



# STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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October 9, 2006

## CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF	)	CERTIFICATE OF NEED
	)	APPLICATION
	)	NO. 06-16
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. 06-16 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, 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. 06-16.

I

## BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") from Maui Memorial Medical Center (MMMC) for the establishment of Interventional Cardiac Catheterization and Heart Surgery services at a capital cost of \$1,500,000.
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 May 9, 2006, the applicant filed with the Agency a Certificate of Need application for the establishment of Interventional Cardiac Catheterization and Heart Surgery services at a capital cost of \$1,500,000 (the "Proposal"). On May 24, 2006, the applicant submitted additional information. On June 8, 2006, the Agency determined that the application was incomplete and requested additional information. On June 19, 2006, June 23, 2006 and June 26, 2006, the applicant submitted additional information. On June 26, 2006, the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #06-16.

5. The period for Agency review of the application commenced on June 30, 2006, the date on which the review schedule for the application appeared in the newspaper of general circulation pursuant to Section 11-186-39 HAR.

6. The application was reviewed by the Tri-Isle Subarea Health Planning Council at a public meeting held July 7th, 8th, and 11th, 2006. The Council voted 7 to 0 in favor of recommending approval of the application.

7. The application was reviewed by the Certificate of Need Review Panel at a public meeting held July 20th and 24th, 2006. The Panel voted 7 to 0 in favor of recommending approval of the application.

8. The application was reviewed by the Statewide Health Coordinating Council at a public meeting held July 27th and August 3rd, 2006. The Council voted 10 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 H2P2 goal of increasing the span of healthy life for Hawaii's residents the applicant states "In 2001, coronary heart disease, or CHD, was the leading cause of death in both the United States and Hawaii. Many recent studies have shown that early aggressive coronary intervention offers the best clinical outcomes for patients with CHD, reducing mortality and risk of recurrence of symptoms. It is now widely statistically evident that the proposed services significantly increase the span of healthy life."

13. With respect to the H2P2 objective of early detection and diagnosing of treatable diseases, the applicant states "The **early detection and diagnosis of treatable diseases** will improve, as the overall program encompassing PCI and cardiac surgical services will increase access to all services, including diagnostic cardiac catheterization, non-invasive cardiac diagnostic CT scanning, as well as cardiac screening and disease management programs."

14. The applicant states that "H2P2 identifies 5 key critical elements that keep health care delivery responsive to community needs and industry standards:

##### 1. Access

The proposal will facilitate more effective and efficient treatment, thereby improving access to care for those in need.

##### 2. Quality management

MMMC is committed to maintaining its high standards of quality and professional ethics. To accomplish this, the facility intends to participate with national registries and organizations such as the American Heart Association, the American College of Cardiology, American College of Surgeons and the American Board of Thoracic Surgery. MMMC will employ guideline-based standardized care shown to significantly reduce morbidity and mortality in patients with a compendium of presentations, from chest pain to acute myocardial infarction.

3. Cost-Effectiveness

H2P2 states that resources should be directed to programs and services that prevent illness and intervene in the early stages of disease... The proposed system outlines, on an elective basis, the capacity to diagnose and simultaneously treat the medical issue, eliminating the current duplicity of service and cost...

4. Continuity of Care

The establishment of interventional cardiac catheterization and cardiac surgical services are necessary to enhance continuity of care on Maui. Local provision of these services will eliminate geographical barriers to care and significantly reduce time to treatment.

5. Constituent Participation

MMMC has developed a multi-faceted cardiovascular steering committee for the purpose of consulting and communicating with all aspects of the medical community.

15. The applicant states that the H2P2 threshold for Adult Cardiac Catheterization Labs is not directly applicable to this case. "MMMC is already operating an Adult Cardiac Catheterization Lab and providing cardiac catheterization service, so this proposal is not technically a 'new service/unit'. However, our service is now limited to diagnostic procedures, and in this application we are proposing to add interventional procedures."

16. The applicant states that "H2P2 provides the following threshold for Open-Heart Surgery Rooms: 'For a new service/unit, the minimum average utilization for all other providers in the service area is 350 adult operations per year, and the new service/unit is projected to achieve a utilization of at least 200 adult open-heart operations in the third year of operation.' As there are no other open-heart surgery programs on Maui, the minimum average utilization threshold does not apply to this proposal. Based on population projections, MMMC anticipates that in Year Three, we will perform approximately 194 cardiac surgeries in Maui County."

17. With respect to the Statewide and Regional Priorities of H2P2, the applicant states:

- "The provision of PCI and cardiac surgery services on Maui will significantly improve the continuum of care for cardiovascular treatment. A considerable volume of cardiac patients, both resident and visitor, will be able to receive care locally. The need for medical

transport of the patient is diminished, resulting in greatly improved treatment times."

- "The comparatively minimal expense to provide PCI and cardiac surgery is far overshadowed by the increased cost effectiveness of being able to obtain these services without inter-island transport. In addition to the obvious cost savings, there is a tremendous cost advantage when it has been shown that delay in treatment has been proven to result in longer patient stays and morbidity, as well as increased mortality."
- "Staff will be appropriately trained, licensed and certified to perform interventional and surgical services. Physicians have been and will continue to be required to obtain privileges and perform greater than 50 interventional procedures per year. Advanced Cardiac Life Support, Basic Life Support, Balloon Pump, and Cardiovascular Interventional certification will be required of nurses and technologists participating in the program. Competency and performance reviews will be conducted on a regular basis to maintain quality of care."
- "Services provided will be justified and appropriate to the clinical situation. Elective procedures discovered under diagnostic circumstances will be evaluated for risk prior to intervention to minimize complications."

18. The Agency finds that this criterion has been met. The applicant has proven by a preponderance of the evidence that the Proposal is consistent with the provisions of the state health services and facilities plan (H2P2).

#### B. REGARDING NEED AND ACCESSIBILITY CRITERIA

19. The applicant states that "MMMC is the sole acute care provider of health care services for the resident and visitor community of Maui County. With only diagnostic cardiac catheterization capabilities, MMMC is not able to provide interventional or surgical cardiac care to those suffering from AMI."

20. The applicant states that "Although MMMC provides diagnostic cardiac catheterization services, a significant number of acute myocardial infarction (AMI), or heart attack, patients on Maui will also require further interventional treatment, such as balloon angioplasty and stent placement. The lack of interventional cardiac catheterization services at MMMC results in the need for patients to be flown to Oahu for treatment. Patients may wait anywhere from 1 to 24 hours (average of 4.5 hours) for availability of medical transport via fixed wing plane, resulting in delayed treatment and an increased risk for diminished clinical outcomes. Current research in progress suggests that each minute below the 90 minute goal for door to balloon

time translates into statistically significant 1 year survival rates of acute MI... Currently at MMMC, a patient experiencing a heart attack can at best only be given a 'clot buster' medication. This...may dissolve the blood clot in the artery that is causing the heart attack... However, there is the potential for the medication to also dissolve blood clots elsewhere in the body. This side effect puts the patient at risk, particularly if it causes bleeding in the brain or in the stomach. Nationally, greater than 40% of patients treated in this manner will have no resolution to their symptoms and require rescue PCI... The vast majority of the patients who do improve or resolve with fibrinolytic therapy will still require an urgent angioplasty and probable intervention."

21. The proposed cardiac surgery program at MMMC would serve to provide surgical backup for PCI procedures, as well as some EP studies. A full spectrum of cardiac surgery services will also be offered, such as Coronary Artery Bypass Graft (CABG) and valve replacement, as well as other intrathoracic open vascular procedures."

22. The applicant states that "The American College of Surgeons Committee on Trauma, in a recent statewide analysis of health care delivery, also recognized the capacity for MMMC to develop a cardiovascular program to properly serve the local population and decompress the air medical transport system."

23. The applicant states that the H2P2 threshold for Adult Cardiac Catheterization Labs is not directly applicable to this case. "MMMC is already operating an Adult Cardiac Catheterization Lab and providing cardiac catheterization service, so this proposal is not technically a 'new service/unit'. However, our service is now limited to diagnostic procedures, and in this application we are proposing to add interventional procedures."

24. The applicant states that "H2P2 provides the following threshold for Open-Heart Surgery Rooms: 'For a new service/unit, the minimum average utilization for all other providers in the service area is 350 adult operations per year, and the new service/unit is projected to achieve a utilization of at least 200 adult open-heart operations in the third year of operation.' As there are no other open-heart surgery programs on Maui, the minimum average utilization threshold does not apply to this proposal. Based on population projections, MMMC anticipates that in Year Three, we will perform approximately 194 cardiac surgeries in Maui County."

25. The applicant states that "Both interventional cardiac and surgical services will be available to all patients on Maui, regardless of income, race or ethnicity, gender, age, or disability."

26. The Agency finds that the applicant has proven by a preponderance of the evidence that the Proposal meets the need and accessibility criteria.

### C. REGARDING QUALITY AND LICENSURE CRITERIA

27. The applicant states that "The proposed cardiac interventional catheterization and cardiac surgery service will improve patient care on Maui in the following manner:

- Establishment of National Standard of Practice on Maui
- Quicker response time to ACS
- Advanced interventional studies
- Increased patient safety and convenience
- Reduced cost due to elimination of transport issues
- Improved outcomes"

28. In regard to the medical literature and guidelines pertaining to PCI, the applicant states:

"The ACC, in conjunction with the AHA and the Society of Cardiovascular Angiography and Intervention (SCAI) have posted a position statement on PCI without surgical backup for several years. To summarize their position, they approach PCI in two perspectives. The first is 'Primary PCI' that refers to PCI being done in an emergent or urgent clinical situation, such as a heart attack, to intervene with the process and save the patient. The second is 'Elective PCI', which is the much more common performance of angioplasty and stenting in patients who are stable and during the diagnostic cardiac catheterization are confirmed as benefiting from intervention. This confirmatory diagnostic catheterization and the interventional procedure are usually done in the same catheterization lab visit. Two statements exist in the most recent guideline update. The first we would like to address is that 'Primary PCI might be considered in facilities without onsite cardiac surgery provided that...there is a proven plan for rapid (access) transportation to a cardiac surgery operating room...with appropriate hemodynamic support capability for transfer.' MMMC has proven staff and equipment (i.e. "balloon pumps") available for hemodynamic support of these patients. MMMC maintains a contract with Fresenius Medical Care to ensure these transports requiring such advanced skill and equipment will be available immediately. The transportation criteria mentioned has been addressed previously in this application, but includes the contractual arrangement for air transport resources on island with a guarantee of 45 minute transit time, and 90 minute request-to-Operating Room door time as a support service for this program. Alternatively, MMMC is simultaneously developing its Open Heart Surgery Program, and at the point cardiac surgery becomes available around-the-clock, the transport need will be negated. New research cited in the Journal of the American Medical Association (JAMA) conclusively

cites the survival advantage, inclusive of long-term survival, of early revascularization in AML, as opposed to the initial "medical management" (JAMA, June 7, 2006—Vol 295, No 21, pp 2511-2515). Current treatment options at MMMC prior to this initiative can only offer initial 'medical management' and as a result of the transport situation, 'delayed revascularization'. The second statement in the guideline refers to Elective PCI: 'Elective PCI should not be performed at institutions that do not provide onsite cardiac surgery. (Level of Evidence: C)\*  
\*Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program. A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgery . . . This recommendation may be subject to revision as clinical data and experience increase.' Further review of the guidelines reveals the 'concern of the writing committee (of the ACC guidelines) that mere convenience should not replace safety and efficacy in the establishment of an elective PCI program without onsite surgery.' And that 'as with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase.' There are over 300 centers in the United States performing elective PCI without on site surgical backup. The situation faced by residents of Maui is not one of 'convenience', as the authors of the guideline may be noting in the majority of situations on the mainland where cardiac surgery backup is typically offered at a facility down or across town. In the Maui situation, many hours and far greater expense is incurred for the elective patient above that of a few minutes drive or a half-gallon of gasoline. The unique geography between Maui and Oahu is unparalleled anywhere else in the United States, and therefore stands outside of any comparison model. The establishment of PCI, of both an elective and emergent nature, will be provided to the residents of Maui as soon as possible pending the approval of this application. This service, although initially without cardiac surgery backup, will have a contracted transport backup to meet previously stated goals. As cardiac surgery is developed and implemented, the need for this transport safety net will decrease."

29. The applicant states that "MMMC's internal policies and procedures ...are consistent with or exceed standards established by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the ACC, and the National Guidelines Clearing House (U.S. Department of Health & Human Services)."

30. The applicant states that "All cardiologists are licensed in the State of Hawaii and certified by the American College of Cardiology (ACC). Interventional cardiologists will similarly be required to be certified in this sub-specialty by the ACC. All cardiac surgeons will be licensed in the State of Hawaii and will be certified by the American Board of Thoracic Surgery."

31. The applicant states that "Angiographic Technologists will be certified radiological technologists licensed in the State of Hawaii. The technologists will have licensure in cardiac and vascular interventional procedures by the American

Registry of Radiologic Technologists (ARRT) and will have advanced training and/or experience in these procedures."

32. The applicant states that "Registered Nurses are licensed in the State of Hawaii and certified in Advanced Cardiac Life Support, Conscious Sedation, Intra-Aortic Balloon Pump Operation. . ."

33. The applicant states that "All staff members are required to be trained on all new equipment and required to pass competency evaluations on procedures and equipment annually."

34. In public testimony dated July 6, 2006, Howard G. Barbarosh, M.D., states "I encourage you to give Maui Memorial Medical Center a CON for a full open heart program. It should be instituted as soon as possible. By not having a full facility here we are practicing cardiology as if it were the 1980s... Give us a full heart program here on Maui, but make it conditional upon the infrastructure being upgraded."

35. In public testimony dated July 11, 2006, Jeffrey M. Droad, M.D., states "In the interest of patient safety, I believe this application should not be approved until Maui Memorial has made the necessary improvements in quality of care to ensure successful outcomes."

36. The Agency finds that the proposal, if modified in accordance with the conditions on pages 12 and 13 of this Decision on the Merits, meets the quality and licensure criteria.

#### D. REGARDING THE COST AND FINANCIAL CRITERIA

37. The applicant states that "The comparatively minimal expense to provide PCI and cardiac surgery is far overshadowed by the increased cost effectiveness of being able to obtain these services without inter-island transport. In addition to the obvious cost savings, there is a tremendous cost advantage when it has been shown that delay in treatment has been proven to result in longer patient stays and morbidity, as well as increased mortality."

38. The applicant states that "There are no capital costs associated with the PCI segment of the proposal. Other expenses, however, would include such items as supplies and employee wages and benefits. After accounting for operating expenses, total annual excess of revenue over expenses is estimated to be \$2,123,732 in the first year of operation; by the second and third year, it is estimated to reach \$2,300,661 and \$2,453,872, respectively."

39. The applicant states that "To implement cardiac surgery, an initial investment of \$1.5 million in minor equipment will be required. After accounting for operating expenses, total annual excess of revenue over expenses is estimated to be \$828,364 in the first year of operation; by the second and third year, it is estimated to reach \$2,295,319 and \$3,421,993, respectively."

40. The applicant states that "Currently, there are no similar services in the community... Although facility expenses will increase due to the nature of the proposed services (i.e. interventional catheterizations require higher-cost supplies such as stents) and addition of staff, the improvement in clinical outcomes (i.e., decrease in length of stay) will likely have a positive impact on the facility's financial base."

41. The Agency finds that the applicant has proven by a preponderance of the evidence that the Proposal meets the cost and financial criteria.

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

42. The applicant states that "The addition of interventional cardiac catheterization and cardiac surgery services will fill a significant void in the delivery of health care on Maui. Currently, patients needing treatment must wait to be transported to an Oahu facility, incurring considerable delays that can hinder patients from receiving optimal treatment. The provision of more timely treatment has the potential to greatly improve the overall health of the community."

43. The applicant states that "MMMC is the only facility providing cardiac services on Maui. Thus, the proposal should have no negative impact on health care services in the community. However, the burden on emergency medical services would be lessened due to the minimization of patient transport issues."

44. The applicant states that "Prior to the implementation of cardiac surgery services at MMMC, we will rely on multiple medical centers on Oahu to meet this need. Processes are currently in place to ensure the timely transfer of emergent patients needing cardiac surgery to those facilities."

45. The applicant states that "As discussed previously, the alternative to the proposal is to continue transporting patients to Oahu for interventional procedures. This, however, is not beneficial to the Maui community, as patients will continue to be denied timely access to essential health care services."

46. The applicant states that "The comparatively minimal expense to provide PCI and cardiac surgery is far overshadowed by the increased cost effectiveness of being able to obtain these services without inter-island transport. In addition to the obvious cost savings, there is a tremendous cost advantage when it has been shown that delay in treatment has been proven to result in longer patient stays and morbidity, as well as increased mortality."

47. The Agency finds that the applicant has proven by a preponderance of the evidence that the Proposal meets the relationship to the existing healthcare system criteria.

#### F. REGARDING THE AVAILABILITY OF RESOURCES

48. The applicant states that "There is no capital cost associated with the implementation of PCI in this proposal. However, capital will be required to implement cardiac surgery. The financial resources for operating the proposed service are available."

49. In Attachment "C" to the application, Dennis F. Stephens, President, *Academic Capital Group, Inc.* states in a letter dated May 3, 2006, "We have reviewed your plans to expand the cardiovascular program at Maui Memorial and are prepared under our Master Municipal Leasing Program with HHSC to provide up to \$12 million dollars in equipment and real property financing for this project."

50. The applicant states that "MMMC currently retains 4.0 FTE Registered Nurses and 3.0 FTE Angiography Technologists to perform diagnostic cardiac catheterization procedures. The establishment of interventional cardiac catheterization services will require the addition of the following staff in Year One of operation: 1.0 FTE Registered Nurse: 1.3 FTE Angiography Technologists In Year Two and Three, an additional 1.0 FTE Registered Nurse and 1.3 Angiography Technologists will be need per year."

51. The applicant states that "The establishment of cardiac surgery will require 13.9 additional FTEs in Year One. Years Two and Three will require an additional 3.8 and 4.8 FTEs, respectively. Some existing staff has prior training and experience in these procedures, and will be provided additional training prior to implementation of the proposed services."

52. The applicant states that "MMMC will actively recruit other qualified personnel to meet additional staffing needs. We also intend to collaborate with other institutions to assist us in developing our staffing resources."

53. The Agency finds that the applicant has proven by a preponderance of the evidence that the Proposal meets the availability of resources criteria.

### III

#### CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 06-16 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, 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 criterion in Section 11-186-15(a) (7), 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 Maui Memorial Medical Center for the proposal described in Certificate Application No. 06-16. The conditions are that:

The applicant shall develop and submit a written plan to the Agency on or before March 2, 2007, which shall include:

- A plan for creating a collaborative organization with the cardiovascular physicians on Maui to ensure appropriate credentialing, staff training, clinical protocols and quality outcomes for the proposed services, including without limitation, a proven plan for rapid transportation to a cardiac surgery operating room.

- A plan for upgrading infrastructure/technology and reconfiguring MMMC's facilities to ensure quality outcomes and an efficient care delivery process for the proposed services.

The plan shall be developed collaboratively with Maui cardiovascular physicians.

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 January 10, 2007 as the date by which the applicant must certify, in writing, that it accepts these conditions 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 \$1,500,000.

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: October 9, 2006  
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY

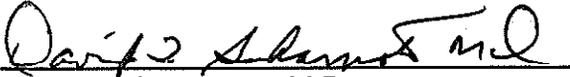
  
David T. Sakamoto, M.D.  
Administrator

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 October 9, 2006.

Wesley Lo  
Chief Operating Officer  
Maui Memorial Medical Center  
221 Mahalani Street  
Wailuku, Maui 96793

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY

  
David T. Sakamoto, M.D.  
Administrator