3000 square feet, access to the required electrical power, access to plumbing, natural barriers for radiation shielding considerations, patient accessibility by car or public transportation, convenient and easy to find location, and parking availability. Given HPI's scanning locations and patient zip code data, the areas of Oahu that were considered include Honolulu, Aiea, Pearl City, and Mapunapuna. Several upper floor locations were evaluated but eliminated due to engineering and construction costs to reinforce the concrete slab for the weight of the PET/CT equipment. Therefore, a ground floor requirement narrowed the scope of options even more.

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After months of searching, a 3000 square-foot, ground floor suite in Waterfront Plaza at 500 Ala Moana Boulevard was chosen and an intent to lease proposal signed. This property is well known in the community, centrally located, and easily accessed by car or public transportation. Parking is available on a reserved basis to HPI and valet service is being considered for those who may require this assistance. A map of the proposed location is included in Attachment E.

*In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below.*

## Relationship to the Hawaii Health Performance Plan (H2P2)

The analysis for the proposed change in service demonstrates that the project continues to support the principles of the state's healthcare delivery system as detailed in the Hawaii Health Performance Plan. Specifically, included in this discussion are the following criteria:

- Need and Accessibility;
- Quality of Service/Care;
- Cost and Finances
- Relationship to the existing health care system; and
- Availability of Resources.

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## ***Need and Accessibility***

Need. The need for this PET scanning service was established by Certificate of Need #01-31 which was awarded in December 2001. Since then, the utilization of PET scanning services in Hawaii has doubled. This is due to several related factors not the least of which is the fact that PET scanning is rapidly becoming the standard of care for cancer related diagnoses. A testimony to this is the fact that the Centers for Medicare and Medicaid Services (CMS) has virtually "approved" the use of PET scans in all

cancer diagnoses. This ruling was made in early 2005; however, a registry system to track efficacy of PET scans in treatment and care is being designed and implemented by the CMS. When this is completed, it is expected that the demand for PET scan procedures will increase dramatically.

In addition to cancer related diagnoses, the use of PET in evaluating patients for Alzheimer's dementia has been approved by CMS as well as additional cardiac conditions. Therefore, the availability of increased PET scan capacity in the Hawaii community will be needed to accommodate the growing number of conditions for which PET scans are approved.

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Accessibility. In addition to capacity, another criteria that affects accessibility is that of location. With the change in service to a fixed site, HPI's proposal represents a change in service location. The target group that is felt to be most affected is that of the patients served at the Ewa Beach scanning location. To assess this, HPI conducted a thorough review of the patients who have been scanned at the Ewa Beach location in the past three years, July 1, 2002 through July 31, 2005. This review included patient zip code data by scanning location, referring physician by scanning location, and anecdotal information. The zip code data was secured from HPI's billing program (Attachment F) and is summarized in the following table:

Table 1—Patients Scanned at Ewa Beach Location  
 July 1, 2002 – July 31, 2005

Number of Patients by Residential Zip Code	Total Ewa Beach Scans = 1110		Percentage of total scans, both locations (2277 scans)
	Number	Percentage	
West and Central Oahu*	481	44%	21%
Aiea and Pearl City	136	12%	6%
Neighbor Island	310	28%	14%
Honolulu	117	11%	5%
Other**	66	6%	3%

\*Includes Ewa Beach, Haleiwa, Kahuku, Kapolei, Mililani, Wahiawa, Waiialua, Waianae, Waipahu  
 \*\*Includes South Pacific, Windward Oahu, Mainland, Honolulu

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As the data demonstrates, the Ewa Beach scanning location has served patients from throughout Oahu as well as the Neighbor Islands. Again, the group that would be most affected by the fixed site location is the West and Central Oahu group, which represents 44% of the patients seen at that location, but represents only 21% of the HPI total scanning volume. The remaining patients could more easily accommodate to a Honolulu location. Aiea and Pearl City patients are located mid-way between Honolulu and Ewa Beach. Neighbor Island patients are scheduled by HPI at either location, but often at the Ewa Beach site to fill the schedule. Since HPI coordinates the Neighbor Island patient travel, which includes round trip ground transportation from the airport to the scanning location, this group will not be affected.

Of interest to note is that an additional 137 patients from the West and Central Oahu areas were scanned at the Honolulu location, by patient choice. This represents 12% of the Honolulu scanning volume.

The referring physician data (Attachment G) was also obtained from the HPI billing system and is pertinent from the standpoint of office location, i. e. where patients go to see their physician. The following table summarizes this data:

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Table 2--Office Location of Physicians Referring to the Ewa Beach Location  
July 1, 2002 – July 31, 2005

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Office Location	Number of Physicians	Number of Patients	Percentage of Total Scans (1110)
Honolulu*	81	494	45%
Aiea and Pearl City	5	110	10%
Neighbor Island	25	236	21%
Other**	11	270	24%

\*Includes private physicians, Tripler, and Honolulu Veterans' Administration (VA)

\*\*Includes private physicians with offices in West and Central Oahu and Honolulu physicians with second offices in West and Central Oahu as well as on a Neighbor Island

The data demonstrates that over 45 % of the patients seen at the Ewa Beach scanning location travel into Honolulu to see their physicians. Additionally, many of the patients have other tests and services at Honolulu locations as seen in their medical records at the time of referral for a PET scan. Therefore, a Honolulu location does not seem to be a significant factor for patients seeking services as many patients travel to Honolulu now for services.

**Summary**—The following is a table that summarizes the significant statistics related to the target group:

Table 3—Patients Scanned at the Ewa Beach Location  
July 1, 2002 – July 31, 2005  
Summary of Significant Statistics

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Patient Characteristic	Total Ewa Beach Scans = 1110		Percentage of Total Scans (2277 scans) Both Locations
	Number	Percentage	
Resides in catchment area	481	44%	21%
Referred by Honolulu MD	494	45%	22%
Referred by MD's in area	270	24%	12%

Given the above discussion and data, it seems that a change in location may truly affect only a small group of patients. This is based on the fact that the while the number of patients scanned in Ewa Beach who reside in the that catchment area represents 44% of the volume at that site, this volume represents only 21% of HPI's total scan volume

for the period. The remaining groups of patients will be affected only minimally, if at all. In addition, 45% of patients scanned in Ewa Beach come into Honolulu to see their referring physicians and often receive other services. In fact, only 24% of Ewa Beach patients scanned see physicians with offices in the catchment area—12% of HPI's total scan volume. For those patients who would be truly impacted for transportation reasons, HPI would provide that service, which has been an ongoing program practice.

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In addition to the target group discussed above, HPI is committed to continuing to make its services available to all groups on Oahu including Hawaii's disadvantaged and underserved groups as outlined in the H2P2, particularly the elderly, low income persons, women and children.

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### ***Quality of Care and Services***

HPI provides high quality PET scanning services as demonstrated by physician and patient feedback. It is believed, however, that HPI services will be improved with a fixed site operation for all of the reasons mentioned in the foregoing discussions:

- Privacy for interview and changing of clothes;
- Bathroom facilities;
- Comfortable injection suites within which to wait during the delay period;
- Waiting space for family and companions, outside of the radioactive area;
- ADA accessible facilities within the PET scanning facility; and
- Improved scheduling options, any day of the week (versus the days that the mobile is present at either scanning location).

It is believed that the above enhancements to service quality will more than offset any convenience and accessibility issues related to the change in service location. Representative letters of support from referring physicians related to this are included in Attachment H.

### ***Cost and Finances***

HPI will continue to provide its high quality services through its partners, which minimizes the overall liability and financial risk to the community. Financing will be available from a combination of resources including cash on hand, tenant improvement allowance, and third party financing. Third party financing has been preliminarily secured through Philips Medical Capital and a letter to this effect is included in Attachment I. HPI is confident that it will continue to generate a positive bottom line as evidenced in the proformas for years one through five included in Attachment I.

### ***Relationship to the Existing Healthcare System***

It is believed that this change to a fixed site location will have no impact on the existing healthcare system and in fact, will assure that future accessibility to PET scanning services will be enhanced as the demand grows.

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The change in service and location affects only Hawaii PET Imaging patients; all patients served at the two scanning locations are direct referrals from physician offices to HPI, registered, scanned, and billed for by Hawaii PET Imaging.

In addition, it is believed that this change in service will not affect the fixed site Hamamatsu/Queen's PET Imaging Center located on the Queen's campus. Like HPI, Queen's has their own referring and loyal physicians, many of who reside in the Queen's physician office buildings, as well as patients who prefer to go to Queen's. Although the change in location may result in some patient exchange between the two PET centers, the overall impact will be minimal. This is especially true with the implementation of the changes in Medicare coverage discussed earlier in this application.

### ***Availability of Resources***

As mentioned above, preliminary funding for this project has already been assured through a combination of cash and debt financing through Philips Medical Capital, guaranteed by National Medical Development, Inc., (NMDI), the majority and managing member in HPI. Operational revenues will provide debt payments for the life of the loan as demonstrated in the attached proformas.

The radiopharmaceutical required for the PET imaging has been and will continue to be provided through HPI's purchasing agreement with the cyclotron facility operated by the Queen's Medical Center.

Medical Direction and professional interpretation services will continue to be provided through a contractual agreement with Medical Imaging, Inc., a local nuclear radiology physician group.

Medical Physics and radiation safety oversight will continue to be provided through contractual agreement with the Medical Physics Service of the Queen's Medical Center.

No new staff is required for this proposal. Professional, technological, management and administrative services will continue to be provided by HPI through its current combination of employed staff and contractual arrangements.

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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.

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