# HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

## STANDARD APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number 06-16

Applicant: Maui Memorial Medical Center
221 Mahalani St., Wailuku, HI
Phone: 808-242-2036

Project Title: Establishment of Interventional Cardiac Catheterization and Cardiac Surgery services at Maui Memorial Medical Center

1. **TYPE OR ORGANIZATION:** (Please check all applicable)

| | |
|---|---|
| Public | X |
| Private | |
| Non-profit | |
| For-profit | |
| Individual | |
| Corporation | X |
| Partnership | |
| Limited Liability Corporation (LLC) | |
| Limited Liability Partnership (LLP) | |
| Other: _____ | |



2. **PROJECT LOCATION INFORMATION:**

A. Primary Service Area(s) of Project: (Please check all applicable)

| | |
|---|---|
| Statewide: | |
| O`ahu-wide: | |
| Honolulu: | |
| Windward O`ahu: | |
| West O`ahu: | |
| Maui County: | X |
| Kaua`i County: | |
| Hawai`i County: | |

REPLACEMENT PAGE

3. **DOCUMENTATION** (Please attach the following to your application form):

A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)
*Not applicable.*

B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)
- Certificate of Need from SHPDA (pending)
- Narcotics License from Drug Enforcement Administration (expires 01/31/07)
- Radiation Facility License from Department of Health (#H0029; expires 03/31/07)
- JCAHO Accreditation (valid 2005 - 2008)

C. Your governing body: list by names, titles and address/phone numbers
*Please see Attachment A.*

D. If you have filed a Certification of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:
- Articles of Incorporation
  *Not applicable. HHSC formed by statute (HRS Chapter 323F).*
- By-Laws
  *Please see Attachment B.*
- Partnership Agreements
  *Not applicable.*
- Tax Key Number (project's location)
  *(2)3-8-046:013*

4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "x" in the appropriate box.

| | Used Medical Equipment (over $400,000) | New/Upgraded Medical Equip. (over $1 million) | Other Capital Project (over $4 million) | Change in ownership | Change in service/ establish new service/facility | Change in Beds |
|---|---|---|---|---|---|---|
| Inpatient Facility | | | | | X | |
| Outpatient Facility | | | | | | |
| Private Practice | | | | | | |



5. **TOTAL CAPITAL COST:** 1. PCI: None

2. Cardiac Surgery: $1,500,000.00

6. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

| Type of Bed | Current Bed Total | Proposed Beds for your Project | Total Combined Beds if your Project is Approved |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| **TOTAL** | | | |

7. **CHANGE IN SERVICE.** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please consult Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

1. Establishment of interventional cardiac catheterization services.

2. Establishment of heart surgery services.

8. **PROJECT COSTS AND SOURCES OF FUNDS (For Capital Items Only)**

A. **List All Project Costs:** **AMOUNT:**

| | | |
|---|---|---|
| 1. | Land Acquisition | -- |
| 2. | Construction Contract | -- |
| 3. | Fixed Equipment | -- |
| 4. | Movable Equipment | $1,500,000.00 |
| 5. | Financing Costs | -- |
| 6. | Fair Market Value of assets acquired by lease, rent, donation, etc. | -- |
| 7. | Other: _____ | _____ |



**TOTAL PROJECT COST:** **$1,500,000.00**

B. **Source and Method of Estimation**

Describe how the cost estimates in Item "A" were made, including information and methods used:

**Estimate from consultant (reflects capital cost for Cardiac Surgery only).**

C. **Source of Funds** **AMOUNT:**

| | | |
|---|---|---|
| 1. | Cash | _____ |
| 2. | State Appropriations | _____ |
| 3. | Other Grants | _____ |
| 4. | Fund Drive | _____ |
| 5. | Debt | _____ |
| 6. | Other: Municipal Lease Financing | $1,500,000.00 |

**TOTAL SOURCE OF FUNDS:** **$1,500,000.00**

9. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

*Implementation Schedule - please see page 6.*

a) Date of site control for the proposed project,
b) Dates by which other government approvals/permits will be applied for and received,
c) Dates by which financing is assured for the project,
d) Date construction will commence,
e) Length of construction period,
f) Date of completion of the project, and
g) Date of commencement of operation.



*Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the Certificate of Need.*

10. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

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*Executive Summary - please see pages 7 –12.*

*Map - please see page 13.*

*A definition of terms (Definition of Medical Terminology and Procedures) has also been provided – please see pages 14 – 15.*

*Additional information on the procedures/services proposed in this application, as well as information on existing facilities at Maui Memorial Medical Center, are also provided – please see pages 16 – 30.*

a) Relationship to the Hawai`i Health Performance Plan (H2P2), also known as the State of Hawai`i Health Services and Facilities Plan
b) Need and Accessibility
c) Quality of Service/Care
d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
e) Relationship to the Existing Health Care System
f) Availability of Resources

## 9. IMPLEMENTATION SCHEDULE

**a) Date of site control for the proposed project.**
Not applicable.

**b) Dates by which other government approvals/permits will be applied for and received.**
Not applicable.

**c) Dates by which financing is assured for the project.**
May 3, 2006 (please see letter from Academic Capital Group, Inc. – Attachment C)

**d) Date construction will commence.**
Not applicable.

**e) Length of construction period.**
Not applicable.

**f) Date of completion of the project.**
Not applicable.

**g) Date of commencement of operation.**
1. PCI - January 2007
2. Cardiac Surgery - January 2008

## 10. EXECUTIVE SUMMARY



**Background**

Maui Memorial Medical Center (MMMC) is the only full service acute care hospital in the County of Maui. Over the last several years with the advent of technology, MMMC has been advancing its clinical service lines to provide the community with improved access to services as well as to relieve the pressure on Oahu acute care hospitals providing specialty care. This has been part of a recent strategy by the Hawaii Health Systems Corporation (HHSC) to convert MMMC into a neighbor island referral center for the eastern half of the State, and to realize many of the principles of H2P2 by creating critical mass for a second regional tertiary care center.

As a result of this strategy, MMMC has dramatically improved its clinical service lines, which now include the only around-the-clock interventional neurology service in the State. MMMC is the only hospital in the State with a 24-hour a day, 7 day a week, fully developed "brain attack" program with interventional neuroradiology and neurosurgery coverage. Through the use of neurovascular stents and coils, patients suffering from stroke or aneurysm are able to receive immediate, state-of-the-art care. MMMC has also acted as a primary trial site for a neurocoil in the process of research and development.

MMMC currently performs advanced cardiac electrophysiology (EP) and ablations. We are the only facility in the State to boast 2 dedicated cardiac electrophysiologists. In addition, we have a world-renowned cardiac electrophysiologist and ablative specialist on staff performing multiple procedures on a quarterly basis within our facility.

In 2002, MMMC opened its Heart, Brain and Vascular Center. The opening of this center has allowed MMMC to enhance its services dramatically. This includes the ability to perform peripheral vascular procedures, pacemakers, biventricular pacemakers, ablations and diagnostic cardiac catheterizations. These are cutting edge services for rural communities. Many of these services are not provided on any other neighbor island in the State of Hawaii.

While MMMC has made tremendous advances in these areas, cardiac care on Maui has not enjoyed similar progress despite the fact that it is the largest and most acute segment of the medical market. In the last decade, health care has seen a general decrease in hospitalization stays. In spite of this trend, 12 specialties showed a slight increase in average length of stay. Of these, cardiology experienced the greatest increase, with hospitalization stays three times that of the next specialty.

In the past, coronary care has been predominantly delivered by cardiologists and cardiac surgeons to hospitalized patients that had suffered a heart attack. Today, coronary care is as likely to be delivered across a much broader continuum of

patients, including the asymptomatic, at-risk outpatient. The scientific and technological forces of change are accelerating in the field, and the management of coronary disease will continue to experience dramatic and unprecedented diversification. The population of patients with cardiac conditions is growing, as is public awareness of new drugs and devices that are saving lives.



**Request**

Based on these recent advancements and future projections, MMMC interprets this as a mandate to expand its cardiac services to include:

1) Percutaneous Coronary Intervention
2) Cardiac Surgery

In order to meet the changing needs of the community, it is imperative that these services are added to the array of services at MMMC.

**Percutaneous Coronary Intervention (PCI)**

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.[1,2] It is therefore reasonable to assume that immediate care and intervention at MMMC would be more appropriate and have a more significant impact on morbidity and mortality than supporting a system totally reliant on rapid transport.

Currently at MMMC, a patient experiencing a heart attack can at best only be given a "clot buster" medication. This "clot buster", or *fibrinolytic*, may dissolve the blood clot in the artery that is causing the heart attack. Dissolving the clot will restore blood flow, stop the heart attack and save heart muscle. 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,[3] and 0.4% will die as a direct effect of this treatment itself. The vast majority of the patients who do improve or resolve with fibrinolytic therapy will still require an urgent angiography and probable intervention.

The American College of Cardiology (ACC) and American Heart Association (AHA) have published professional practice guidelines for interventional cardiac catheterization (these guidelines are too voluminous to include with this proposal,

but will be provided upon request). The ACC previously recommended that interventional cardiac catheterization be performed only in institutions with heart surgery capability. However, there is enough compelling evidence to show that lives would be saved, the debilitating effects of chronic diseases reduced, and safe outcomes ensured by immediate coronary intervention in institutions without heart surgery capability. Currently, in the United States, there are over 300 facilities performing PCI procedures without surgical backup. Clinical trials have shown that institutions performing PCI without on-site cardiac surgery have safe outcomes.[4,5] In the acute setting of myocardial infarction/ischemia, the ACC/AHA recommended definitive treatment within 60-90 minutes to reduce debilitating outcomes of chronic heart disease. On May 17, 2005, the State Health Planning & Development Agency (SHPDA) approved a Certificate of Need for establishment of an interventional cardiac catheterization service at Castle Medical Center (CMC). CMC does not have on-site cardiac surgery availability.





It has been demonstrated in this country that efficient systems for transfer to tertiary PCI centers are at best able to obtain door-to-balloon times (elapsed time from the arrival of the patient in the emergency room to the opening of the blocked artery with balloon angioplasty) of 195 minutes.[1] Based on this analysis, a current belief system exists[3] that a policy of transfer for direct PCI is not feasible in the United States. MMMC has been confronted with even greater transport delays and geographical barriers than typically found across the country.

The proposed PCI program would, for a short time, exist without on-site cardiac surgery backup. However, recent technological improvements have greatly improved the safety of PCI procedures and have drastically reduced complication rates. Procedures likely to result in complications can now be accurately predicted. Also, current technology now provides endovascularly deployed rescue devices to be utilized in the event of complications (puncture or dissection) unavailable as little as one year ago. These devices drastically reduce, if not eliminate, the need for emergent cardiac surgery. MMMC has initiated the process to make these devices available to our facility. An example of a rescue device MMMC is researching with the manufacturer is enclosed as Attachment D. Additionally, MMMC has negotiated a letter of intent with AirMed Hawaii to ensure that emergent evacuation of patients could be completed within 90 minutes of the request for service (please see Attachment E).

**Cardiac Surgery**

The development of the final phase of the program that encompasses cardiac surgery will eliminate the need for rapid transport. 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. As the

program matures, cardiac surgery will enhance other areas of care at MMMC such as trauma and endovascular care.

MMMC also plans to implement an "umbrella" of cardiovascular-related services. This includes developing a full spectrum of EP studies and expanding the ability to rapidly identify and appropriately treat the chest pain patient. The implementation of PCI and cardiac surgery will be facilitated by a strong foundation of support services, including the development of preventative and wellness clinics within the community, a full cardiac rehabilitation program, comprehensive community screening programs, disease management programs, and a streamlined in-hospital guideline based standard of care for the cardiovascular patient.

Another segment of the plan for cardiovascular services will be applied for separately, but bears mention in this application, as it will improve the non-invasive diagnosis of CHD. MMMC plans to procure and implement a 64-slice computed tomography (CT) scanner for the evaluation of coronary disease as a component of a broad program to improve diagnosis and patient access.

The safe and effective delivery of PCI and cardiac surgery at MMMC has significant clinical advantages, as well as economic benefits. There are enormous gains to be realized with respect to improved health outcomes for CHD, resulting in improved cardiac function and quality of life for patients and less burden on the health care delivery system. John Goodman and Associates, a nationally recognized cardiovascular consulting firm, has performed an analysis of our facility and the local health care market and has recommended that we implement a full-service cardiovascular program (please see Attachment F). 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.[6]

**a. Relationship to the Hawaii Health Performance Plan (H2P2), also known as the State of Hawaii Health Services and Facilities Plan.**

The proposal is consistent with the H2P2-stated goals and objectives for realizing the Hawaii health care vision. As proposed in the application, the timely provision of interventional cardiac catheterization and cardiac surgery has the demonstrated ability to reduce morbidity and mortality for patients with CHD, allowing this growing patient population to live a longer, better quality of life. Local provision of this service also translates to more equitable and effective access to treatment for the Maui community, helping to reduce health disparities among Hawaii residents. While the proposed service itself proves valuable to improving clinical outcomes, cost-effectiveness can also be realized. Reduced hospitalization periods and improved overall health leads to cost savings for both patient and provider.

The implementation of a large number of cardiovascular-related support services will have a tremendous positive impact on the health and wellness of all Maui residents. Through this network of services, Maui cardiac patients will enjoy a continuity of care that translates to an improved quality of life.

H2P2 requires that a new cardiac catheterization service/lab achieve a minimum of 750 adult cardiac catheterization procedures by the third year of operation. National guidelines project about 11 cardiac catheterization procedures per 1,000 population (Cath Lab Digest, Volume 13, Issue 7, July 2005). Using a slightly more conservative rate of 10 per 1,000 population, MMMC projects to perform approximately 1,050 diagnostic-equivalent procedures by the third year of operations. Considering the resident population of Maui County is approximately 138,000 (2005 Maui County Data Book), the projected volume could be slightly higher. H2P2 also states that a new open-heart surgery service achieve a utilization of 200 surgeries by the third year of operation. MMMC conservatively projects performing approximately 194 cardiac surgeries by the third year of operations (please see below, *b. Need and Accessibility*, for methodology). MMMC plans to exceed the threshold with the addition of those visitors to the island and residents of Hawaii County needing cardiac surgery.

**b. Need and Accessibility** REPLACEMENT PAGE

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. Many patients requiring interventional treatment must rely on services currently offered only on Oahu, resulting in delayed treatment and an increased risk for adverse clinical outcomes.

MMMC data reveals that in 2004 more than 200 patients required emergent air transport to Oahu for interventional treatment. This number is expected to rise considerably in the future, as the occurrence of heart disease and stroke will continue at or above the present level.[7] MMMC conservatively expects to perform 200 emergent interventional procedures in Year One of operations. Projections from John Goodman & Associates (Attachment F) indicate that by 2010, MMMC will perform 576 PCIs. Using a conservative market share estimate of 60% (approximately 40% of the population are Kaiser members who primarily receive care on Oahu), we estimate performing about 350 PCIs in 2010. This would indicate an annual increase of 50 PCIs. MMMC anticipates performing 300 emergent interventional procedures by Year Three (2009). We also conservatively estimate that diagnostic procedures will increase by this same number. According to Hawaii Health Information Corporation, approximately 89-108 cardiac surgeries per year (average of 98 per year) were performed on Maui County residents at Oahu facilities between 2003-2005. Thus, we anticipate performing 98 cardiac surgeries in the first year of implementation. Utilization rates from John Goodman & Associates also project, at full market share, approximately 242 cardiac surgeries (194 CABG surgeries as referred to in Attachment F, and 48 other cardiac surgeries (e.g., valve replacement), for a total of 242 total cardiac surgeries). Of this number, MMMC would

initially retain 60% market share due to Kaiser membership (146 cardiac surgeries). An additional 10% market share would be regained from Kaiser members needing emergent cardiac surgery (24 cardiac surgeries), and another 10% would be regained from referrals from other facilities (24 cardiac surgeries). Based on these projections, MMMC estimates performing 194 cardiac surgeries by Year Three (2010).



While there is an obvious need for this service, access remains an obstacle. The proposed services will significantly improve accessibility by providing prompt, effective treatment and minimizing geographic barriers to care.



**c. Quality of Service/Care**



Quality of care will be vastly improved under this proposal. The increased access to services will result in more rapid response time to acute coronary syndrome (ACS) and increased patient safety. Hospitalization stays will be shortened and outcomes will be enhanced through diminished morbidity and mortality. Formalized protocols for transfer to a cardiac surgical facility will be established in the event that emergency surgery is called for in the time period prior to obtaining on-site cardiac surgery.

Policies and procedures, as well as clinical protocols, will be established for this service. Angiography staffing resources are currently in place (3:1 staff-to-patient ratio), and all registered nurses and technologists will meet clinical certification and continuing education requirements. All cardiologists will be licensed and certified by the American Board of Cardiology. Cardiac surgeons will be licensed and certified by the American Board of Thoracic Surgery.

**d. Cost and Finances**



MMMC does not expect to incur any capital costs related to this proposal for the implementation of the PCI portion. The existing unit can perform interventional as well as diagnostic procedures.

The implementation of a cardiac surgery program will require approximately $1,500,000 in surgical equipment and associated support services.

**e. Relationship to the Existing Health Care System**

The proposal has the ability to strengthen the existing health care system by filling a critical gap in care delivery. Dependence on medical transport and Oahu facilities is reduced, and efficient access to safe, effective interventional services will be made available to the Maui community. The proposal will positively affect the long-term health of the community.

**f. Availability of Resources**

As discussed previously, MMMC retains the resources needed to implement the proposal. All health and management personnel and operating needs have been or will be satisfied prior to implementation.