



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: # 18-03A Date of Receipt:
To be assigned by Agency

APPLICANT PROFILE

Project Title: Establishment of Ambulatory Surgery Center Limited to Neurological and Pain Management Procedures

Project Address: 137 and 141 Ma'a Street, Lots 2 and 3
Kahului, Hawaii 96793

Applicant Facility/Organization: Maui Spine & Laser Institute, LLC

Name of CEO or equivalent: Jon E. Graham, M.D.

Title: Member

Address: 1380 Lusitana Street, Suite 502, Honolulu, HI 96813

Phone Number: (808) 550-4969 Fax Number: (808) 550-2842

Contact Person for this Application: J. George Hetherington

Title: Attorney

Address: 700 Bishop Street, 15th Floor, Honolulu, HI 96813

Phone Number: 808-523-6000 Fax Number: 808-523-6001

CERTIFICATION BY APPLICANT

I hereby attest that I reviewed the application and have knowledge of the content and the information contained herein. I declare that the project described and each statement amount and supporting documentation included is true and correct to the best of my knowledge and belief.

Signature: Jon E. Graham

Date: 3/19/2018

Name (please type or print): Jon F. Graham, M.D.

Title (please type or print): Member

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

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

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

A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)

See Attachment 1.

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.)

Building Permit – Maui County  
License – State of Hawaii, Department of Health  
Medicare Certification – State of Hawaii, Department of Health

C. Your governing body: list by names, titles and address/phone numbers

See Attachment 2.

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: See Attachment 3 (Articles of Organization)
- By-Laws: Not Applicable.
- Partnership Agreements: Not Applicable.
- Tax Key Number (project's location): (2) 3-8-101-10

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					
Outpatient Facility				X	
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.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
<b>TOTAL</b>			

**6. PROJECT COSTS AND SOURCES OF FUNDS**

<b>A. List All Project Costs:</b>	<b>AMOUNT:</b>
1. Land Acquisition	<u>\$1,900,000</u>
2. Construction Contract	<u>\$3,375,000</u>
3. Fixed Equipment	<u>\$1,438,050</u>
4. Movable Equipment	<u>\$61,950</u>
5. Fair Market Value of assets acquired by lease, rent, donation, etc.	<u>N/A</u>
6. Other: Working capital and soft costs	<u>\$450,000</u>
<b>TOTAL PROJECT COST:</b>	<b><u>\$7,225,000</u></b>

<b>B. Source of Funds</b>	
1. Cash	<u>N/A</u>
2. State Appropriations	<u>N/A</u>
3. Other Grants	<u>N/A</u>
4. Fund Drive	<u>N/A</u>
5. Debt	<u>\$7,225,000</u>
6. Other: _____	<u>N/A</u>
<b>TOTAL SOURCE OF FUNDS:</b>	<b><u>\$7,225,000</u></b>

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.

Implementation of ambulatory surgery services limited to neurological and pain management procedures in Maui County. Reference HAR § 11-186-5-3(c).

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:

- a) Date of site control for the proposed project: February 3, 2018
- b) Dates by which other government approvals/permits will be applied for and received:
  - Floorplan submitted to State and approved: Between February 1-28, 2018
  - Building permit: Between May 1-29, 2018
  - State application for L&C: Between February 1-28, 2019
  - Certificate of occupancy: June 28, 2019
  - File CMS 855B Application: Between March 1-29, 2019
  - State licensing survey: June 28, 2019
  - CMS accreditation: Between July 1, 2019, and August 30, 2019
- c) Dates by which financing is assured for the project: Between February 1-28, 2018
- d) Date construction will commence: Between June 1-29, 2018
- e) Length of construction period: Between June 1, 2018 and June 27, 2019
- f) Date of completion of the project: Between July 1, 2019, and August 30, 2019
- g) Date of commencement of operation: Between July 1, 2019, and August 30, 2019

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.

- a) Relationship to 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.

Dr. Jon Graham is a board certified neurosurgeon who performs cranial and spine surgery at his offices in Honolulu, and Kealahou and Kamuela on the Island of Hawaii. Dr. Jerald Garcia is an Interventional Pain Specialist who is double board certified in both Pain Management and Anesthesiology. Together, Dr. Graham and Dr. Garcia (the "Physicians") own Maui Spine & Laser Institute, LLC, a Hawaii limited liability company. The Physicians specialize in performing procedures using minimally invasive surgical techniques, many of which can be performed on an outpatient basis.

Because of the longer blocks of time required for outpatient neurological procedures, Maui's existing ambulatory surgery centers cannot accommodate the Physicians' request for placement into their surgery schedules. Accordingly, the Physicians now seek to establish an ambulatory surgery center, on Ma'a Street in Maui, Hawaii, that focuses solely on neurological and pain management procedures (the "Proposed ASC").<sup>1</sup> A site map is included with this application as Attachment 4.

- a) Relationship to the State of Hawai'i Health Services and Facilities Plan ("HSFP").

As described below, the Proposed ASC will advance the following State Health Coordinating Council's general principles:

- (i) Strive for equitable access to health care services.
  - Reasonable facility fees will be assessed to cash paying patients without health insurance.
  - The Proposed ASC will focus on providing affordable neurological and pain management services.
- (ii) Ensure that any proposed service will at least maintain overall access to quality care at a reasonable cost.

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<sup>1</sup> The site of the proposed ASC is currently vacant land and has not yet been assigned a street address.

- The Physicians are committed to implementing facility fees that are comparable to the fees charged by similar facilities in the service area.

(iii) Expand and retain the health care workforce to enable access to the appropriate level of care in a timely manner.

- There will be regular training for staff of the Proposed ASC.
- The services of experienced neurosurgeons and pain management specialists will be offered to residents of Maui County without needing to travel off-island.
- Qualified support staff will be employed for the benefit of all patients.

(iv) Promote and support the long-term viability of the health care delivery system.

- Steps will be taken to ensure that health care costs associated with the Proposed ASC will remain reasonable.
- Travel expenses will be eliminated for Maui County residents who may otherwise need to seek specialized neurological and pain management treatment on Oahu or another island.
- Reasonable costs for services provided by the Proposed ASC will maintain overall access to quality care.

The Proposed ASC will also advance the following Maui County/Tri-Isle's Subarea Planning Council's priorities:

(i) Provide community-based emergency and health care services to underserved communities.

- A full range of specialized procedures will be available to Maui County residents for reasonable fees.

(ii) Modernize facilities via construction.

- The facilities for the Proposed ASC will be constructed and kept up with the latest building and technology standards in mind.

(iii) Create innovative solutions for making Hawaii health care systems responsive to community needs by recognizing efficient and inefficient facilities and services and exploring capital partnerships, joint ventures, consolidations, and other financial arrangements.

- The Proposed ASC responds to the community's need for specialized neurological and pain management procedures on Maui.
- The Proposed ASC will enable the Physicians to closely monitor the specialized health care demands of Maui County residents and other relevant factors unique to Maui County.
- The Physicians will be better situated to make adjustments to the Proposed ASC, its services, and its facilities to meet Maui County's needs.

(iv) Recruit and educate an optimal supply of health care workers to meet Maui County's demands.

- Qualified and capable health care workers will be hired to support the Physicians.
- An effective training program will be implemented for all staff and will entail continuing education.

(v) Investigate public and private partnerships to ensure optimal, cost effective, and quality care.

- The Physicians will continue to look for and seize opportunities to optimize the number of patients that the Physicians can serve in the community.

The HSFP provides capacity (utilization) thresholds for certain standard categories of health care services to guide the initial determination of need for a service area. A Certificate of Need applicant looking to establish a freestanding ASC is ordinarily expected to enter into a collaborative arrangement with an existing acute care hospital in the county, which entails (1) a transfer agreement, (2) a commitment to support all training and recruitment of health care personnel for the benefit of the area, and (3) a commitment to enhance the EMS and trauma care systems of the area by using the Proposed Center, when necessary, such as in cases of natural disaster or pandemic.

The Applicant has sent a letter of intent regarding a collaborative arrangement to Maui Memorial Medical Center ("MMMC") for its review. However, MMMC has not yet responded to the Applicant's request to finalize such a collaborative arrangement. The Applicant believes that MMMC may be willing to enter into such an agreement in the near future. If so, the Applicant will seek to amend its application accordingly. However, to neutralize the impact of the present delay on the proposed project, the Applicant proposes to instead meet the collaborative arrangement requirement through sub-optimum utilization as described below.

The HSFP expressly recognizes that some service areas may not meet the required threshold for a health care service and allows for sub-optimum utilization. As set forth in the HSFP, "sub-optimum utilization may be proposed if the benefits clearly outweigh the costs to the community of duplicating or under-using services, facilities, or technologies." The HSFP defines benefits as "the form of improved access for the service area(s) population combined with significant improvement in quality and/or significant reduction in cost to the public." In addition, the HSFP allows thresholds to be modified to:

- Incorporate current and best clinical practices;
- Allow for the cost-effective transition and capital investment in moving traditional inpatient services to outpatient modalities;
- Allow for the cost-effective introduction of modern technology to replace existing technology;
- Address the documented needs of an actual population rather than basing care design on statistical generalizations;
- Create opportunities for price reduction through competition, without sacrificing quality or cost-effectiveness of care; and
- Encourage innovation in improving health care services that contribute to enhancing a community's health status.



The following features and benefits of the Proposed ASC support sub-optimum utilization with respect to the collaborative arrangement requirement:

(1) *Transfer Agreement*: The same protections afforded by a transfer agreement with an acute care hospital can instead be offered through the admitting privileges of physicians performing procedures at the Proposed ASC. Pursuant to Medicare regulations (42 C.F.R. §416.41(b)), all physicians performing procedures in an ASC must have admitting privileges at a local hospital. Accordingly, the Applicant will maintain documentation of the current admitting privileges of all physicians, including Dr. Graham and Dr. Garcia, who perform procedures at the Proposed ASC. In addition, the Proposed ASC will implement clear policies to be followed in the case of an emergency, including instructions to immediately call 911 for emergency transport of the patient via ambulance. If a patient of the Proposed ASC requires hospitalization, the physician who performed the surgery on the patient requiring emergency transfer will arrange the hospital admission of the patient, unless there is a compelling clinical reason to transfer the patient to a different local hospital where the physician does not have admitting privileges.

(2) *Health Care Personnel Recruitment and Training*: The Applicant intends to hire staff employed by Dr. Graham's and/or Dr. Garcia's medical practices. To the extent that additional personnel will be required, the Applicant will be mindful of the needs of existing health care providers, including hospitals, and will work with them so as not to interfere with their staffing needs. In addition, for the benefit of the area, the Applicant pledges to facilitate training opportunities for health care personnel employed by the Proposed ASC, as appropriate.

(3) *Enhancement of EMS and Trauma Care Systems*: The Applicant consents to the use of the Proposed ASC when necessary, such as in cases of natural disaster or pandemic. The Applicant is agreeable to placing a condition on its CON that obligates the Proposed ASC to make itself available for the enhancement of EMS and trauma care systems of the area during times of need.

(4) *Benefits*: As explained herein, the Applicant's goal is to enhance patient safety and realize cost savings by performing procedures that would otherwise be performed in a hospital setting. Performing technologically-advanced, minimally invasive procedures incorporates best clinical practices, achieves cost-effectiveness by transitioning traditional inpatient services to outpatient modalities, and will provide overall improved health care services to the area in the area of pain management, where safe and effective interventional treatments are extremely vital. For these reasons, the benefits of the Proposed ASC clearly support approval of this application notwithstanding the lack of a collaborative arrangement.

b) Need and Accessibility

The Proposed ASC's service area includes all of Maui County. The site, located in Kahului, is easily accessible and will feature ample parking, including reserved stalls for handicapped patients. The same day surgeries and noninvasive procedures offered at the Proposed ASC will treat neuropathic pain and a range of neurological disorders. Currently, there is no other facility dedicated to spine and pain management on Maui.

It is difficult to identify the extent, significance, and prevalence of pain because of the way in which pain is typically treated (as a symptom) and the varied data collection methods utilized. To further complicate the analysis, current data on the incidence, prevalence, and consequences of pain are not consistent or complete. Cultural differences impacting pain expression and interpretation likely also play a factor in skewing statistics.

According to a 2006 National Center for Health Statistics Report on Pain, more than 26% of Americans age 20 years and over report problems with pain that has persisted for more than 24 hours in duration.<sup>2</sup> The US Census estimated that, as of July 1, 2015, the population on Maui was 161,637 persons, approximately two-thirds of whom are over age 20. Therefore, it would be reasonable to presume that as many as 28,000 Maui residents are affected by persistent pain from time to time. Any of these residents could benefit from the pain management treatments offered at the Proposed ASC.

The proportion of neuropathic pain<sup>3</sup> sufferers among those reporting chronic pain is a smaller subset. Notwithstanding, some estimate that over six million Americans are living with unrelenting nerve pain.<sup>4</sup> Based on that figure, over 3,000 people in Maui County alone likely suffer from chronic nerve pain.

It is universally recognized that pain contributes to, among other things, morbidity, mortality, and disability. It also places significant demands on the health care system, both physically and economically. The services offered at the Proposed ASC would address these issues through pain management procedures aimed at improving comfort and quality of life for Maui residents, which will in turn relieve some of the burdens currently shouldered by less appropriate providers in the health care system.

In addition to offering pain management procedures, the Proposed ASC will be the first ASC on Maui specifically targeting the treatment of spinal conditions. Therefore, valid comparisons with other similarly situated ASCs in the service area as to certain specialized procedures cannot be made. However, given the current lack of any Maui-based clinics equipped to treat conditions of the spine, it can be assumed that there is a need for the services slated to be offered by the Proposed ASC.

The Proposed ASC's focus on spinal conditions also affords several accessibility benefits. The staff of the Proposed ASC will receive specialized training and experience in performing the targeted procedures. In addition, the limited range of procedures offered by its staff of specialty surgeons will minimize costs by limiting capital investment and maintenance expense to only that necessary for the specific procedures performed, thereby reducing costs to the patient. The focus on spinal surgery will also enable the Proposed ASC to employ an intense care model that will provide spinal patients with a level of service not found elsewhere on Maui.

The Hawaii Department of Business, Economic Development and Tourism predicts that the population of Maui will increase by approximately 23% to 240,880 by the year 2025. The

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<sup>2</sup> This number does not account for acute pain.

<sup>3</sup> The National Academy of Sciences defines neuropathic pain, in part, as "a disease of the peripheral or central nervous system that arises when a person's nerves, spinal cord, or brain is damaged or fails to function properly for any of a large number of reasons."

<sup>4</sup> Oral testimony to the Committee on Advancing Pain Research, Care and Education from Tina Tockarshefsky of The Neuropathy Association, November 2010.

official publication of the American Society of Interventional Pain Physicians, *The Pain Physician*, has noted a 156% utilization increase of pain management services, from 2000 to 2013 of, per 100 fee-for-service Medicare beneficiaries (an annual average growth rate of 7.5%). Accordingly, the demand for neurological and pain management procedures can be expected to rise in correlation with such population growth and increasing utilization rates.

The Proposed ASC will perform the procedures set forth on Attachment 5.

The Proposed ASC will be accessible to all residents of Maui County, including low income persons, racial and ethnic minorities, people with disabilities, the elderly, and the medically underserved. The Proposed ASC will provide services to patients covered by Medicare and Medicaid, and will provide charity care to individuals with significant need and limited financial resources who do not have health insurance.

c) Quality of Service/Care

The Proposed ASC will comply with State and Federal regulations for delivery of care, maintenance of equipment, and maintenance of the clinical environment. It will seek accreditation from the Accreditation Association of Ambulatory Health Care, be licensed by the Department of Health, and be certified by Medicare. The facility will implement a Quality Assessment and Performance Improvement program that will comply with the requirements of the Medicare conditions of participation for ASCs, provide patient care through well-defined processes for caregivers, and conduct ongoing quality review.

The Physicians are both licensed by the Department of Health. In addition, Dr. Graham is board certified by the American Board of Neurological Surgery and Dr. Garcia is board certified in Pain Management and Anesthesiology by the American Board of Anesthesiology.

As described above, in the event of a medical emergency that requires a higher level of care than can be provided by the Proposed ASC, the Proposed ASC would immediately call 911 for emergency transport of the patient via ambulance. If a patient of the Proposed ASC requires hospitalization, the physician who performed the surgery on the patient requiring emergency transfer will arrange the hospital admission of the patient, unless there is a compelling clinical reason to transfer the patient to a different local hospital where the physician does not have admitting privileges. In addition, a registered nurse ("RN") will be available at all times the Proposed ASC is open to provide emergency treatment.

Dr. Graham, Dr. Garcia, and any other physician performing procedures at the Proposed ASC will be assisted by RNs, certified neurosurgical assistants and technicians. Staff competency will be maintained by regular-in-service education.

d) Cost and Finances (include revenue/cost projections for the first and third year of operation).

	Projected 1st Full Year Operations	Projected 3rd Full Year Operations
<b>Total Operating Revenue</b>	<b>\$5,429,942</b>	<b>\$5,934,740</b>
<b>Operating Expenses</b>		
Salaries, Wages, Benefits	\$437,520	\$464,165

Other Expenses	\$3,031,543	\$3,190,973
Depreciation	\$268,451	\$268,451
Total Expenses	\$3,737,514	\$3,923,589
<b>Net Income (Loss) from Operations</b>	<b>\$1,692,428</b>	<b>\$2,011,151</b>
<b>Add Back:</b> Depreciation	\$268,451	\$268,451
<b>Less Principal Payments</b>	(\$100,266)	(\$110,788)
<b>Excess (Deficit) Fund from Operations</b>	<b>\$1,860,613</b>	<b>\$2,168,814</b>

e) Relationship to the existing health care system.

The Proposed ASC will have a significant positive impact on the health care system in Maui County by providing access to certain neurological and pain management procedures within Maui County. Currently, such procedures are not performed in Maui County because existing facilities cannot accommodate the scheduling demands necessary for these procedures. As described in Section (b), above, the Proposed ASC will enable Maui County residents to access a wide array of specialized procedures that are not currently available on their island.

f) Availability of Resources.

The Proposed ASC will employ six (6) full-time employees including: one (1) receptionist, two (2) registered nurses, one (1) clinical director, one (1) scrub tech, and one (1) business office manager. The Physicians are confident that qualified personnel can be acquired through inquiries and interviews with persons in the community with requisite training and experience.

There are minimal financial obstacles to the Proposed ASC. FirstBank has pre-committed to funding the entire cost of the project through a commercial loan. A letter dated April 18, 2018 from FirstBank, indicating that such loan has been pre-approved, is included with this application as Attachment 6.

**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.