

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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April 29, 2004

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 04-04
Maui Memorial Medical Center)	
)	
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. 04-04 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. 04-04.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the addition of a second Magnetic Resonance Imaging (MRI) unit at Maui Memorial Medical Center, at a capital cost of \$2,172,648.
2. The applicant, Maui Memorial Medical Center, is a health facility of the Hawaii health systems corporation, a public body corporate established pursuant to the laws of the State of Hawaii.

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 February 4, 2004, the applicant filed with the Agency a Certificate of need application #04-04 for standard review for the addition of a second Magnetic Resonance Imaging (MRI) unit at Maui Memorial Medical Center (MMMC), at a capital cost of \$2,172,648. On February 5, 2004, the Agency determined that the application was incomplete and requested additional information. On February 5, 2004, the applicant submitted additional information and the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #04-04.

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 4 to 2 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 9 to 1 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. With respect to the H2P2 goal to "Increase the span of healthy life for Hawaii's residents", the applicant states that its proposal "...will help increase life span by early and accurate diagnosis of disease (and even by 'ruling out' different categories of disease)."

13. With respect to the H2P2 critical element of continuity of care, the applicant states that "The proposal assures continuity of care by establishing the unit at Maui's only Medical Center, where it becomes another element in the broad range of services provided there."

Statewide and Regional Values and Priorities (Chapter III)

14. With respect to the Tri-isle Subarea Priority 2, the applicant states that "MRI is used in emergency care, with about 11% of the scans (281 patients in 2003) being emergency patients."

15. With respect to the Tri-isle Subarea Priority 5, the applicant states that "MMMC is the community's hospital. It serves all patients regardless of their ability to pay."

Diseases and Conditions (Chapters IV-XI)

16. The applicant states that "MRI is useful in diagnosing cancer, and its usefulness is increasing as new uses are found for the technology."

17. The applicant states that "...MRI is useful in diagnosing diseases of the central nervous system, and useful in the assessment of stroke."

18. The applicant states that "MRI is appropriately used in the diagnosis of different head and neck cancers."

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

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

20. In written testimony dated March 22, 2004, John Schaumburg, CEO, Maui Memorial Medical Center, states "In our application we have assumed that the existing status quo will continue, i.e. that the second closed bore unit at MRC/MDI will continue. In our application we demonstrate that Maui has reached the point where: it needs a third MRI unit; it needs an open unit; the unit must be located at the hospital if it is to be accessible to all the patients who need it."

21. The applicant states that "MMMC has defined the Maui need for MRI services as the need of the target group, i.e., those residents who are likely to stay on the island for service. We have projected this need to be 6,000 procedures in 2004."

22. The applicant states that "We assume that the two existing scanners on Maui will continue to operate, one at MMMC and one at MDI. Therefore, the potential supply of services would be the potential capacity of the existing two units. The MMMC unit is now operating at a rate of about 3,250 procedures annually... We conclude that the existing supply of MRI service on Maui, (MMMC's 3250 + MRC/MDI's 2250), is 5500 procedures."

23. The applicant states that "Given these assumptions, the deficit between need and supply would be roughly 500 procedures in 2004."

24. In written testimony dated March 16, 2004, Brian Cody, Ancillary Services Director of Kaiser Permanente, states "It is our position that adding a third MRI on Maui is not needed at this time and we do not support approval of a CON allowing its installation...The threshold for service expansion is 2,750 and the MMMH volume exceeds that threshold by 500 scans. We suggest that this incremental increase could be readily accommodated by adjusting hours of operation on the existing unit."

25. In his testimony, Mr. Cody further states "In the current setting, the two MRI's (sic) on the island have the capacity to take on additional volume, making the third machine unnecessary."

26. In certificate of need application #04-01, Maui Diagnostic Imaging, LLC (MDI) states "The ability of the current imaging facilities to handle the current and estimated near term growth is good. The existing imaging facilities represented by this proposal and which will remain in operation if this application is approved, operate at a combined 65 percent of 'normal' capacity. Normal is defined as 8 hour per day operations. Given the ease and frequency that many imaging facilities on Oahu operate on ten hour days the ability to absorb growth is

evident. The CT and MRI specifically operate with an 8 hour day and show a 60% and a 70% capacity respectively. This demonstrates both consistent utilization and adequate supply of imaging services, further, scheduling wait time averages 1 day over all locations and one day for the CT and MRI as well. As all locations could expand to 10 hour days the ability to absorb future growth is assured."

27. The applicant, MMMC, states that "The MMMC unit... has operated as high as 4,653 scans in 2002 (scheduled 6 days a week)."

28. The Agency finds that there is proven excess capacity at the MMMC MRI unit in at least the amount of 1,403 scans (4653 scans in 2002 minus 3250 scans in 2003) and a projected excess capacity of 30% at the MRC/MDI MRI unit.

29. In a memorandum dated March 24, 2004, Winifred Odo, Chair, Certificate of Need Review Panel forwarded the Panel's recommendation for disapproval of this application. The recommendation states in pertinent part:

"There is a need for two MRI's on Maui but not necessarily a need for a third at this time."

30. The Agency finds that the need does not exist for a third MRI on Maui at this time.

31. The Agency finds that the applicant has not met the need and accessibility criteria.

C. REGARDING QUALITY AND LICENSURE CRITERIA

32. The applicant states that "MMMC has a long history of providing quality care to inpatient, emergency room, and outpatient population of Maui... MMMC is accredited by JCAHO."

33. The applicant states that "All of the MMMC MRI technologists are and will be AART (American Registry of Radiologic Technologists) registered, with special certification in MRI."

34. The applicant states that "MMMC is already licensed by the State of Hawaii, accredited by JCAHO and certified by Medicare... MMMC will seek accreditation for its MRI service from ACR (the American College of Radiology)."

35. The Agency finds that quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

36. The applicant projects that, in Exhibit D-2 of its application, the excess revenue over expenses will be \$173,598 in year one and \$479,784 in year three of its proposal.

37. The applicant states that "The capital cost of the project will be \$2.17 million. The project will be financed 100% through a loan from Academic Capital."

38. The applicant states that "Exhibit D-2, our projections of revenues and expenses; show that the revenue from the new unit will exceed the expenses. Thus, the resources exist to successfully implement the project."

39. 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

40. As the Agency has found that the need does not exist for a third MRI unit on Maui at this time (See Finding 30), it is unnecessary to consider the impact that the applicant's proposal (as the third MRI unit on Maui) would have on the existing healthcare system of the area.

41. 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 the establishment of a 1.5T MRI unit.

42. 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 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."

43. 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."

44. 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."

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 1.5 T 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 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 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 community's sole MRI unit at MMMC.

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

F. REGARDING THE AVAILABILITY OF RESOURCES

50. The applicant states that its proposal will require the following additional FTE staff in year one of operation: 1 MRI Technologist, 1 MRI Tech Assistant

and 1 Clerk III.

51. The applicant states that "Nationwide there is high demand for MRI techs, but we have been successful so far in finding such staff and believe that we can continue that success."

52. The applicant states that "The capital cost of the project will be \$2.17 million. The project will be financed 100% through a loan from Academic Capital... Exhibit D-2, our projections of revenues and expenses; show that the revenue from the new unit will exceed the expenses. Thus, the resources exist to successfully implement the project."

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 criteria as established in Section 11-186-15(a)(1) and (10), HAR.

2. The applicant has not proven by a preponderance of the evidence that there is a 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 for 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 Maui Memorial Medical Center for the project described in Certificate Application No. 04-04.

WRITTEN NOTICE

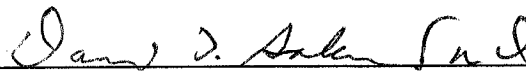
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

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 29, 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 29, 2004.

John Schaumburg
Chief Executive Officer
Maui Memorial Medical Center
221 Mahalani Street
Wailuku, Maui, HI 96793

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



David T. Sakamoto, M.D.
Administrator