

HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number 06-04 A
Applicant: Maui Memorial Medical Center
221 Mahalani St., Wailuku, HI
Phone: 808-242-2036

Project Title: Establishment of an Extracorporeal Shockwave Lithotripsy
(ESWL) service

Project Address: same

1. TYPE OF ORGANIZATION: (Please check all applicable)

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

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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:
- Kaua`i County: _____
- Hawai`i County: _____

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

- A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent) **The site of the project is within an existing building on the MMMC campus**
- 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.) **N.A.**
- C. Your governing body: list by names, titles and address/phone numbers **ATT. A**
- D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:
 - Articles of Incorporation **N/A, HHSC formed by Statute HRS Chapter 323F**
 - By-Laws **See Attachment B**
 - Partnership Agreements **N/A**
 - Tax Key Number (project's location)(2) **3-8-046:013**

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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 Service	Change in Beds
Inpatient Facility				XX	
Outpatient Facility					
Private Practice					

5. **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.

N.A. (no bed changes)

	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved

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6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:		AMOUNT:
1.	Land Acquisition	_____
2.	Construction Contract	_____
3.	Fixed Equipment	<u>\$868,105</u>
4.	Movable Equipment	_____
5.	Financing Costs	_____
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	_____
7.	Other: <u>(Room prep, testing, etc)</u>	<u>\$21,895</u>
	—	
TOTAL PROJECT COST:		<u>\$890,000</u>

B. Source of Funds		
1.	Cash	_____
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt	<u>\$890,000</u>
6.	Other: _____	_____
TOTAL SOURCE OF FUNDS:		<u>\$890,000</u>

7. **CHANGE OF 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 reference the 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.

Maui Memorial Medical Center (MMMC) proposes to establish an Extracorporeal Shock Wave Lithotripsy (ESWL) service at MMMC

8. **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:

Please see page 7

- 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,
- 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.

9. **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.

Please see page 7

- 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.

10. **Eligibility to file for Administrative Review.** This project is eligible to file for Administrative review because: (Check all applicable)

It involves bed changes, which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.

It involves service changes which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.

It is an acquisition of a health care facility or service, which will result in lower annual operating expenses for that facility, or service.

It is a change of ownership, where the change is from one entity to another substantially related entity.

It is an additional location of an existing service or facility.

The applicant believes it will not have a significant impact on the health care system.

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8. Implementation Schedule

- a) Date of site control for the proposed project. **Not applicable. MMMC already controls the site.**
- b) Dates by which other government approvals/permits will be applied for and received. **No other government approvals are necessary.**
- c) Dates by which financing is assured for the project. **Financing for the project was approved by the Board of Directors of the Hawaii Health Systems Corporation in March 2005.**
- d) Date construction (renovations) would commence: **No major construction is necessary. Minor renovations of the room and installation of the new urology table (which includes ESWL) began on January 10, 2006.**
- e) Length of construction period: **Approximately 2 weeks.**
- f) Date of completion of the installation: **February 13, 2006.**
- g) Date of commencement of operation: **Immediately upon receipt of the CON.**

Note: The ESWL equipment is part of a new urology table, which is now being installed to replace an old urology table in the "Cysto Room," a room dedicated to urologic procedures. We estimate that, once operational, approximately 75% of the procedures will be kidney stone related, with about 50% of those being treatable by ESWL. The other 50% will require some method of treatment including transurethral lithotripsy. The remaining 25% of the procedures include such things as cystoscopies, biopsies, and transurethral prostate resection. MMMC will provide other services on the new table as soon as it is operational, but will not provide ESWL until the CON is received.

9. Executive Summary

Ultrasonic lithotripsy is a procedure by which stones in the kidney or upper ureter are broken up by sound waves, and the subsequent particles are then passed through the urinary tract in the urine.

MMMC has been providing ultrasonic lithotripsy since about 1984, and has more recently been providing laser lithotripsy as well. Both of the current procedures are invasive, i.e. they involve inserting a probe through the urethra, through the bladder and then into the ureter. When the stone is contacted, ultrasound or laser energy is delivered through the probe and the stone fragmented. In 2005, MMMC did 574 urologic procedures of which 461 or 80% involved kidney stones.

Extracorporeal shockwave lithotripsy (ESWL) is a new technology, which is replacing about half of the lithotripsy procedures done with the older, invasive technology. ESWL is delivered from outside the body, and thus is not invasive. Under this new technology, the stone is first imaged through x-rays, and then ultrasound waves are focused and directed to the stone from outside the body. There are many advantages to the patient, including a more effective treatment, reduced discomfort, less time in the facility and faster recuperation.

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As noted, ESWL is now "state-of-the-art" for treating kidney stones, and is already available for patients on O`ahu and the Island of Hawai`i. Maui patients currently must travel to O`ahu to have ESWL procedures performed. Maui residents deserve to have this noninvasive and less costly procedure performed on their island home.

A. Relationship to the H2P2 Criteria

The proposal in this application relates well to the provisions of the H2P2. MMMC is the only full service acute care facility on the island, and must be able to meet the community's need for a wide range of outpatient and inpatient services, including the best technology for treating kidney stones.

The critical elements of a health care delivery system, as defined in the H2P2, are access, quality management, cost-effectiveness, continuity of care and constituent participation. All these elements are addressed by MMMC in general and this proposal in particular.

- Timely access to ESWL service requires that the service be available on-island. Without this, patients eligible for ESWL either have to travel to O`ahu for service or undergo an invasive and uncomfortable procedure.
- Quality is assured through the hospital's standard quality control programs.
- Cost-effectiveness is assured through the provision of state-of-the-art treatment to patients. The cost of an ESWL procedure is roughly equivalent to the current invasive procedures, especially considering the reduction in supplies and labor costs necessary for the invasive procedures and the frequent repairs needed for equipment.
- Continuity of care is assured through the provision of ESWL service at Maui's only acute care medical center, with its comprehensive range of medical professionals and services.
- Constituent participation is assured through the input of various consumer and provider groups in the functions of the medical center.

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The proposal also relates well to the values and priorities of the Maui County "Tri-Isle" Subarea Health Planning Council ("SAC") as identified on pages III-9 to III-12 of the H2P2. For example, the first value listed by the SAC is "Accessible/Easy Access . . . Ability to be seen in acute and chronic situations; on-island. . ." (emphasis added)

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H2P2 threshold. The H2P2 contains the following capacity threshold for lithotripsy units:

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For a new unit/service, the minimum average annual utilization for all other providers in the service area is 1,000 procedures, and the new unit/service is projected to meet the minimum utilization rate by the third year of operation.

Our service area is the County of Maui, with the Island of Maui being the primary service area. Since there are no other lithotripsy units on the island or in the county, the first part of this threshold standard is not applicable.

We are conservatively projecting that in the third year of operation we will be performing 305 lithotripsy procedures. We acknowledge that this falls short of the 1,000 procedure threshold.

However, the H2P2 also contains the following provision for proposals that fall below the thresholds:

In each case where sub-optimum utilization is proposed, the benefits – in the form of improved access for the service area(s) population combined with significant improvement in quality and/or significant reduction in price to the public – clearly outweigh the costs to the community of duplicating or under-using services, facilities, or technology.

The H2P2 then goes on to cite the approval of a CT scanner for Molokai General Hospital as a situation where "concerns about access and quality of care (CT is a standard of care for hospitals) outweighed the sub-optimum utilization data."

We believe that this situation is similar. For approximately 50% of kidney stone patients, the standard of care is lithotripsy. With no such service on-island, access is difficult. Patients have to either travel to O`ahu or undergo a less optimal procedure. This lack of immediate access is especially burdensome on those patients who are in acute pain and need urgent attention.

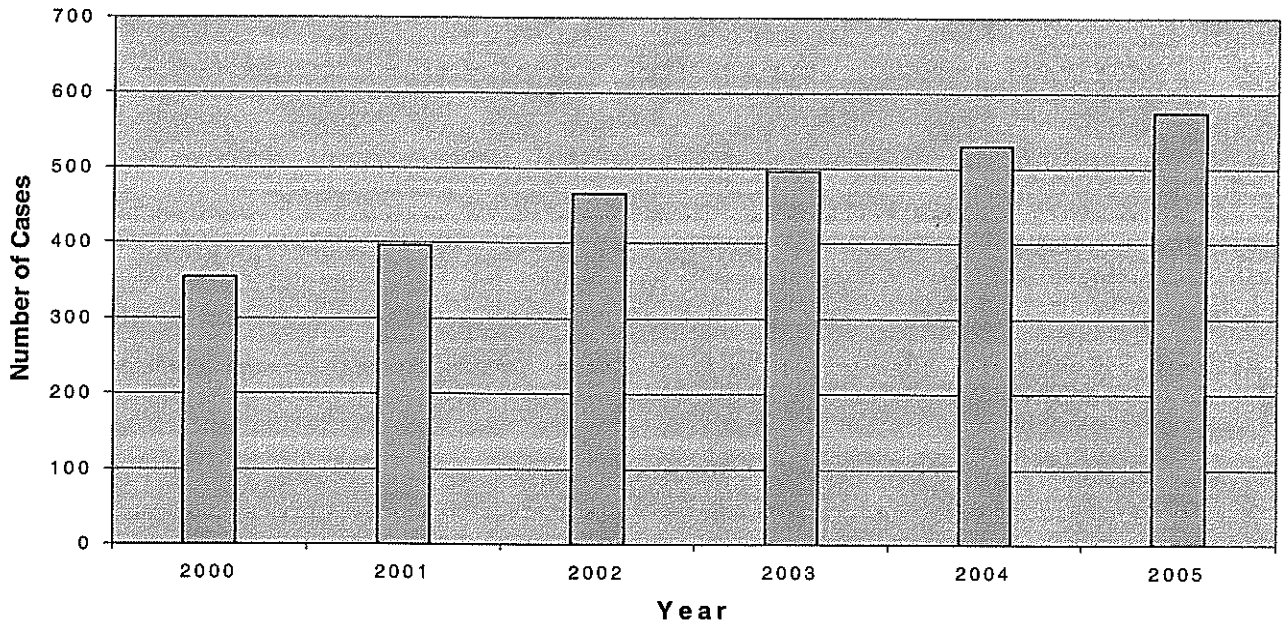
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B. Need and Accessibility Criteria

The proposal relates well to these criteria. Kidney stones affect approximately 12% of the population in the United States. Men are afflicted more often than women at a ratio of about 3:1.

MMMC has seen a significant increase in urology cases (about 75% of the cases are kidney stones) from 2000 to 2005. The caseload performed on the urology table has increased from 354 procedures in 2000 to 574 procedures in 2005. The following graph illustrates the utilization of the urology table.

Urology Procedures



MMMC estimates that we saw about 461 kidney stone procedures in 2005. Of these, approximately 50% or 230 procedures are suitable for ESWL treatment. In addition, our physicians estimate that approximately 50 patients annually are referred to O`ahu for ESWL treatment.

Need/utilization estimate. In summary, we estimate that 75% of urology procedures are and will be kidney stone patients. Of these, approximately 50% are suitable for ESWL treatment. Using the trend data from 2000 to 2005, we estimate that the need will increase 10% annually. We further assume that the patients now traveling to O`ahu for ESWL will remain on

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Maui for the treatment. Finally, we assume that the utilization of the MMMC service will equal 100% of the Maui non-Kaiser ESWL patients.

The table below shows the predicted need and utilization for ESWL service at the MMMC urology service. Again, we assume that the utilization will equal 100% of the need. RECEIVED

MMMC UROLOGY AND ESWL NEED/UTILIZATION

	2006	2007	2008
Urology procedures	681	745	814
Kidney stone procedures*	511	559	610
ESWL procedures**	255	279	305

*Assumes 75% of urology procedures are kidney stone procedures

**Assumes 50% of kidney stone procedures are appropriate for ESWL

The services at MMMC are accessible to all patients. MMMC has provisions to assure that services are provided to all residents of the area, including low income persons, racial and ethnic minorities, women, handicapped persons, other underserved groups and the elderly.

C. Quality of Service/Care Criteria.

The proposal relates well to these criteria. As noted above, ESWL is the "state-of-the-art" technology for approximately 50% of kidney stone patients. If this high-quality service is not available on Maui, patients are either denied access altogether or forced to travel to O`ahu for treatment.

If we measure quality as a successful outcome of a procedure, i.e. the removal of the kidney stone, then the ESWL and the invasive procedures are roughly equivalent – the stone is removed. There is a major exception. In some cases, the physician may initiate the invasive procedure on a patient, going as far as the stone, only to discover for one reason or another that the invasive procedure will not work. The procedure then has to be interrupted and the patient sent to Honolulu for ESWL. In such a case, the patient has to undergo two procedures, with the accompanying expense, discomfort and risk.

If we measure quality as a process, particularly from the patient's point of view, the ESWL process is higher quality than the invasive process. For example, and speaking very generally:

- The average invasive process takes about one hour, vs. about a half hour for the average ESWL.
- The average invasive procedure subjects the patient to more fluoroscopy than the ESWL procedure.

- The patient undergoing an invasive procedure usually requires general or spinal anesthesia, while most ESWL patients will only need IV sedation.
- The recovery at the facility is shorter for the ESWL patient.

MMMC is accredited by the Joint Commission of Accreditation of Healthcare Organizations, licensed by the Department of Health and certified by Medicare. MMMC has ongoing quality improvement programs, and a history of providing quality service.

D. Cost and Finances Criteria.

The proposal meets these criteria. The unit to be acquired is a new urology table for the Cysto Room, and one component of that table is the ESWL component. It is prudent to replace the old table at this time. Although it is still within its useful life expectancy, it is subject to frequent breakdowns, especially with the attached fluoroscopy unit. Certain parts are no longer manufactured, so it is getting harder and harder to make repairs. Also it is incapable of providing ESWL, the current state-of-the-art service for about 50% of kidney stones.

The capital cost for the entire project, including room preparation, is \$890,000, and the funds have already been made available from the Hawaii Health Systems Corporation through a municipal lease from Academic Capital.

There will be an increase in the operating costs of the Cysto Room, much of it due to the depreciation and interest costs of the new table. However, the status quo is not an alternative since some of the existing table's equipment had deteriorated to the point where it needed replacement anyway. It would be imprudent to replace an old technology when a new technology, which supplies a higher quality service and is less invasive, is available.

There will be no specific "charge" at MMMC for an ESWL procedure. Rather, as with other operating rooms, patients are charged according to the amount of time they use in the Cysto Room

We estimate that the cost to the patient for an ESWL procedure will be approximately 60% less than the cost of an invasive procedure, for the following reasons:

- Patients are charged by time in the room, and we estimate that an ESWL procedure will average one-half hour vs. one hour for an invasive procedure.

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- When fully operational, most ESWL patients will only require IV sedation. In contrast, patients undergoing an invasive procedure usually require general or spinal anesthesia, with the subsequent material costs and the professional costs of an anesthesiologist.
- ESWL uses less supplies and materials than an invasive procedure.
- An invasive procedure always requires the presence of a technician to operate the fluoroscopy unit. This technician is not always required for an ESWL.
- Invasive procedures require the services of a scrub tech. The ESWL does not.
- With the ESWL, recovery time and discharge are quicker.

From the revenue and expense projections in Attachment C we estimate that the average reimbursement ("cost") for an ESWL procedure will be \$1,681, vs. an average "charge" of \$3,735.

Attachment C to this application is a 3-year revenue and expense projection for the service. The projections show that the revenues from the service will be enough to cover the direct expenses.

E. Relationship to the Existing Health Care System Criteria.

The proposal relates well to these criteria. MMMC is the only full service acute care hospital on the island of Maui and should be able to provide the best possible service for kidney stone patients. The only other ESWL units in the State are on the islands of O`ahu and Hawai`i, so no other Maui provider will be affected.

F. Availability of Resources.

The proposal meets these criteria. The capital funds are already available in the form of a municipal lease from Academic Capital. The operating revenues will be sufficient to meet expenses.

No additional staff will be required. Staffing may actually be reduced, as an Imaging Tech may not be necessary for the ESWL procedure. The professional and technical staff practicing in the Cysto Room is sufficient