

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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April 28, 2004

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)

Island Imaging L.L.C.)

Applicant)

CERTIFICATE OF NEED
APPLICATION
NO. 04-03

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. 04-03 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 Tri-Isle Subarea Health Planning Council, Certificate of Need Review Panel and 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. 04-03.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of an open Magnetic Resonance Imaging (MRI) service at 441 Ala Makani Street, Kahului, HI, at a capital cost of \$2,535,000.
2. The applicant is a Hawaii 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 January 29, 2004, the applicant filed with the Agency a Certificate of need application #04-03 for standard review from Island Imaging L.L.C. for establishment of an open Magnetic Resonance Imaging (MRI) service at 441 Ala Makani Street, Kahului, HI, at a capital cost of \$2,535,000. On January 30, 2004, the Agency determined that the application was incomplete and requested additional information. On January 30, 2004 and February 2, 2004 the applicant submitted additional information. On February 2, 2004, the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #04-03. On March 22, 2004, the applicant submitted to the Agency a Letter of Intent dated March 1, 2004, between Kalama Land Company and Island Imaging, Inc. offering to lease a portion of 151 Wakea Ave., Kahului, HI to Island Imaging for use as an "Imaging Center for CAT scans, MRI's and X-rays." This application was consolidated for review with application #04-01 for standard review from Maui Diagnostic Imaging L.L.C. for the change of ownership of imaging services at 425 Koloa Street #102, Kahului, HI (Magnetic Resonance Imaging, Ultrasound, Mammography, Dexascanner), 221 Piikea Ave #B, Kihei, HI (X-ray, Ultrasound), 53 Puunene Ave. #115, Kahului, HI (Computerized Tomography, X-ray) and 99 South Market St. Wailuku, HI (X-ray) at a capital cost of \$3,118,637 pursuant to Section 11-186-10 HAR.

5. The period for Agency review of the application commenced on February 12, 2004, the day notice was provided to the public pursuant to 11-186-39 HAR.

6. The application was reviewed by the Tri-Isle Subarea Health Planning Council at a public meeting on February 27, 2004. The Council voted 2 to 0 in favor of disapproving this application with three abstentions.

7. The application was reviewed by the Certificate of Need Review Panel ("Panel") at a public meeting on March 22, 2004. The Panel voted 5 to 1 in favor of disapproving this application.

8. The application was reviewed by the Statewide Health Coordinating Council ("Council") at a public meeting on March 25, 2004. The Council voted 6 to 4 in favor of disapproving this application with one abstention.

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"

Vision and Guiding Principles (Chapter II)

12. The applicant states that its proposal "...will achieve the following H2P2 goals: 1) enhanced capabilities for treatment, 2) increased flexibility in treatment, 3) a broader patient population, 4) access to cost-efficient services, and 5) access to up-to-date technologies."

13. The applicant states that its proposal most directly addresses H2P2's objectives of reducing the effects of chronic disease and prolonging health related quality of life, reducing morbidity and pain through timely and appropriate treatment and establishing regionalized health care delivery systems that include community input, are cost effective and that foster improved access to quality health care services.

14. The applicant states that "Further, our proposal also seeks to ensure that access to Maui's health care delivery system includes comprehensive, cost effective and well-coordinated imaging services as part of our region's health care system."

Statewide and Regional Values and Priorities (Chapter III)

15. With respect to the Statewide priority of the prevention and early intervention which target the areas of heart disease/stroke, cancer and diabetes,

the applicant states that " our proposed imaging center will participate in early interventional medical diagnostic activities as prescribed by an individual's physician for the areas of heart disease/stroke, cancer and diabetes as all of the disease areas may involve the need for soft tissue imaging available via the MRI."

16. With respect to the Tri-isle Subarea Values and Priorities, the applicant states that "... the Tri-Isle SAC's priorities do not address imaging services directly. However, as a support diagnostic tool to physicians, we would be involved on an intermittent basis with certain behavioral health care/substance abuse cases (for patients needing brain scans), emergency medical services (as the back-up MRI for the hospital), and dental services (for certain dental surgery cases)."

Diseases and Conditions (Chapters IV-XI)

17. The applicant states that its proposal "...would be an integral part of cancer treatment and care on Maui" and "...is used in diagnosing cancer and monitoring the efficacy of cancer treatment."

18. The applicant states that "...MRI does serve in a support role to physicians in treating stroke and heart disease patients."

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

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

20. The applicant states that "... there is also prior SHPDA CON application approval for a second MRI service on record showing that the Agency believes that a need exists on Maui for a second MRI. This approval was granted to MRC."

21. In its application, the applicant does not state whether a need exists for a third MRI on Maui at this time.

22. The applicant states that its proposal "...will serve low-income persons, racial and ethnic minorities, women, people with disabilities, other underserved groups, and the elderly who need MRI services."

23. The Agency finds that the applicant has established that a need exists for a second MRI unit on Maui and that its proposal will be accessible to all residents of the area, and in particular low-income persons, racial and ethnic minorities, women, people with disabilities, other underserved groups, and the elderly.

C. REGARDING QUALITY AND LICENSURE CRITERIA

24. The applicant states that "All four Diagnostic Radiologists providing professional services at Island Imaging MRI Center are American Board of Radiology certified."
25. The applicant states that "Mr. Steven Newinsky RT (R) (MR) will be the Island Imaging MRI technologist. Mr. Newinsky is AART certified with advanced certification in Magnetic Resonance Imaging, as well as licensed as a Radiology Technologist by the State of Hawaii."
26. The applicant states that "Island Imaging will apply for American College of Radiology Certification of its MRI center as soon as it becomes eligible (1yr)."
27. The applicant states that "Island Imaging, LLC is a newly created entity and will seek affiliations with or accreditations by local and national organizations in the field of radiology and MRI."
28. The applicant states that "Management of Island Imaging MRI center will be provided by Scott Boren, MD and George Boren, MD., as well as the Island Imaging Board of Directors."
29. The applicant states that "The Boren doctors have a combined 30 years experience providing Radiology to Maui's residents and visitors at both Maui Memorial Medical Center and Kaiser Permanente."
30. In his written testimony in opposition to application #04-03 dated February 27, 2004, John Schaumburg, CEO, Maui Memorial Medical Center, states (in regard to the quality criteria) "Island Imaging would meet these criteria. The equipment is quality equipment and the Drs. Boren have an impeccable track record of providing quality service."
31. The Agency finds that quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

32. The applicant projects that, in Exhibit D-2 of its application, the funds from operations will be \$330,167 in year one and \$498,206 in year three of its proposal.
33. The applicant states that "The project will have minimal impact on health care costs. This is because it seeks to replace services that were in existence on Maui before the recent bankruptcy of MRC. However, because Island Imaging is

a newly created entity, the first 6 to 8 months of operations will be at a loss due to start-up expenses and capital costs. During this time, the focus will be on building the infrastructure and staffing requirements. It is anticipated that Island Imaging will reach breakeven by the end of month eight (inclusive of the startup period prior to commencement of services)."

34. The applicant states that "We anticipate that we will be able to run our clinic at a lower cost than a hospital setting and with lower overhead expenses."

35. The Agency finds that cost and financial criteria have been met.

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

36. The applicant states that "...we believe we will have little impact on other imaging providers in the area."

37. In written testimony in opposition to application #04-03 dated February 27, 2004, John Schaumburg, CEO, Maui Memorial Medical Center, states "Maui Memorial estimates that establishing a freestanding unit would divert about \$460,000 in the first year from the hospital. This would weaken the hospital and its ability to support other services which the community needs but which lose money. Weakening the hospital will weaken the system. "

38. In a letter to the Agency dated October 8, 2003, Mr. Schaumburg, states: "As the only acute care facility on the island, Maui Memorial Medical Center (MMMC) is greatly concerned with the level and quality of care provided in the community. In an effort to achieve the highest quality of care while minimizing the resources needed to meet the needs of the community, we have been collaborating with our locally-based hospital physicians to build a relationship which best meets the needs of all the stakeholders: the community, physicians and MMMC. Most recently, we have been working with our radiologists who are current members of Maui Radiology Consultants (MRC)... MMMC has been in negotiations with members of this group, and as a result we have developed a collaborative relationship that we believe will meet the needs of the community and the respective partners. However, we have recently learned that another entrant has come forward with the intent of securing the Certificate of Need (CON), currently held by MRC, for a second MRI themselves. We view this action as a direct assault on the effort to develop a collegial relationship with the surviving members of the failed MRC enterprise. This relationship is not only key to the continual improvement of quality care in our community, but is essential to the health and prosperity of MMMC as well."

39. The Agency finds that the applicant's proposal would impair MMMC's ability to support other needed services in the community which lose money and therefore would have a negative impact on the existing healthcare system.

40. The impact of establishing a second MRI unit (in addition to the existing 1.5T at MMMC) on the existing healthcare system of Maui was considered in two previously consolidated certificate of need reviews; #01-11 and #01-26. In those reviews, the Agency found that application #01-11 for the establishment of an open .2T MRI unit did not meet the criteria for relationship to the existing healthcare system of Maui. The Agency conditionally approved application #01-26 from MRC for a 1.5T MRI unit (the same unit that is the subject of current application #04-01).

41. In its Decision on the Merits dated December 17, 2001, conditionally approving MRC's proposal for the 1.5T MRI unit as the second MRI unit on Maui, the Agency considered written testimony dated October 2, 2001, from R. Brooke Jeffrey, M.D., Professor of Radiology, Chief of Abdominal Imaging at Stanford University Medical Center, who stated in pertinent part: "... where there are a limited number of magnets on the island, (Maui) not to purchase a fully complemented, highly versatile, high-resolution unit such as the 1.5T system in my view represents a missed opportunity for the Maui community."

42. The Agency also considered written testimony received by the Agency October 24, 2001, from Barton Lane, M.D., Professor of Neuroradiology and Neurosurgery, Stanford University Medical Center and Chief of Radiology, Palo Alto Veterans Administration Medical Center, who stated: "Especially in an environment like Maui, where scanners are limited in number, it makes no sense to install a 'niche' scanner such as a low field or 'open' magnet, which would severely limit applications and uses."

43. The Agency also considered written testimony dated September 28, 2001, from Joseph T.T. Hew Jr., M.D., who stated, in pertinent part, "... the community of Maui needs another high field strength MRI unit to ... act as support of the MRI services at the Maui Memorial Medical Center when its MRI unit malfunctions."

44. The applicant states that "Today's high-field open MRIs are capable of images that are the same as the closed bore. The only difference is the imaging speed."

45. In written testimony received by the Agency February 10, 2004, Jay A. Kaiser, MD, President, California Advanced Imaging Associated states "The first

question I would like to address is whether the image quality of a .7 open MRI is equal to a true high field system which utilizes a 1.5T magnet. The simple answer is that it is not... the detailed resolution needed for state of the art imaging requires the use of a true high field scanner... it is my opinion that a .7T open architecture MRI scanner cannot be considered equal to a 1.5T high field strength scanner, and that image quality will be inferior in all areas of the body, especially the breast."

46. With respect to breast biopsies, Dr. Kaiser states "It should be noted that in our area, however, that most MRI guided breast biopsies done at the University of California San Francisco and Stanford University are done using short bore 1.5T MRI scanners. So it would not be accurate to state that an open architecture magnet is required for breast biopsy."

47. The Agency finds that the second MRI unit on Maui should be a 1.5T scanner capable of the performing state of the art imaging for all areas of the body in the event that the MMMC unit is being utilized or is not operating due to malfunction or scheduled service.

48. The Agency finds that a 1.5T MRI unit provides the service area with the most effective back-up to the MRI unit at MMMC.

49. The Agency finds that the applicant's proposal to acquire a .7T MRI unit (as a second MRI unit to the existing 1.5T at MMMC) does not relate well to the existing healthcare system of the area at this time.

50. The Agency finds that the applicant has not proven by a preponderance of the evidence that its proposal will have a favorable relationship to the existing health care system of the area.

F. REGARDING THE AVAILABILITY OF RESOURCES

51. The applicant states that the overall capital cost is \$2,535,000 (which includes \$840,000 as estimated market value of leased facility space). The applicant states that the capital cost will be funded by a lease/option to purchase agreement with Hitachi Medical Systems and cash contributions from Dr. Scott Boren and Dr. George Boren.

52. The applicant states that "We anticipate no problems in securing staff and already have found a MRI technologist with advance certificate in Magnetic Resonance Imaging..."

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

III

CONCLUSIONS OF LAW

Based on the findings of fact herein, relative to the Criteria for Review as provided in Section 11-186-15 HAR, the Agency finds as follows:

1. The applicant has not proven by a preponderance of the evidence that the proposal meets the criterion as established in Section 11-186-15(a)(10), HAR.
2. The applicant has not proven by a preponderance of the evidence that there is a public need for the proposal in accordance with Section 323D-43(b)(1) HRS.
3. The applicant has not proven by a preponderance of evidence that 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 in accordance with Section 323D-43(b)(2) HRS.
4. Accordingly, as required by Section 323-43(b), HRS, no certificate of need shall be issued to this proposal.

ORDER

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

The State Health Planning and Development Agency hereby DISAPPROVES and DENIES a certificate of need to Island Imaging L.L.C. for the project described in Certificate Application No. 04-03.

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 of the Agency's Certificate of Need Program rules. 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.

DATED: April 28, 2004
Honolulu, Hawaii

(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.)

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY




David T. Sakamoto, M.D.
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 April 28, 2004.

Scott Boren, M.D.
President/Manager
Island Imaging LLC
2374 Waipua Street
Paia, HI 96779

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY


David T. Sakamoto, M.D.
Administrator