



ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: 10-09A Date of Receipt:
To be assigned by Agency

APPLICANT PROFILE

Project Title: Addition of Ultrasound and Digital Mammography services

Project Address: 1029 Kapahulu Avenue, Suite 500, Honolulu, Hawaii

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

Name of CEO or equivalent: Scott B. Halliday

Title: President, National Medical Development, Inc, Majority Member, Maui Diagnostic Imaging, L.L.C.

Address: 101 Elliott Avenue South, Seattle, WA 98119

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

6-7-2010
Date

Scott Halliday
Name (please type or print)

President
Title (please type or print)

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: X
Honolulu: _____
Windward O`ahu: _____
West O`ahu: _____
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.)

Radiology Facility License from State of Hawaii Department of Health

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
- By-Laws (not applicable)
- Partnership Agreements
- Tax Key Number (project's location)
3-2-007-019 (portion of)

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					

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			

6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:	AMOUNT:
1. Land Acquisition	_____
2. Construction Contract	\$100,000
3. Fixed Equipment	_____
4. Movable Equipment	_____
5. Financing Costs	_____
6. Fair Market Value of assets acquired by lease, rent, donation, etc.	\$500,000
7. Other: _____	_____
TOTAL PROJECT COST:	\$600,000

B. Source of Funds	
1. Cash	_____
2. State Appropriations	NA_____
3. Other Grants	NA_____
4. Fund Drive	NA_____
5. Debt-Lease	\$600,000__
6. Other: FMV of Leased Assets incl. space lease	NA_____
TOTAL SOURCE OF FUNDS:	\$600,000

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.

This is the addition of Ultrasound and Digital Mammography services to the existing x-ray and dexta services located at 1029 Kapahulu Avenue, suite 500, Honolulu, HI.

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, - May 1, 2010
- b) Dates by which other government approvals/permits will be applied for and received, - NA
- c) Dates by which financing is assured for the project, - May 1, 2010
- d) Date construction will commence, - May 1, 2010
- e) Length of construction period, - 6 weeks
- f) Date of completion of the project, - June 15, 2010
- g) Date of commencement of operation – upon receipt of CON

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.

- a) Relationship to the State of Hawai'i Health Services and Facilities Plan.
- b) Need and Accessibility
- c) Quality of Service/Care
- d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
- e) Relationship to the existing health care system
- f) Availability of Resources.

Hawaii PET Imaging, L.L.C. ("HPI") seeks approval to expand the diagnostic radiology services (currently x-ray and dexta services) at 1029 Kapahulu Avenue, suite 500, Honolulu, Hawaii to include ultrasound and digital mammography. The facility is currently owned and operated by HPI.

Dr Sharon Lawler, the building owner, originally sought NMDI's participation and operation of the existing facility (previous CON app.s 06-25A, 10-03A and later transfer of ownership to HPI, CON app. 10-06A) to continue to provide services to the elderly and low-income residents of nearby neighborhoods at the location. As referenced in

these previous applications, Dr. Lawler did complete her building at the location, and it is occupied by many specialty physicians that were utilizing the x-ray and dexa services in the building and have expressed a real need for digital mammography and ultrasound services for their patients. In addition, several area physicians from East Oahu have also heard that we might be able to add these needed services, and as shown by their letters of support, they too feel that these services are needed at this location. The area physicians have expressed their need for these modalities on one location as it assists them in diagnosing patients on a timely basis, rather than having patients have only the x-rays done on site, and then having to drive to at least one additional location (with additional paperwork, parking, and confusion).

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

The expansion of services to include Digital Mammography and Ultrasound are consistent with the several of the SHCC priorities:

- 1 These additional services will enable HPI to expand our healthcare workforce and retain existing technicians providing important increased access to these needed services for East Oahu residents.
- 2 The addition of Digital mammography, as the "gold standard" of mammography procedures, increases the access to "quality healthcare" for area residents.
- 3 Having these services in one location will provide area physicians easier access and time savings with regard to referrals and results from tests (being a small, outpatient facility close to the referring physicians of East Oahu will make it easier to deliver results and efficient care).
- 4 The expansion of this location provides more access to the elderly and low income residents of the area in working with their area primary care physicians.
- 5 Further, we shall continue in this Facility to use the HPI management and education to support and further healthcare education and prevention initiatives.

Specifically, by the addition of Digital Mammography, we are supportive of the HSAC priorities by "improving access" to this high level service as well as the increased quality of mammography services to the area residents.

This facility also assists in providing the services capacity and access to the important primary care services in the building and the area physicians, addressing one of the SHCC "Important Health Areas of Concern".

With regard to the Honolulu Sub Area Priorities, this Facility provides more access and availability of these needed and supportive services to the areas' elderly and poor population that have difficulty traveling to hospital and other further distanced services.

This will enhance to some degree their quality of life by reducing and or eliminating travel, its costs and complications, for these local residents

We shall maintain a local, Honolulu based staff.

b) Need and Accessibility

Referring to the Need for these two modalities to be in the same facility with regards to identification of various diseases, specifically cancer:

When ultrasound was added to mammography, 28% more cancers were found than when mammography was the only screening method used, researchers reported in the May 14 issue of *The Journal of the American Medical Association*.

Breast ultrasound is a procedure that may be used to determine whether a lump is a cyst (sac containing fluid) or a solid mass which could be cancer. If it is found to be a cyst, fluid is typically withdrawn from it using a needle and syringe (a process called aspiration). If clear fluid is removed and the mass completely disappears, no further treatment or evaluation is needed.

Ultrasound can also be used to precisely locate the position of a known tumor in order to guide the doctor during a biopsy or aspiration procedure. Ultrasound helps confirm correct needle placement.

1. The lifetime risk (to age 85) of a woman developing breast cancer in 1940 was 5% or one in 20; the risk is now 13.4% or almost one in 8.
2. It is estimated that in 2009, there will be 192,370 new cases of breast cancer and 40,170 deaths from the disease.
3. Women who undergo breast cancer screening mammograms have demonstrated significantly reduced deaths from the disease.
4. The effectiveness of any breast cancer screening program will depend on how often women are screened, compliance with screening recommendations, and the quality of the screening test.

Your risk for breast cancer increases as you age. About 77% of women diagnosed with breast cancer each year are over age 50, and almost half are age 65 and older. In women 40 to 49 years of age, there is a one in 68 risk of developing breast cancer. In the 50 to 59 age group, that risk increases to one in 37.

Mammography is the only screening tool for breast cancer that is known to reduce deaths due to breast cancer through early detection. Even so, mammograms do not detect all breast cancers. Some breast lesions and abnormalities are not visible or are difficult to interpret on mammograms. In breasts that are dense, meaning there is a lot of glandular tissue and less fat, many cancers can be hard to see on mammography. Many studies have shown that ultrasound and magnetic resonance imaging (MRI) can help supplement mammography by detecting small breast cancers that may not be visible with mammography. When ultrasound is used for screening, many abnormalities are seen which may require biopsy but are not cancer (false positives), and this limits its cost effectiveness.

Ultrasound can be offered as a screening tool for women who:

- are at high risk for breast cancer and unable to tolerate an MRI examination.
- are at intermediate risk for breast cancer based on family history, personal history of breast cancer, or prior biopsy showing an abnormal result.
- have dense breasts.
- have silicone breast implants and very little tissue can be included on the mammogram.
- are pregnant or should not to be exposed to x-rays (which is necessary for a mammogram).

Breast cancer is the most common type of cancer among women in Hawai'i. Breast cancer rates in Hawai'i have generally been lower than those for the nation. However, Hawai'i's breast cancer rates increased by 65 percent between 1980 to 2005. Even within Japan, affluent women who eat meat daily have an 8.5 times higher risk of breast cancer than poorer women who rarely or never eat meat. The Surgeon General's Report on Nutrition and Health stated: "Indeed, a comparison of populations indicates that death rates for cancers of the breast, colon, and prostate are directly proportional to estimated dietary fat intakes."

Specifically the need for adding Ultrasound and Digital Mammography as a part of those services is needed mostly for women, who often require various related diagnostic approaches. For example Mammography, Ultrasound and X-Ray in the same office is typical for a "women's center". This will provide the area's East Oahu patients and physicians with these needed and basic imaging services allowing them to avoid time and travel costs to other, more distant services.

The imaging services will be available to all on a non-discriminatory basis consistent with our policy of imaging all patients 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.

c) Quality of Service/Care

HPI is accredited by the American College of Radiology and licensed by the State of Hawaii. The MRA staff Radiologists are certified by the American Board of Radiology and are licensed physicians in Hawaii. They are members of a wide variety of professional organizations. The current technologists, and our new technologists (which we shall hire upon CON approval) will maintain certification 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.

The facility already operates in accordance with all applicable state and federal guidelines and the standards of the accrediting body, and has the HPI policies and procedures to insure continuing quality and safety of patient care.

The facility's patient care staff currently includes 2.0 FTE Radiology/Dexascan Technicians which shall be expanded to one additional mammo/ultrasound technician.

The staff-to-patient ratio will be 1:1. The technician will be with each patient at all times while a procedure is being performed.

National Medical Development, Inc. ("NMDI"), is the owner of both Maui Diagnostic Imaging, L.L.C. ("MDI") and HPI. MDI has been providing x-ray, dexa, ultrasound, digital mammography, CT, and MRI services on Maui in association with Maui Radiology Associates, Inc. ("MRA") for many years. MRA does provide the professional radiology portion of services to HPI and MDI. HPI and MDI, as NMDI wholly owned affiliates, are recognized as a quality providers that continually upgrade and enhances their services and facilities to the local population.

The services included in this application will constitute a second site for ultrasound and digital mammography services for NMDI and MRA and new ultrasound and digital mammography services for HPI.

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

The total capital expenditure for the project is estimated at 600,000 which includes purchasing/leasing the equipment and constructing the site. There are no other expenditures needed to begin and maintain this service, as HPI already has the office space under lease.

Purchase/Lease payments will be made from HPI operating revenue and the proposal is financially feasible starting in year three of the proposal.

The following are the internal HPI financial projections as they relate to the Ultrasound and Digital mammography additions:

		<u>YEAR 1</u>	<u>YEAR 2</u>	<u>YEAR 3</u>
		(VOLUMES PER DAY)		
US		3	5	7
Mammo		4	6	8
<u>Reimbursements</u>				
US	<u>\$110</u>	\$85,140	\$141,900	\$198,660
Mammo	<u>\$105</u>	\$108,360	\$162,540	\$216,720
	<u>NET REVENUE</u>	\$193,500	\$304,440	\$415,380
costs:				
finance		\$120,000	\$120,000	\$120,000
techs		\$75,000	\$75,000	\$75,000
supplies/service		\$10,000	\$90,000	\$110,000
NET PROFIT(LOSS)		<u>\$11,500</u>	<u>\$19,440</u>	<u>\$110,380</u>

The facility's proposed charges will be within the range of charges for similar procedures billed by other providers on Oahu.

The project will help to keep health care costs down by facilitating the provision of primary care to elderly and low-income persons in the neighborhoods surrounding the new medical complex. By improving the complex's primary care physicians' effectiveness in detecting and treating such chronic health problems as osteoporosis (Dexa), cancer (mammography and ultrasound), and other related diseases needing mammography and ultrasound, these proposed modalities will help patients avoid more costly treatment and nursing and home care that may be needed if these chronic health problems are allowed to go untreated. Finally, by facilitating the complex's physicians' efforts to improve access to primary care, the proposed increase in this radiology facility will help patients avoid resorting to more costly hospital emergency rooms for treatment of conditions that can be treated at the complex in a less costly manner.

e) Relationship to the Existing Health Care System

The expansion of this service is part of a complex that was developed as a result of the efforts of Dr. Lawler, who is dedicated to providing integrated primary care that will reduce the fragmentation of medical services available to residents of nearby neighborhoods. It currently cooperates with other medical service providers located at the complex and in the greater East Oahu area, in order to provide a comprehensive array of services at a single site in order to facilitate access to persons who now are forced to rely largely on downtown hospitals for much of their medical care

and for whom transportation can create a barrier to receiving care and to improve the cost effectiveness of care offered to the target population.

By providing fast and effective diagnostic tools to the complex's urgent care clinic, this radiology facility helps to provide an alternative to use of costly emergency room facilities for non-emergency conditions and thereby free up hospital emergency room resources for treatment of true medical emergencies

f) Availability of Resources

There is little additional capital required for this project. The equipment will be leased and the addition of only one staff member (we have several applications for the Ultrasound/mammography technician already) as part of HPI operations will have minor affect on HPI cash flows.

There are no financial or operational obstacles to this project. The Facility will be managed thru HPI, which has been providing these services (thru the parent company and affiliate NMDI, and MDI, respectively) and management resources on Oahu and Maui for many years.

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.