

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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September 25, 2007

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
Advanced Medical Imaging, LLC)	NO. 07-10
)	
Applicant)	
_____)	DECISION ON THE MERITS

DECISION ON THE MERITS

The State Health Planning and Development Agency (hereinafter "Agency"), having taken into consideration all of the records pertaining to Certificate of Need Application No. 07-10 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Oahuwide Certificate of Need Review Committee, the Certificate of Need Review Panel and the Statewide Health Coordinating Council, the Agency hereby makes its Decision on the Merits, including findings of fact, conclusions of law, order, and written notice on Certificate of Need Application No. 07-10.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of Computed Tomography (CT), Magnetic Resonance Imaging (MRI) and X-ray services at 95-1147 Ukuwai Street – Building C – Suite 5, Mililani, Hawaii, at a capital cost of \$5,807,522.

2. The applicant, Advanced Medical Imaging, LLC, is a limited liability corporation.
3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).
4. On March 30, 2007, the applicant filed with the Agency a Certificate of Need application for the for the establishment of Computed Tomography (CT), Magnetic Resonance Imaging (MRI) and X-ray services at 95-1147 Ukuwai Street – Building C – Suite 5, Mililani, Hawaii, at a capital cost of \$5,807,522. (the "Proposal"). On May 29, 2007, the applicant submitted additional information. On July 2, 2007, the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #07-10.
5. The period for Agency review of the application commenced on July 11, 2007, the day notice was provided to the public pursuant to 11-186-39 HAR.
6. The application was reviewed by the Oahuwide Certificate of Need Review Committee at a public meeting on July 18, 2007. The Committee voted 4 to 0 in favor of recommending approval of the application.
7. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on July 26, 2007. The Council voted 13 to 0 with one abstention in favor of recommending approval of the application.
8. The application was reviewed by the Certificate of Need Review Panel at a public meeting on August 2, 2007. The Panel voted 7 to 0 in favor of recommending approval of the application.
9. This application was reviewed in accordance with Section 11-186-15, HAR.
10. Pursuant to Section 323D-43(b), HRS:

“(b) No Certificate shall be issued unless the Agency has determined that:

 - (1) There is a public need for the facility or service; and
 - (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs.”
11. Burden of proof. Section 11-186-42, HAR, provides:

“The applicant for a certificate of need or for an exemption from certificate of need requirements shall have the burden of proof, including the burden of producing

evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence."

II

FINDINGS OF FACT

A. REGARDING THE RELATION OF THE PROPOSAL TO THE STATE HEALTH SERVICES AND FACILITIES PLAN (HAWAII HEALTH PERFORMANCE PLAN) OR "H2P2"

12. With respect to the goals and objectives of H2P2, the applicant states that "Imaging continues as the primary resource for identifying medical conditions, prolonging health-related quality of life and contributing to a possible reduction in patient morbidity and pain. Prompt and timely access will further contribute to identification of a potentially serious medical condition, chronic disease, and potentially reducing the possible option of selected invasive procedures to obtain the same result."

13. The applicant states that "As identified in Chapter III, of H2P2, and confirmed by AMI operational values, the structure of a quality health care system must be accessible, responsive and cost-effective. The description of these values as it pertains to this proposal, include delivery of diagnostic imaging services with accountability, compassion, comprehensiveness and concern for community. AMI intends to develop a strong interrelationship between the community and the delivery of services by being responsive to their needs for the overall benefit and convenience of the patient. Imaging services that are essential and critical should be affordable and accessible to all residents."

14. The applicant states that "The utilization data substantiates that no one is being under utilized. Providers on Oahu are in excess of the minimum thresholds for the implementation of a new service as set forth in H2P2."

15. The applicant states that "Recommended statewide and regional priorities applicable to this proposal should include but not be limited to increasing access, delivery of services in a prudent and cost-effective manner, and ensure that the needs of elderly and chronically ill patients be of high priority. Early detection will lead to prompt treatment. Services will be effective, integrated and always be delivered with compassion."

16. The applicant states that "MRI is able to provide orthopedic, neurological, vascular, cardiac, neck, spine, and upper and lower extremity images, and has significant impact on the diagnosis and treatment of many of the conditions listed in H2P2 Chapters IV through XI, particularly infectious diseases (Chapter IV), cancer (Chapter V), diabetes (Chapter VI), heart disease and stroke (Chapter VII), and injuries resulting from trauma and violence (Chapter VIII)."

17. The applicant states that "The proposed CT scanner will enable radiologists to more easily diagnose such conditions as infectious diseases, cancer, cardiovascular disease, stroke, trauma, and musculoskeletal disorders. CT scanning is frequently used for the detection, treatment, planning and monitoring of cancers (Chapter V), including cancers of the lung, liver and pancreas. CT scanning can also improve the effectiveness of radiation treatments for tumors by allowing physicians to better target the sites for radiation treatments, and assist in the planning and performance of biopsies and other invasive procedures. CT scans can also assist physicians in screening for and staging cancers. Other common uses of CT scanning include examining the head for causes of stroke (Chapter VII) or head injuries (Chapter VIII); diagnosing spinal disorders or injuries to the extremities, (Chapter VIII); measuring bone density for the detection of osteoporosis (Chapter VIII); diagnosing injuries to the liver, spleen, kidneys and other internal organs from trauma (Chapter VIII); and diagnosing vascular disease which can lead to strokes or heart disease (Chapter VII) or liver or kidney diseases (Chapter VI)."

18. The Agency finds that this criterion has been met.

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

19. The applicant states that "Based on projected estimates for demand, MRI and CT providers on the island of Oahu are operating at or exceeding the current thresholds as referenced in H2P2."

20. The applicant states that based upon the SHPDA Utilization Report, the number of MRI and CT procedures performed in Honolulu County in 2005 were 63,628 and 160,452, respectively.

21. The applicant projects that, based upon a projected population growth in Honolulu County of 0.675% annually, with a MRI and CT average percent increase per 1000 people of 11.88% and 10.9% annually respectively, there will be a demand for 73,626 MRI procedures and 182,698 CT procedures by the year 2010.

22. The applicant projects that the demand for MRI and CT procedures in the Central and North Shore communities will be 15,812 MRI procedures and 41,355 CT procedures by 2010.

23. The applicant states that the 2005 supply in the Central and North Shore communities for MRI and CT is 6,032 MRI procedures and 20,502 CT procedures.

24. The applicant states that "While we cannot eliminate the shortage for health care delivery in this area, it is most certain to reduce the disparity and allow residents who reside in this general geographic area the option to access the latest diagnostic imaging technology within their community."

25. The applicant states that "Imaging services at this facility is available to all patients without discrimination whatsoever. All patients requiring imaging services who are referred by a licensed practitioner for a specific diagnosis will be treated."

26. The applicant states that "X-ray is widely used through out the health care industry for many diverse purposes...the inclusion of x-ray services is necessary for purposes of pre-screening a number of patients to rule out contraindications for MRI."

27. The Agency finds that the proposal, if modified in accordance with the condition on page 8 of this Decision on the Merits, meets the need and accessibility criteria.

C. REGARDING QUALITY AND LICENSURE CRITERIA

28. The applicant states that "AMI shall be fully accredited by the American College of Radiology and licensed in the State of Hawaii. All radiologists are certified by the American Board of Radiology and licensed in the State of Hawaii as a Medical Doctor (MD). All procedures will be conducted under the direct supervision of the attending radiologist."

29. The applicant states that "Every technologist in the various modalities is certified by the American Registry of Radiologic Technologists (ARRT) and licensed in the state of Hawaii as a radiology technologist."

30. The applicant states that "AMI will...adhere to the standards and requirements of the American College of Radiology and comply with any and all other required city, state and governing agencies."

31. The applicant states that "Both professional and technical staff will comply with all CME requirements as defined by their (sic) respective governing entities."
32. The Agency finds that the quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

33. The applicant states that "It is anticipated that the projected operating revenue for year one at \$757,194 and the operating expense at \$646,873, which equates to an operating net income of \$110,321. By year three, the operating revenue is projected to adjust to \$2,889,991 with expenses of \$2,425,700 equating to an estimated net income of \$464,291."
34. The applicant states that "AMI will attempt to control health care costs by providing immediate access to improved quality services resulting in earlier detection for various medical issues which require diagnostic testing."
35. The applicant states that "In an effort to be competitive and sensitive to healthcare delivery costs as it relates to MRI, CT, and X-ray services, AMI intends to implement the following: MRI procedure -\$725, CT Procedure -\$300, X-ray procedure -\$11."
36. The Agency finds that the cost and financial criteria have been met.

E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA

37. The applicant states that "...there is a noticeable difference between the health care availability in Honolulu versus other areas of Oahu, specific to availability and need. While we cannot eliminate the shortage for health care delivery in this area, it is most certain to reduce the disparity and allow residents who reside in this general geographic area the option to access the latest diagnostic imaging technology within their community."
38. The applicant states that "Any possibility of negative impact on Oahu providers is anticipated to be minimal, if at all. This assumption is primarily based on the continuing increase in utilization for the various imaging modalities... The utilization data substantiates that no one is being under utilized. Providers on Oahu are in excess of the minimum thresholds for the implementation of a new service as set forth in H2P2."

39. The Agency finds that that the applicant has met these criteria.

F. REGARDING THE AVAILABILTY OF RESOURCES

40. The applicant states that "This application does not have any financially related obstacles to overcome. Equipment financing, site acquisition, site improvement financing, marketing and other start up and on-going operational expenses have been identified and secured (See Exhibit F-1, financing commitment letter from Toshiba America Medical Credit for capital equipment)."

41. The applicant states that "Toshiba America Medical Credit will also be financing \$785,000 of the costs for construction, tenant improvement expenses, and miscellaneous equipment...The remaining balance for start-up expenses (\$164,822) will be from resources provided by The Radiology Group, Inc. /AMI and from operating capital as needed."

42. The applicant states that "The imaging center does not anticipate human resources to be an issue since we have already communicated with a number of qualified applicants who wish to return to Hawaii. These potential applicants are all certified, currently possess state of Hawaii licensing credentials and have cross training in various modalities."

43. The Agency finds that the applicant has met this criterion.

III

CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 07-10 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Oahuwide Certificate of Need Review Committee, the Certificate of Need Review Panel and the Statewide Health Coordinating Council and based upon the findings of fact contained herein, the Agency concludes as follows:

1. The applicant has failed to show by a preponderance of the evidence that its proposal, as it is currently written, meets the certificate of need criteria in Section 11-186-15(a) (1) HAR.
2. The applicant's proposal, if it were modified as specified in the Order below, would meet the criteria.

Conditional Certification

ORDER

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a CONDITIONAL certificate of need to Advanced Medical Imaging, LLC for the proposal described in Certificate Application No. 07-10. The condition is that on or before December 3, 2007, the applicant shall submit to the Agency, for Agency approval:

- A written charity care policy that will provide access to its services for patients that are unable to pay for such services.

This modification is required for the application to successfully meet the criteria in Section 11-186-15 HAR.

As provided under Section 323D-46, HRS and Section 11-186-77 HAR, the Agency establishes Noon, October 29, 2007 as the date by which the applicant must certify, in writing, that it accepts this condition and that its application is thereby modified accordingly, otherwise this application shall be deemed to be DENIED as provided under Section 11-186-77 HAR.

The maximum capital expenditure allowed under this conditional approval is \$5,807,522.

WRITTEN NOTICE

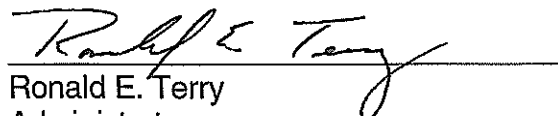
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 HAR. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

(Note, pursuant to Chapter 323D-47, Hawaii Revised Statutes, a request for reconsideration shall be received by the Agency within ten working days of the state agency decision.)

DATED: September 25, 2007
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY

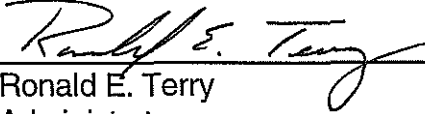

Ronald E. Terry
Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Decision on the Merits, including findings of fact, conclusions of law, order, and written notice, was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on September 25, 2007.

Jerel Saito, M.D.
President/CEO
Advanced Medical Imaging, LLC
c/o 941 Kamehameha Highway, Suite 208
Pearl City, HI 96782

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



Ronald E. Terry
Administrator