



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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April 28, 2004

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 04-01
Maui Diagnostic Imaging L.L.C.)	
)	
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. 04-01 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. 04-01.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") 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.
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 26, 2004, the applicant filed with the Agency a Certificate of need 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. On January 27, 2004, the Agency determined that the application was incomplete and requested additional information. On January 27, 2004, January 29, 2004 and January 30, 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. #04-01. This application was consolidated for review with application #04-03 for standard review from Island Imaging LLC for the establishment of a Magnetic Resonance Imaging (MRI) service at 441 Ala Makani Street, Kahului, HI at a capital cost of \$2,535,000 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 4 to 0 in favor of approving this application with one abstention.

7. The application was reviewed by the Certificate of Need Review Panel ("Panel") at a public meeting on March 22, 2004. The Panel voted 6 to 0 in favor of approving 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 5 to 4 in favor of approving this application with two abstentions.

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 respond directly to the H2P2 goals and objectives including the reduction of health disparities among Hawaii's residents and equitable access at reasonable cost by providing imaging services not only in Kahului, but also in Kihei and Wailuku.

13. The applicant states that "Disparities exist when a significant population must travel to access services. Approval of this application will provide for continued services in these areas allowing the population in Kihei and Wailuku to receive imaging services locally, in their neighborhoods."

14. With respect to the H2P2 desired characteristic of supporting collaborative relationships between local, regional, and state health care providers in order to provide the most appropriate care coverage to our communities (Chapter II, Part E), the applicant states that its proposal "...will increase collaborative relationships significantly. This application is supported, in writing by Maui Memorial Medical Center."

15. In written testimony dated October 8, 2003, John Schaumburg, Regional Chief Executive Officer, Maui Memorial Medical Center, 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 stakeholders: the community, physicians and MMMC. Most recently, we have been working with our radiologists who are current members of Maui Radiology Consultants (MRC). As you are aware, MRC has been going through some difficult financial times and will be exiting out of Chapter 7 bankruptcy in the near future. 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."

16. In written testimony dated October 8, 2003, Wayne Fairchild, Assistant Administrator, Maui Memorial Medical Center, states: " Due to their over 40 years of collective experience in providing Maui residents with quality care, we believe that this group of radiologists (MDI) is not only essential to the community's well being, but that of the facility as well. This group has demonstrated their commitment and willingness to collaborate with the facility to continue to improve the operation of the diagnostic imaging department here at MMMC."

Statewide and Regional Values and Priorities (Chapter III)

17. With respect to the Statewide priority to "increase access to cost effective health care services, especially services that reduce the overall cost to the community through prevention...", the applicant states that "The facilities within this application will continue to provide screening for many forms of chronic disease through imaging, such as cancer and chronic lung disease."

18. With respect to the Tri-isle Subarea Values and Priorities, the applicant states that "This project will continue to provide access to radiology physician services."

Diseases and Conditions (Chapters IV-XI)

19. The applicant states that "The five primary cancer sites for Hawaii residents are prostate, lung, colon, breast and lymphoma. Lung, Colon and Breast cancer outcomes are significantly enhanced through early detection and imaging is the primary method of early detection. The facilities involved in this application, if approved will be able to continue to provide imaging for early detection of these cancers... Without approval of this proposal local access to early detection will be limited and longer queues for the remaining services will negatively impact this important community function."

20. The applicant states that "The diagnosis of Heart Disease and Stroke requires access to imaging modalities. If this application is not approved the remaining imaging services will be utilized at such a high frequency that delays in diagnosis are likely to occur."

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

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

22. The applicant states that "The target population for these imaging services is that population requiring imaging services in the tri-isle area. This would incline but not be limited to: sports injuries; disease screening such as breast and colon cancer screening; early detection of disease process such as chronic lung condition, pneumonias and abdominal problems; pregnancy tracking and fetal monitoring; cardiac valvular diagnosis; accident victims; neurological conditions such as stroke detection and diagnosis; and finally disease follow up such as post cancer treatment, fracture healing and many others."

23. The applicant states that "The need for outpatient imaging services has been consistently demonstrated through previous CON applications approved and granted to MRC (Maui Radiology Consultants) in the past. Given the continued population growth, outstripping all other counties in the State of Hawaii, the need for such outpatient imaging centers remains clear. "

24. The applicant states that "The population growth of Maui County is expected to outstrip all other Counties in the state. There was a 26% increase in population over the last ten years and a 5% growth in (sic) first two years since the last 2000 census." The applicant further states that "Utilization is anticipated to increase following the percentage of the general population growth."

25. The applicant states that its proposal "...will continue to be accessible to all persons, 'in particular low-income persons, racial and ethnic minorities, women, people with disabilities, other underserved groups, and the elderly.' "

26. In written testimony in support of this application dated February 5, 2004, Cora Tasaki, M.D. states: "I support:

- A continuation of services the business currently offers-the technology of MRI, CT and general X-ray but also their Women's Center providing exams in support of women's health care: mammography, ultrasound, and bone density.
- Easy access to care in a widespread community-MRC provides services not only in Kahului but also to outlying areas such as Kihei and Wailuku. MDI will continue to provide services to those areas. . .
- Continued care for not only for the community of Maui but also for the people of Lanai that MRC provides services for."

27. The Agency finds that the need and accessibility criteria have been met.

C. REGARDING QUALITY AND LICENSURE CRITERIA

28. The applicant states that "The six physician partners in this project are all licensed in the State of Hawaii, all the physicians are board certified and 4 have completed specific MRI and CT fellowships and have been previously practicing radiographic medicine at these facilities."

29. The applicant states that "The nine radiographic technologists (RT's) who have been performing the radiographic studies previously will continue to work with the new entity; all RT's are licensed by the State of Hawaii and have ARRT certification and maintain continuing education to stay current in their field of expertise...The current high level of quality will be maintained through the retention of these highly skilled individuals."

30. The applicant states that "The existing accreditation from the American College of Radiology (ACR) to operate mammography units will be maintained by MDI. The voluntary accreditation for Ultrasound provided by the ACR will also be maintained."

31. The applicant states that "There is no certification specifically for general outpatient imaging facilities at this time. If and when such a certification or accreditation becomes available, MDI is committed to obtaining the accreditation and/or certification in its continual efforts to achieve and maintain quality."

32. The applicant states "This project, if approved, will become licensed by the State Department of Health, radiation branch and will be regularly inspected by the State regulatory agency responsible for ensuring radiation safety meets or exceeds statutory requirements."

33. The applicant states that "The new administrator for this project, Scott Stienfeldt (sic), has over 10 years of imaging experience and has relocated from Montana and a similar outpatient imaging project to bring expertise and financial acumen to this project."

34. With respect to the applicant's proposed MRI service, in written testimony dated March 22, 2004, Guy Hirayama, MD, President of Maui Medical Group, Inc. states "Our neurologist and orthopedist, our primary utilizers of MRI, no longer utilize the MDI-owned MRI, due to the fact that utility of their services is too restrictive. They do not get their films or reports on a timely basis, which restricts their quality of care and therefore have chosen to opt, for lack of a better

choice, for the hospital's MRI..."

35. In his testimony, Dr. Hirayama states "The Maui Medical Group has had a PACS system within our facility for the past couple of years, which enables the digitalization of films for storage and rapid transmission to providers for viewing in any location. This is a dramatic improvement in the delivery of care for us. We have pleaded with both the hospital and MDI in the past to likewise install such a system, which would enable our providers to easily view films and consult with our radiologists, affording a higher standard of care."

36. The Agency finds that, with the exception of the delivery of their MRI films and reports, which are not delivered on a timely basis to Maui Medical Group (as stated in Dr. Hirayama's testimony), the quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

37. The applicant projects that, in Exhibit D-2 of its application, the earnings from operations will be \$598,825 in year one and \$838,570 in year three of its proposal.

38. The applicant states that "If this application is not approved there will be a gap in health care services as four separate locations currently providing imaging services will close. This will have the effect of increasing the cost of health care through delays in early detection and diagnosis. Some residents may need to travel to Oahu to receive timely care currently provided by the facilities represented in this proposal. Early detection and care remain the cornerstones to provide a downward trend in costs even in the face of increasing utilization with the aging of the population."

39. The applicant states that "...if this application is approved there will be no additional impact on healthcare costs."

40. 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

41. The applicant states that "The services covered with this change of ownership application have been integrated into the health care system for some time. Therefore there is no expected impact on other institutions regarding their utilization."

42. The applicant states that "We believe there will be a negative effect on providers without the continued operations of these existing facilities through an overload and burden due to a sudden and sharp increase in utilization for which they are unprepared, understaffed and under-equipped."

43. The applicant states that "The approval of this application will fulfill the intent of certain conditions set in the conditional approval of CON application 01-26 for an MRI by Maui Radiology Consultants (MRC). Collaboration between MDI and MMMC is shown through the letters of support and agreement to admit member documentation in this application. This demonstrates integration into the existing healthcare system."

44. In written testimony dated October 8, 2003, John Schaumburg, Regional Chief Executive Officer, Maui Memorial Medical Center, 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 stakeholders: the community, physicians and MMMC. Most recently, we have been working with our radiologists who are current members of Maui Radiology Consultants (MRC). As you are aware, MRC has been going through some difficult financial times and will be exiting out of Chapter 7 bankruptcy in the near future. 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."

45. In written testimony dated October 8, 2003, Wayne Fairchild, Assistant Administrator, Maui Memorial Medical Center, states: " Due to their over 40 years of collective experience in providing Maui residents with quality care, we believe that this group of radiologists (MDI) is not only essential to the community's well being, but that of the facility as well. This group has demonstrated their commitment and willingness to collaborate with the facility to continue to improve the operation of the diagnostic imaging department here at MMMC."

46. The impact of establishing a second MRI unit (in addition to the existing 1.5T at MMMC) on Maui was considered in two previous 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 for the establishment of a 1.5T MRI unit (the unit that is the subject of this application #04-01).

47. In its Decision on the Merits dated December 17, 2001, conditionally approving MRC's proposal for the 1.5T MRI unit at MRC as the second MRI 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."

48. 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, stating that: "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."

49. 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."

50. In its written testimony presented to the CON Review Panel on March 22, 2004, Island Imaging LLC, whose application #04-03 was consolidated for review with this application, 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. "

51. 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. "

52. 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."

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

54. The Agency further finds that the applicant's proposal to operate a 1.5T MRI unit, as the second MRI unit on Maui, relates well to the existing healthcare system of the area.

55. The Agency finds that, for Maui, a 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.

56. The Agency finds that a 1.5T MRI unit provides the service area with the most effective back-up to the community's sole MRI unit at MMMC.

57. The Agency finds that applicant has met these criteria.

F. REGARDING THE AVAILABILITY OF RESOURCES

58. The applicant states that the overall capital cost is \$3,118,637 (which includes \$523,637 as estimated market value of leased facility space). The applicant states that the capital cost will be funded by a lease/purchase agreement and financing through Philips Medical Capital and cash contributions from National Medical Development and Maui Radiology Associates.

59. The applicant states that "Existing employees will be retained to provide a seamless transition and have all agreed to remain as employees of MDI should this application be approved."

60. 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. 04-01 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, 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 criterion in Section 11-186-15(a) (7), HAR "The quality of the health care service proposed."
2. The applicant's proposal, if it were modified as specified in the Order below, would meet the criterion.

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 Maui Diagnostic Imaging, L.L.C. for the proposal described in Certificate Application No. 04-01. The conditions are that:

1. On or before December 31, 2004, the applicant shall submit to the Agency, for Agency approval:
 - A. A plan for the establishment of a PACS system, which enables the digitalization of films for storage and rapid transmission to providers for reviewing in any location in order to improve the applicant's delivery of care, including without limitation:
 - a timetable for implementation of the said PACS system on or before October 31, 2005

- provisions for consulting with Maui Medical Group (MMG) and other providers on Maui who either currently operate or are planning to operate a PACS system ("other providers") to ensure that the proposed system will be compatible with the PACS system at MMG and with PACS system(s) of other providers

B. A plan for ongoing examination and monitoring of future open MRI technology with the objective of the plan being the replacement of the existing MDI MRI unit with a open MRI unit when (in the opinion of the MMMC medical executive committee or its appointee) open MRI technology has advanced to the stage where the image quality of an open architecture MRI scanner can be considered equal to a 1.5T scanner for state of the art imaging for all areas of the body. When such a unit is available, it will provide Maui County with state of the art MRI imaging for the second (and only back-up) to the existing unit at MMMC and will also enhance MRI accessibility on Maui for patients who are disabled, obese or claustrophobic. The applicant shall not be required to implement this plan (#1B) in the event that the Agency hereinafter approves or conditionally approves a certificate of need application for an open MRI unit on Maui.

2. Maui Diagnostic Imaging, L.L.C shall facilitate a collaborative planning process with MMMC and Kaiser Permanente for the purpose of exploring ways in which to significantly increase the utilization of the MRI units at MDI and MMMC by Kaiser Permanente patients on Maui. The purpose of this planning process shall be to promote the accessibility for Kaiser Permanente patients to quality MRI services on Maui at reasonable cost and to minimize the need for these patients to travel to Kaiser on Oahu. On or before August 1, 2004, MDI shall submit to the Agency, for approval, an outline for this planning process which shall include provisions for submitting an action plan in this regard to the Agency on or before December 31, 2004.

These modifications are 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, June 1, 2004 as the date by which the applicant must certify, in writing, that it accepts these conditions 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 \$3,118,637.

WRITTEN NOTICE

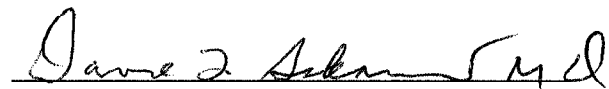
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

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 Halliday
President, National Medical Development
53 Puunene Ave., Suite 115
Kahului, HI 96732

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY


David T. Sakamoto, M.D.
Administrator