REPLACEMENT PAGE

HAWAI`I STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: # 12-24A Date of Receipt:
To be assigned by Agency

APPLICANT PROFILE

Project Title: Establishment of Ambulatory Surgery Center Limited to Ophthalmologic Procedures

Project Address: 450 Hookahi Street
Wailuku, Hawaii 96793

Applicant Facility/Organization: Aloha Eye Clinic Surgical Center, LLC

Name of CEO or equivalent: Jivin Tantisira, M.D.

Title: President

Address: 450 Hookahi Street, Wailuku, Hawaii 96793

Phone Number: (808) 877-3984 Fax Number: (808) 871-6498

Contact Person for this Application: Jivin Tantisira, M.D.

Title: President

Address: 450 Hookahi Street, Wailuku, Hawaii 96793

Phone Number: (808) 877-3984 Fax Number: (808) 871-6498

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

Date

Jivin Tantisira, M.D.
Name (please type or print)

President
Title (please type or print)

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) 3-4-043-055-0001

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
TOTAL			

6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:

		AMOUNT:
1.	Land Acquisition	_____
2.	Construction Contract	$ 982,800
3.	Fixed Equipment	_____
4.	Movable Equipment	$ 662,400
5.	Financing Costs	_____
6.	Fair Market Value of assets acquired by lease, rent, donation, etc. (site lease)	$ 432,000
7.	Other: _____	_____
	TOTAL PROJECT COST:	**$2,077,200**

B. Source of Funds

1.	Cash	_____
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt	$1,645,200
6.	Other: Fair market value of lease payments to be paid over the term of the lease	$ 432,000
	TOTAL SOURCE OF FUNDS:	**$2,077,200**

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 ophthalmologic 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: Site is owned by DEK, LLC, a limited liability company owned by Dr. Tantisira.

b) Dates by which other government approvals/permits will be applied for and received:

Building permit applied for: November 2012
Building permit received: March 2013

c) Dates by which financing is assured for the project: August 9, 2012

d) Date construction will commence: April 2013

e) Length of construction period: 4 months

f) Date of completion of the project: July 2013

g) Date of commencement of operation: August 1, 2013

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

Executive Summary

Dr. Jivin Tantisira owns and operates Aloha Eye Clinic, Ltd., the largest provider of eye care on Maui, and has been serving the Maui community for over 35 years. Dr. Tantisira now seeks to establish an ambulatory surgery center limited to ophthalmologic surgery (the "Proposed ASC") at 450 Hookahi Street in Wailuku, Maui. The free standing facility will be adjacent to the Wailuku Aloha Eye Clinic. The Proposed ASC will consist of one operating room, an ophthalmologic laser room, and an ophthalmologic minor procedure room.

The Proposed ASC will provide services in three separate stages to ensure uninterrupted eye care to the Maui community. Stage one will consist of procedures that are currently being performed at the Aloha Eye Clinics and is expected to be implemented upon the opening of the ASC. Stage two will consist of anterior segment and medical oculoplastic procedures that include cataract surgery, glaucoma surgical procedures, corneal surgical procedures, and pterygium surgery, some of which are not currently being performed on Maui such as procedures utilizing the Amniograft. The second stage is anticipated to be implemented within six months of opening the ASC. Stage three will consist of retinal surgical procedures and pediatric ophthalmologic surgical procedures. Currently, there are no retinal surgical procedures being performed on Maui. Pediatric ophthalmologic surgical procedures are performed on Maui on an extremely limited basis. The final stage is projected to be implemented within one to two years of opening the ASC.

a) Relationship to the State of Hawai`i Health Services and Facilities Plan

The Proposed ASC will enter into the required collaborative arrangement, including a transfer agreement, with Maui Memorial Medical Center ("MMMC") and, in the event that one of its patients requires hospitalization, Dr. Tantisira will coordinate the patient's transfer to MMMC. *See* Attachment 4. In addition, Dr. Tantisira will commit to support all training and recruitment of health care personnel for the benefit of Maui County and commit to enhance the EMS and trauma care systems of Maui County by using the ASC, when necessary, for cases such as natural disaster or pandemic.

The Proposed ASC will advance the Statewide Health Coordinating Council's ("SHCC") general principles of (i) striving for equitable access to health care services, (ii) ensuring that any proposed service will at least maintain overall access to quality care at a reasonable cost, (iii) expanding and retaining the health care workforce to enable access to the appropriate level of care in a timely manner, and (iv) promoting and supporting the long-term viability of the health

care delivery system. Dr. Tantisira is committed to charging a reasonable facility fee to cash paying patients without health insurance and patients having cosmetic procedures done. The facility fees will be significantly less costly than the fees other facilities currently charge Maui County residents. The more affordable ophthalmologic facility fees will improve equitable access to health care services. In addition, the Proposed ASC will perform procedures not currently performed on Maui or performed on an extremely limited basis and will continue to offer the services of one of Hawaii's most experienced cataract surgeons to Maui County residents. This will decrease health care costs by eliminating travel expenses for Maui County patients who would otherwise need to fly to Oahu to receive specialized ophthalmologic surgery. This will also ensure that the Proposed ASC will maintain overall access to quality care at a reasonable cost.

The Proposed ASC will also increase the number of health care jobs on Maui County and, thus, expand and/or retain the health care workforce to enable access to the appropriate levels of eye care in a timely manner on Maui County.

Additionally, the Proposed ASC will be adjacent to the Wailuku Aloha Eye Clinic. This will provide better access for patients who would go to one familiar location to get their clinical and surgical eye care needs met. It will also allow the physicians to work more efficiently because they could readily go back and forth between the clinic and ASC to perform eye exams and eye surgeries on the same day. This will promote and support the long-term viability of the health care delivery system by effectuating efficient health care delivery coupled with increased access and convenience for patients.

The Proposed ASC will also advance the Maui County/Tri-Isle Subarea Health Planning Council's ("SAC") priorities of (i) optimize reimbursement through Medicare, Medicaid and third party insurers, (ii) create innovative solutions for making Hawaii health care systems responsive to community needs, and (iii) contribute to the development of a comprehensive Maui County Disaster Plan through its collaborative arrangement with MMMC. The Proposed ASC will increase the number of health care jobs on Maui County and, thus, promote the priority of recruiting and educating an optimal supply of health care workers to meet the eye care demands of Maui County.

The Proposed ASC will promote greater efficiency of health care delivery. Currently, Dr. Tantisira is restricted to scheduling one cataract surgery per 45-minute time period using the facilities of the only multispecialty ASC in Maui County. Cataract surgery commonly takes fifteen minutes or less to perform. The Proposed ASC will allow Dr. Tantisira to perform a greater number of cataract surgeries, which in turn will optimize the number of patients that Dr. Tantisira can serve.

As discussed in greater detail in Section (b), below, the Proposed ASC's provision of procedures, not currently performed on Maui or performed on an extremely limited basis, will decrease health care costs by eliminating travel expenses of Maui County residents who would otherwise need to fly to Oahu for the same procedures. Thus, the Proposed ASC will create an innovative solution that is responsive to the community's needs of having specialized eye surgery procedures available on Maui County.

Finally, the Proposed ASC will enter into a collaborative arrangement with MMMC that includes a commitment to enhance the emergency medical and trauma care system of Maui

County by making the ASC available when needed to respond to natural disasters or pandemics.

b) Need and Accessibility

The Proposed ASC's service area includes all of Maui County. It will be adjacent to the Wailuku Aloha Eye Clinic in proximity to the Wailuku Town Center, which is easily accessible via public transportation and has ample parking. A Maui Bus stop is located at the Wailuku Town Center and is immediately across from the Proposed ASC. In addition, the Proposed ASC is readily accessible by private transportation from Hana, Paia, Kihei, Lahaina, Waihee or Upcountry Maui and has plenty of free parking.

A significant number of procedures performed at the facility will involve surgical procedures to treat cataracts, glaucoma, diabetic retinopathy, and age-related macular degeneration. Typically, older adults are at greatest risk for developing these eye diseases. CDC, Health Across Lifespan, http://www.cdc.gov/visionhealth/basic_information/lifespan.htm. Statistics compiled by the Centers for Disease Control in 1996 showed that, nationally, about 56 outpatient ophthalmologic surgery procedures per 1000 population age 45 and older were required. Multiplying that utilization rate by the number of Maui residents age 45 and older shows that Maui requires about 3671 outpatient ophthalmologic procedures annually to meet the needs of its 45 population alone. Typically, between 1600 and 2000 outpatient procedures are performed in an ASC operating room annually. Accordingly, Maui needs two outpatient procedure rooms dedicated to ophthalmologic surgery to meet current demand. However, there are no such dedicated facilities on Maui at this time. The Proposed ASC expects to provide about 1975 procedures during its first year of operation, thereby satisfying a little more than half of the demand for such procedures on Maui.

The shortage of outpatient ophthalmologic surgery capacity can be expected to worsen. In 2010, about 42% of the Maui County population was composed of adults aged 45 years and older. *See* http://hawaii.gov/debdt/info/census/Census_2010/demographic. The Hawaii Department of Business, Economic Development and Tourism predicts that about 45% of Hawaii's population will aged 45 or older by 2025. The State of Hawaii Data Book 2010, Table 1.28. Moreover, Maui's total population is expected to grow by about 22% from 2010 to 2025. The State of Hawaii Data Book 2010, Table 1.27. Accordingly, the demand for ophthalmologic procedures on Maui is expected to increase as its population grows and ages.

Moreover, the Proposed ASC will perform the following procedures that are not currently available on Maui because existing facilities lack equipment necessary to perform them:

Corneal procedures:

- 65756 Keratoplasty (Corneal transplant); endothelial; Descemet's Stripping with Auromated Endothelial Keratoplasty (DSAEK)
- 65757 Backbench preparation of corneal endothelial allograft prior to transplantation
- 65710 Keratoplasty (corneal transplant); lamellar
- 65730 Keratoplasty (corneal transplant); penetrating (except in aphakia)

- 65750 Keratoplasty (corneal transplant); penetrating (in aphakia)
- 65755 Keratoplasty (corneal transplant); penetrating (in pseudophakia)

Anterior Segment Procedures using amniotic membrane graft:

- 65780 Ocular surface reconstruction; amniotic membrane transplantation; for diagnoses like conjunctivochalasis
- 372.81 may be combined with other procedures like 68110-51 or 68115-15, Excision of lesion, conjunctiva

Intraocular Retinal Surgical Procedures:

- 65260 Removal of foreign body, intraocular; from posterior segment, magnetic extraction, anterior or posterior route
- 65265 Removal of foreign body, intraocular; from posterior segment, nonmagnetic extraction
- 67027 Implantation for intravitreal drug delivery system, includes concomitant removal of vitreous
- 67036 Vitrectomy, mechanical, pars plana approach
- 67039 Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation
- 67040 Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation
- 67041 Vitrectomy, mechanical, pars plana approach; with epiretinal membrane stripping
- 67042 Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (e.g., for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (i.e., air, gas or silicone oil)
- 67043 Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (e.g., choroidal neovascularization), includes, if performed, intraocular tamponade (i.e. air, gas or silicone oil) and laser photocoagulation
- 67101 Repair of retinal detachment, one or more sessions; cryotherapy or diathermy, with or without drainage of subretinal fluid
- 67107 Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), with or without implant, with or without cryotherapy, photocoagulation, and drainage of subretinal fluid

- 67108 Repair of retinal detachment; with vitrectomy, any method, with or without air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique
- 67110 Repair of retinal detachment; by injection of air or other gas (e.g., pneumatic retinopexy)
- 67112 Repair of retinal detachment; by scleral buckling or vitrectomy, on patient having previous ipsilateral retinal detachment repair(s) using scleral buckling or vitrectomy techniques
- 67113 Repair of complex retinal detachment (e.g., proliferative vitreoretinopathy, stage C-1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, may include air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens
- 67115 Release of encircling material (posterior segment)
- 67120 Removal of implanted material, posterior segment; extraocular
- 67121 Removal of implanted material, posterior segment; intraocular
- 67141 Prophylaxis of retinal detachment (e.g., retinal break, lattice degeneration) without drainage, one or more sessions; cryotherapy, diathermy
- 67208 Destruction of localized lesion of retina (e.g., macular edema, tumors), one or more sessions; cryotherapy, diathermy
- 67218 Destruction of localized lesion of retina (e.g., macular edema, tumors), one or more sessions; radiation by implantation of source (includes removal of source)
- 67227 Destruction of extensive or progressive retinopathy (e.g., diabetic retinopathy), 1 or more sessions, cryotherapy ,diathermy

In addition, the Aloha Eye Clinic Surgical Center will be able to offer Phakic Intraocular lens procedures utilizing lenses such as the Staar, Visian, ICL (Implantable Collamer Lens) or the AMO Verisyse Lens to treat significant degrees of myopia (near sightedness), as well as clear lens extractions with placement of intraocular lenses for people with significant myopia (near sightedness) or hyperopia (far sightedness). These procedures, which are not covered by insurance, are not currently done on Maui because the facility fees at the current ASC are too high for most people to be able to afford. Finally, the proposed ASC will perform certain cosmetic oculoplastic procedures, which are also not covered by insurance and, therefore, rarely performed on Maui because of their relatively high cost.

The Proposed ASC will be accessible to all the residents of Maui County, including low income persons, racial and ethnic minorities, people with disabilities, the elderly, and the medically underserved. It is conveniently located on public transportation routes and has ample

free parking. 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.

Patient care will be provided by ophthalmologists licensed by the Department of Health and board certified or board eligible by the American Board of Ophthalmology. The Proposed ASC will have a transfer agreement with MMMC, in the event of a medical emergency that requires a higher level of care than can be provided by the Proposed ASC. In addition, a registered nurse ("RN") will be available for emergency treatment.

Physicians will be assisted by RNs, certified ophthalmologic 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)

As documented on page 4 of 13 of this Application form, the Proposed ASC is estimated to cost $2,077,200. Funds for the project will come from a commercial loan from American Savings Bank. Attachment 5 is a non-binding letter of intent from American Savings Bank to make a loan in the amount of $2,000,000. The additional funds will provide working capital. The site will be leased and paid for via monthly rent payable over the term of the lease.

Revenue and cost projections for the Proposed ASC's first and third years of operation are summarized in the table below:

	Projected 1st Full Year Operations	Projected 3rd Full Year Operations
Net Operating Revenue	$1,171,669	$1,274,286
Operating Expenses		
Salaries, Wages, Benefits	$278,720	$295,694
Other Expenses	$508,490	$554,345
Interest Expense	$96,066	$78,605
Depreciation	$272,561	$272,561
Total Expenses	$1,155,837	$1,201,205
Net Income (Loss) from Operations	$15,832	$73,081
Add Back: Depreciation	$272,561	$272,561
Excess (Deficit) Fund from Operations	$288,393	$3456423

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 specialized ophthalmologic surgical procedures within Maui County. Currently, retinal surgical procedures and certain anterior segment surgical procedures are not performed in Maui County because existing facilities lack the equipment necessary for these procedures. Pediatric surgical procedures are performed on an extremely limited basis in Maui County. Maui County residents have to fly to Oahu to receive those ophthalmologic surgeries. As described in Section (b), above, the Proposed ASC will enable Maui County residents to access a wide array of specialized ophthalmologic surgical procedures that are not currently available within Maui County.

For the past six years, no routine eye cases needing ophthalmologic surgery have been performed at MMMC. Only emergency ophthalmologic trauma surgeries have been performed at MMMC during the same period. In addition, the only free-standing multispecialty ASC on Maui often has long wait times to schedule ophthalmologic surgical procedures for Aloha Eye Clinic patients and has a high demand from surgeons in other specialties wanting to utilize the center. The existing multispecialty ASC is expected to reach its surgical capacity in the near future. Accordingly, Dr. Tantisira does not expect the Proposed ASC to negatively impact MMMC and/or the existing multispecialty ASC.

f) Availability of Resources

The Proposed ASC will employ 1.0 FTE RN/Director, 0.5 FTE Pre-Op/Post-Op RN, 0.5 FTE RN Circulator, 0.5 FTE Surgical Technician. 0.4 FTE billing and collections staff, and 0.4 FTE office personnel. Dr. Tantisira is 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. Funding for the Proposed ASC will be obtained from a commercial loan from American Savings Bank. A limited liability company owned by Dr. Tantisira already owns the site and has entered into a letter of intent to lease it to the ASC. *See* Attachment 1.

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.

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