



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

STANDARD APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number: #09-08

Applicant: Pacific ASC, LLC
1946 Young Street, Suite 480
Honolulu, HI

Project Title: Establishment of an ambulatory surgery center specializing in
ophthalmologic procedures

Project Address: 735 Iwilei Road, Suite 225, Honolulu, Hawaii

1. **TYPE OR 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: _____

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2. **PROJECT LOCATION INFORMATION:**

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

- Statewide: _____
- O`ahu-wide: X
- 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)

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.)

City and County of Honolulu – Building Permit
 Department of Health – Licensure and Medicare Certification
 Drug Enforcement Administration/Narcotics Enforcement Division – narcotics registration

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

Pacific ASC is a member managed limited liability company, whose sole member is CBI ASC, LLC. A list of CBI ASC's officers is included in Attachment 6.

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: See Attachment 2 (Articles of Organization).
- By-Laws: Not applicable.
- Partnership Agreements Not applicable.
- Tax Key Number (project's location): 150100100000 (portion thereof)

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						
Outpatient Facility					X	
Private Practice						

5. **TOTAL CAPITAL COST:** \$4,517,442.00

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.

Establishment of a new ambulatory surgery center (ASC) that will specialize in ophthalmologic procedures. HAR § 11-186-5(3)(C).

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

A. List All Project Costs:

AMOUNT:

1.	Land Acquisition	09 JUN 18 P 3 :56	_____
2.	Construction Contract		<u>\$1,625,000.00</u>
3.	Fixed Equipment		<u>80,700.00</u>
4.	Movable Equipment		<u>904,700.00</u>
5.	Financing Costs		<u>32,542.00</u>
6.	Fair Market Value of assets acquired by lease, rent, donation, etc. (site lease)		<u>1,296,000.00</u>
7.	Other: <u>architectural and consulting fees,</u> construction contingency fund, legal and accounting expenses, interior design fees		<u>578,500.00</u>
	TOTAL PROJECT COST:		<u>\$4,517,442.00</u>

B. Source and Method of Estimation

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

The cost of site acquisition was calculated from the terms quoted by the prospective landlord. Construction cost estimates were obtained from the architectural consultant. Equipment costs were provided by the project consultant, who has assisted in the development of more than 30 ophthalmic surgery centers.

C. Source of Funds

AMOUNT:

1.	Cash		<u>\$ 840,000.00</u>
2.	State Appropriations		_____
3.	Other Grants		_____
4.	Fund Drive		_____
5.	Debt		<u>2,381,442.00</u>
6.	Other: <u>fair market value of leased space</u> to be paid via lease payments		<u>1,296,000.00</u>
	TOTAL SOURCE OF FUNDS:		<u>\$4,517,442.00</u>

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:

- a) Date of site control for the proposed project: Upon receipt of Certificate of Need
- b) Dates by which other government approvals/permits will be applied for and received:

Building Permits:	Applied for September 2009 Expected Approval December 2009
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DOH Licensure:	June 2010
Medicare Certification:	June 2010
DEA/NED Registration:	June 2010

- c) Dates by which financing is assured for the project: Upon receipt of Certificate of Need
- d) Date construction will commence: December, 2009
- e) Length of construction period: 6 months
- f) Date of completion of the project: June 30, 2010
- g) Date of commencement of operation: July 31, 2010

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.

- 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

Executive Summary

Project Description

Pacific ASC, LLC ("Pacific ASC") seeks to develop a single specialty ambulatory surgery center ("ASC") at the Shops at Dole Cannery, located at 735 Iwilei Road, Suite 225, in Honolulu. See Attachment 3. Pacific ASC was organized by CBI ASC, a wholly owned subsidiary of Cellular Bioengineering, Inc. ("Cellular Bioengineering").

The proposed ASC will consist of two operating rooms, a pre-operative area, post-operative recovery room and business office area. See Attachment 4.

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

The proposed ASC is consistent with the values and priorities established by the H2P2. It will advance the goals of reducing health disparities among Hawaii's residents and achieving equitable and effective access at reasonable cost for all Hawaii's residents to health services that are responsive to the holistic needs of the community's members and the objective of establishing a regionalized health care delivery system that fosters improved access to quality health care services by improving access to corneal transplant procedures for all Hawaii residents and access to complex ophthalmologic surgery for neighbor island residents, who now lack such access on their home islands. It will be staffed by cornea, retina and glaucoma specialists and will be located near Honolulu airport to facilitate access by individuals coming to Oahu for ophthalmologic surgery. Because the focus on a single specialty will allow the ASC to provide procedures within the specialty more efficiently than they can be provided at multi-specialty surgical facilities, it will offer reduced costs, when compared to similar treatment at major hospitals and multi-specialty ASCs and eliminate the impediments that hinder efficient and effective scheduling of ophthalmologic procedures at such facilities.

Pacific ASC will advance the goal of increasing the span of healthy life for Hawaii residents and the objectives of reducing the effects of chronic disease, prolonging health-related quality of life and reducing morbidity through timely and appropriate treatment by providing restorative and curative treatment for Hawaii residents suffering from vision disorders, thereby enabling them to resume active lifestyles.

Moreover, Pacific ASC is phase I of a larger plan that will include the launching of an international center of excellence, which will serve the mission of bringing sight back to people the world over who suffer from corneal

blindness. Opacity resulting from corneal disease and injury is the fourth leading cause of blindness, accounting for approximately 10 million cases worldwide. Currently, the only cure is corneal transplant from a human cadaver and access to the procedure is limited by the availability of suitable corneas. Only about 120,000 corneal transplants are performed annually, and the Eye Bank Association of America reports that, in 2007, approximately 50,000 of those were performed in the United States. Demand for the procedure is highest in Asia, where the incidence of corneal infections that cause corneal blindness is often higher and cultural beliefs conflict with the practice of organ donation and transplant.

Vision Share, a not-for-profit consortium of eye banks, has entered into a memorandum of understanding with Pacific ASC to provide up to 5000 corneas per year for transplant at the proposed ASC. This volume of corneas will allow Pacific ASC not only to meet the need for corneal transplants in Hawaii, but also to serve patients from Asia, for whom corneal transplant services are typically not available. These patients will facilitate the development and maintenance of a specialized, tertiary facility by ensuring the volume of procedures necessary to ensure high quality care.

Ultimately, however, the availability of corneas from cadavers will be supplemented by an artificial cornea material, which has been developed by Cellular Bioengineering and is currently in clinical trials in Europe and Canada. The company hopes to receive the Food and Drug Administration's ("FDA") approval for use of the new material in the United States by 2010. By making corneal transplants with the new artificial material available through the proposed facility, Pacific ASC will bolster both Hawaii's economy by stimulating income from both the medical and hospitality industries and the state's stature as a center for medical research and innovation.

b) Need and Accessibility

The anticipated increase in the age of Hawaii's population will exacerbate the need for ophthalmologic surgery procedures in coming years. The Centers for Disease Control ("CDC") has indicated that adults aged 40 and over are at greatest risk for eye disease. More than 3.4 million (3%) of American 40 years of age and older are either blind or visually impaired and millions more are at risk for developing vision impairment and blindness. The leading causes of blindness and vision impairment in the United States are age-related eye disease.

Over the next decade, the CDC predicts that prevention of vision impairment from eye disease will become an increasingly important concern as the prevalence of adult vision impairment and age-related eye disease in America is expected to double, due to the rapidly aging U.S. Population and the increasing epidemic of diabetes and other chronic diseases.

The growth in age-related eye disease will translate into a greater demand for ophthalmologic surgery facilities. One recent study of the impact of the aging population on the surgery workforce found that, of all the surgery specialties examined, ophthalmology has the largest forecasted increase in workload. The 2003 study estimated a 15% increase in the demand for ophthalmologic surgery by 2010, and a 47% increase in demand for such procedures by 2020.

One means of improving surgeons' ability to meet forecasted increased demand for ophthalmologic surgical procedures is increasing surgeons' productivity by enhancing environmental factors related to increased efficiency. Pacific ASC will provide an environment that will facilitate physicians' efficiency, by providing staff with enhanced experience and training in the specialty that will optimize efficiency during both surgery and room turn around.

In light of the huge disparity between the number of people suffering from corneal blindness and the number of transplant procedures performed each year, Pacific ASC is also confident that there is a need for each of the up to 5000 corneas Vision Share has committed to providing to Pacific ASC. Moreover, upon FDA approval of the artificial corneal material developed by CBI and now in clinical trials, Pacific ASC expects its facilities will

be used at maximum capacity to provide this new, sight-restoring technology to individuals suffering from corneal blindness who would otherwise be unable to obtain a suitable donor cornea.

c) Quality of Service/Care

The proposed ASC will comply with applicable federal and state statutes and regulations governing the delivery of care and maintenance of service equipment and the clinical environment. It will seek accreditation from Accreditation Association of Ambulatory Health Care, be licensed by the State of Hawaii Department of Health and participate in the Medicare and Medicaid programs. The facility will implement a Quality Assessment and Performance Improvement program that complies with the requirements of the Medicare conditions of participation for ASCs and provide patient care through well-defined processes for caregivers.

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

The total capital cost of the project is estimated at \$4,517,442, which includes \$1,296,000 attributable to the site lease, \$1,625,000 for site improvements, \$80,700 for fixed equipment, \$904,700 for movable equipment, \$32,542 for financing costs, and \$578,500 for other costs.

The project will be funded by through a combination of equity and debt. Approximately 19% of the project cost, \$840,000, will be financed through cash contributions of Cellular Bioengineering. Debt financing of approximately \$2.4 million will comprise approximately 53% of the project funding, which will be used both for capital expenditures as well as to fund initial operating expenses and equipment purchases. Pacific ASC does not foresee any difficulty in obtaining a commercial loan for the project. The site will be leased from Castle & Cooke Properties, Inc. Funding for the site lease, which accounts for 28% of the total cost of the project, will be obtained through revenues generated by the ASC's operations.

The operating revenue for the first year of operation is projected at \$3,746,101, and operating expenses for the same period are projected at \$3,086,222, resulting in a net operating profit of \$659,879. By the third year of operation, revenue is expected to increase to \$4,187,246, with total expenses for year three projected at \$3,268,855, resulting in an operating profit of \$918,391.

e) Relationship to the existing health care system

The Proposed Project will have a significant positive impact on health care in the State, because it will provide enhanced access to corneal transplant procedures, draw patients to Hawaii for ophthalmologic surgery that are not widely available in other areas in the Western Pacific Rim and develop Hawaii's role as a center for medical research and innovation. The proposed facility will also provided additional capacity that will be need to meet the growing need for ophthalmologic procedures that will result from the aging of the Hawaii's population.

f) Availability of Resources.

As discussed in part (d), above, the project will be financed through a combination of equity and debt financing. Pacific ASC does not anticipate difficulty in securing financing for the project.