



## HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

### STANDARD APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number 06-01

Applicant: Leeward Advanced Medical Imaging, LLC  
500 Ala Moana Blvd., Tower 4, #510  
Honolulu, HI  
Phone: 808-521-9551

Project Title: Establishment of Computed Tomography Imaging (CT) and  
Magnetic Resonance Imaging (MRI) services

Project Address: 98-1005 Moanalua Road, Aiea, Hawaii

1. TYPE OR 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   (secondary)
  - Honolulu: \_\_\_\_\_
  - Windward O`ahu: \_\_\_\_\_
  - West O`ahu:   X   (primary)
  - 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 from City and County of Honolulu  
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 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: See Attachment 3 (Articles of Organization)
- By-Laws: Not applicable
- Partnership Agreements: See Attachment 4
- Tax Key Number (project's location) (1) 9-8-016-49

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 ownership	Change in service/ establish new service/facility	Change in Beds
Inpatient Facility		RECEIVED				
Outpatient Facility		'06 JAN 18 P 4:13			X	
Private Practice		ST. HLTH. PLNG. & DEV. AGENCY				

5. **TOTAL CAPITAL COST:** \$7,060,069

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
<b>TOTAL</b>			

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.

Establishment of outpatient CT Scanning and MRI Services in Pearl Ridge Shopping Center.

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

<b>A. List All Project Costs:</b>	<b>AMOUNT:</b>
1. Land Acquisition	_____
2. Construction Contract	\$ 933,570.00
3. Fixed Equipment	\$4,437,867.00
4. Movable Equipment	\$ 277,082.00
5. Financing Costs	_____
6. Fair Market Value of assets acquired by lease, rent, donation, etc.	\$1,411,550.00
7. Other: _____	_____
<b>TOTAL PROJECT COST: \$7,060,069.00</b>	

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**B. Source and Method of Estimation**

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

Estimates were obtained from Equipment Manufacturers and potential construction Contractors

<b>C. Source of Funds</b>	<b>AMOUNT:</b>
1. Cash	_____
2. State Appropriations	_____
3. Other Grants	_____
4. Fund Drive	_____
5. Loan from Equipment Manufacturer	\$ 590,193.80
5. Capital Lease	\$5,058,325.20
6. Other: <u>Site Lease (Rent)</u>	\$1,411,550.00
<b>TOTAL SOURCE OF FUNDS: \$7,060,069.00</b>	

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: November 2005
- b) Dates by which other government approvals/permits will be applied for and received:  
Applied for: March 2006  
Received: April 2006
- c) Dates by which financing is assured for the project: March 2006
- d) Date construction will commence: April 2006
- e) Length of construction period: 4 months
- f) Date of completion of the project: August 2006
- g) Date of commencement of operation: September 18, 2006

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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.

#### EXECUTIVE SUMMARY

Leeward Advanced Medical Imaging, LLC (Leeward) seeks approval to implement Computed Tomography Imaging (CT) and Magnetic Resonance Imaging (MRI) services (referred to collectively, hereafter, as "the proposed imaging services") at Pearl Ridge Shopping Center ("the proposed imaging center"). See Attachment 5. The site was chosen to facilitate ease of access for patients in the growing West Oahu, many of whom lack transportation to downtown Honolulu or for whom driving to downtown Honolulu is difficult because of their medical condition or disability.

Leeward is wholly owned by Radiology Associates, Inc. (RAI). RAI is comprised of 10 radiologists who have provided image interpretive services to many hospitals on Oahu including Waianae Coast Comprehensive Coast Health Center (Waianae Comp), Queen's Medical Center and Shriner's Hospital, as well as Molokai General Hospital and Kwajalein Hospital since the company's incorporation in 1970.

- 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 imaging services will help meet the H2P2's goal of increasing the span of healthy life for Hawaii's residents by providing timely access to imaging services that facilitate early detection and

diagnosis of treatable diseases and by reducing the effects of chronic disease and reducing morbidity and pain by facilitating effective treatment of medical conditions.

It will reduce disparities among Hawaii's residents and promote equitable and effective access to health care for all Hawaii residents at reasonable cost by providing much needed treatment options to West Oahu residents, who may have difficulty traveling to Honolulu where the majority of imaging service providers are now located.

The proposed imaging services will also promote cost-effective treatment by reducing the need for many invasive procedures such as exploratory surgery and surgical biopsy and, when such procedures are necessary, permitting them to be done in a more precise manner that minimizes risks and discomfort to patients. Moreover, the proposed imaging center will also provide continuity of care by providing appropriate care to West Oahu residents in an accessible outpatient setting.

Finally, the proposed imaging services will improve detection and treatment of such conditions as heart disease and stroke, which are health care priorities for the Waianae Coast, as well as cancer and other disabling conditions, which are targeted in Chapters IV through XI of the H2P2.

b) Need and Accessibility

The project will be located in Pearl Ridge Shopping Center in Order to insure easy access by West Oahu residents. The site is located on established public transportation routes and has ample handicapped accessible parking.

While all CT and MRI providers on Oahu are currently operating at or above the minimum thresholds for initiation of new service that are set out in the H2P2, calculation of demand for West Oahu residents based on the number of procedures performed annually per 1000 population shows that the area's two current providers **are not performing even half the number of CT or MRI procedures needed by the community**. As a result, many must travel to downtown Oahu to obtain needed imaging services. However, one must question whether these patients are traveling out of the area for services, or are simply not receiving services due to the lack of local accessibility. According to The IMV Medical Information Division's (IMV) Benchmark Report for CT – 2004, Hawaii ranks 48<sup>th</sup> out of the 50 states in utilization of CT scanning. See Attachment 6 at 13. The IMV Benchmark Report for MRI – 2004, shows that Hawaii's utilization of MRI is also low compared to national averages; the State ranks 43<sup>rd</sup> among the 50 states in utilization of MRI scanning procedures. See Attachment 7 at 15. These low utilization rates support the conclusion that West Oahu patients – and patients throughout Hawaii – are **not** receiving needed services, and appropriate and timely medical intervention is **not** being offered to these patients. As a result, they are suffering the mortality and morbidity associated with late intervention. The proposed imaging center will help to alleviate this problem by providing an alternative provider to West Oahu's significant medically underserved population.

The proposed imaging center will feature an open MRI unit that is more easily accessible to the elderly, children and persons suffering from claustrophobia than the closed MRI units now use by most other imaging service providers in West Oahu. Additionally, the Espree 1.5 Tesla (T) Ultra Short Bore MRI from Siemens Medical Solutions USA, Inc. (the "Espree") that will be used at the proposed imaging center is the **first equipment of its type to offer "scan equity" for obese patients and offers double the field strength and more than double the signal-to-noise ratio that can be achieved with 0.7T MRI units that are in use by most MRI providers on Oahu**. Doubling the

signal-to-noise ratio allows the 1.5T systems to use shorter echo-times, allowing significantly thinner slices and more rapid acquisitions (less time), which results in less patient motion – a significant problem with MRI images. The 1.5T system produces significantly better views of blood vessels. Over 90% of the bodies arteries and veins cannot be imaged adequately on a 0.7T system, and many physicians will not refer a patient for a brain magnetic resonance arteriogram on a low field system. Additionally, the 1.5T system produces superior tissue contrast, which is of critical importance in defining CNS tumors. The images obtained on a 0.7T system cannot be used for decision making concerning the need for precision Stereotactic Radiosurgery (Gamma and/or X-knife radiosurgery). As a result of the unreliability of the 0.7T systems, many Oahu patients must undergo repeat MRI imaging prior to Gamma knife surgery for brain cancer **thereby increasing the overall cost of their care**. The 0.7T systems also cannot perform magnetic resonance spectroscopy, or functional imaging, which is equally necessary for adequate brain tumor evaluations. Functional imaging allows visualization of critical areas of the brain, such as the motor, speech or vision centers so that damage to these areas can be avoided during surgery or radiosurgery. Currently, spectroscopy and functional imaging are not reimbursed by insurers, but on 1.5T systems, they are performed along with routine imaging, for which insurers do provide reimbursement. RAI interprets the spectroscopy and functional imaging at no additional charge to the patient because they provide significant additional diagnostic information. If a patient's initial imaging is done on a 0.7T system, patients must pay out of pocket for the second scan prior to surgery. Accordingly, the 1.5T Espree, which will be available at the proposed imaging center, will provide optimal, reliable MRI imaging for a segment of the population that is currently being denied these benefits.

The proposed imaging center will also utilize the most up-to-date CT technology, which will permit performance of both peripheral and coronary angiography (CTA) and other procedures that cannot be performed by other CT scanners now available in Hawaii. In addition to producing higher quality angiograms without the use of beta-blockers to slow the heart – as is required when these procedures are attempted on older CT equipment – the CT units that will be available at the new imaging center will do so using only 30 to 57% of the dose of radiation administered by the older equipment, yielding a net 1.7 to 3.0 reduction in radiation exposure. Both the reduction in radiation dosage and the ability to perform these procedures without the risk of side effects from the administration of beta-blockers will increase patient safety. As a safer alternative to peripheral catheter angiography, CTA is important to such at risk patients as diabetics and individuals suffering from peripheral vascular disease (PVD). For example, CTA does not subject these patients to the risk that a clot or plaque will be dislodged as can occur in catheter angiography.

The proposed imaging services will be available to all on a non-discriminatory basis consistent with RAI's policy of imaging all patients with a physician's order without regard to ability to pay. Leeward has entered into negotiations with Waianae Comp to develop a shuttle service to provide transportation to Leeward from Waianae in order to enhance accessibility for indigent patients, who will be provided needed services without charge.

### c) Quality of Service/Care

The facility will be accredited by the American College of Radiology and licensed by the State of Hawaii. The staff Radiologists will be certified by the American Board of Radiology and be licensed physicians in Hawaii. All technologists will be certified by the American Registry of Radiologic Technologists, certified as CT or MRI technologists, and licensed by the State of Hawaii. The facility will operate in accordance with all applicable state and federal regulations and the standards of the

accrediting body, and will have a written policies and procedures to insure the quality and safety of patient care.

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 \$7,060,069, which includes \$933,570 for site improvements, \$4,437,867 for fixed equipment, \$277,082 for movable equipment, and \$1,411,550 for acquisition of the site pursuant to a five year lease with option for renewal. The cost of the imaging equipment and a substantial portion of the construction expenses will be financed by the equipment manufacturer via a lease agreement. The remainder of the project costs will be financed by means of a loan from the manufacturer.

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The operating revenue for the first year of operation is projected at \$860,312 and operating expenses for the same period are projected at \$1,640,378, resulting in an operating loss of \$780,066. By the third year of operation, operating revenue is expected to increase to \$2,787,596, with total expenses projected at \$2,483,820, resulting in net income of \$304,473. A summary of the projected annual revenues and costs associated with the facility is set forth in Exhibit D-2.

e) Relationship to the Existing Health Care System

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This proposal will address the imbalance of CT and MRI services on Oahu by providing more capacity and increased access to imaging services to residents of West Oahu, who are currently underserved and has the support of Waianae Comp, a major provider of services of health care services to West Oahu residents. Services at the proposed imaging center will be priced at or below the prevailing market price for services of a similar nature on Oahu. All CT and MRI service providers on Oahu are currently operating at or above the minimum threshold levels for initiation of new services set out in the H2P2. In any event, there is unmet need both in West Oahu and throughout the island, and Leeward anticipates that many of the procedures performed at the proposed imaging center will be of types that cannot be performed with the equipment now in use by existing providers. Accordingly, this proposal will have minimal impact on the operations of existing providers. The demonstrated unmet demand for services in West Oahu, along with the growing need for CT and MRI services resulting from technological advances and the wide range of procedures that will be done at the proposed imaging center that cannot be done with equipment currently available at other imaging centers in Hawaii, insure that any minor disruptions will be of short duration.

f) Availability of Resources

There are no financial obstacles to this project. The acquisition of the project site and equipment needed for this project will be made through lease financing and a loan from the equipment manufacturer.

RAI already employs one CT technologist, who will be assigned to Leeward. RAI has initiated recruiting of additional staff with the assistance of mainland recruiters and has already received letters of inquiry from technologists interested in relocating to Hawaii to work at the proposed imaging center.