



## HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

### STANDARD APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number: #08-15

Applicant: Kauai Oncology, LLC  
c/o Jacksonville Oncology Institute  
567 N. Westgate  
Jacksonville, IL 62650

Phone: 217 243 8400

Project Title: Establishment of Radiation Therapy services

Project Address: 4388 Pahee Street, Lihue, Kauai, 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: \_\_\_\_\_
- Honolulu: \_\_\_\_\_
- Windward O'ahu: \_\_\_\_\_
- West O'ahu: \_\_\_\_\_
- Maui County: \_\_\_\_\_
- Kauai County:   X
- 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.)  
See Attachment 2
- C. Your governing body: list by names, titles and address/phone numbers  
See Attachment 3
- 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
  - By-Laws
  - Partnership Agreements
  - Tax Key Number (project's location)
 See Attachment 4

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/Updated Medical Equipment over \$100,000	Other Capital Project over \$50,000	Change in ownership	Change in service/establish new service facility	Change in Beds
Inpatient Facility						
Outpatient Facility					<b>X</b>	
Private Practice						

5. TOTAL CAPITAL COST: **4,036,000**

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
<b>TOTAL</b>			

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 Radiation Therapy Services

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

A. List All Project Costs:	AMOUNT:
1. Land Acquisition	0
2. Construction Contract	0
3. Fixed Equipment	0
4. Movable Equipment	25,000
5. Financing Costs	0
6. Fair Market Value of assets acquired by lease, rent, donation, etc.	4,011,000
7. Other:	.....
<b>TOTAL PROJECT COST:</b>	<b><u>4,036,000</u></b>

## B. Source and Method of Estimation

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

Quotes for vendors and local contractors, contracts for purchase.

C. Source of Funds	AMOUNT:
1. Cash	25,000
2. State Appropriations	.....
3. Other Grants	.....
4. Fund Drive	.....
5. Debt	.....
6. Other: <b>Lease</b>	4,011,000
<b>TOTAL SOURCE OF FUNDS:</b>	<b><u>4,036,000</u></b>

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: See Attachment 5

- 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. See Attachment 6

- 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

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HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY  
CERTIFICATE OF NEED APPLICATION  
KAUAI ONCOLOGY, LLC

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10. Executive summary:

- A. Relationship to the Hawaii Health Performance Plan (H2P2), also known as the State of Hawaii Health Services and Facility Plan.

The proposed project to established a radiation therapy center on the island of Kauai in Lihue meets one of the priorities of the Kauai Subarea Plan in that the plan states priority should be given to establishing radiation therapy services to residents on the island of Kauai. As such, the proposed project will meet one of the plan's priorities and should be considered in conformance with the plan.

- B. Need and accessibility.

The proposed project will service the island of Kauai and may provide specialized services, which may not be available to cancer patients on other islands. The specific target population of the proposed project is the population on the island of Kauai, estimated to be approximately 63,000 people. The methodology utilized to establish the need and demand for services include the American Cancer Society report on the incidence of cancer in Hawaii and, more specifically, the incidence of cancer on the island of Kauai as well as statistics from the Cancer Research Center in Hawaii. At the current time, approximately 250 patients a year are diagnosed with cancer on Kauai. Of those 250 patients, it is estimated that approximately 60% will require some type of radiation therapy. However, the exact number of patients will most likely be determined by the type of cancer diagnosed and the stage at which the cancer is diagnosed. It is estimated that one treatment vault may serve the needs of approximately 350 patients per year. The proposed project to establish a single radiation therapy vault meets the needs for the present time as well as the foreseeable future. Due to the ability of the equipment to provide accelerator-based stereotactic radiosurgery as well as a physician trained to perform that service provides another weapon in the armamentarium used to treat various types of brain cancer.

It is estimated that the number of patients to be treated at Kauai Oncology will be approximately 120 patients in the first

year of operation. As the population is educated regarding the quality and availability radiation therapy services, the percentage of patients receiving treatment locally will increase towards 100% utilization of local facilities instead of the 80% market penetration assumption used for the first year of operation.

In estimating future utilization, the applicant assumed that an additional market penetration of 7.5% per year would occur for the next two years until operation of the facility was at 95% of the target market. Additionally, with an aging population, it was assumed that the percentage of Medicare patient treatments would increase 1% a year as would the number of Medicaid treatments, while the number of commercial insurance and private pay patients would decrease 1% per year. While the population growth on the island of Kauai is significantly higher than the population growth on some of the other islands, the applicant did not allow the operational assumptions to be significantly increased for population growth, given the relatively low population (63,000) on the island at present.

The radiation therapy center will be designed to accommodate individuals with disabilities and will be located in an area central on the island of Kauai. The location in Kukui Grove Village West in Lihue close to retail operations should tend to eliminate transportation barriers to the facility. The facility will be a participating facility with CMS as well as Medicaid. The facility anticipates providing approximately 5% of its services for charity care. The facility will rely on representatives of the American Cancer Society to assist in navigating the geographic, transportation, and cultural barriers that may currently exist for those patients who may require radiation therapy services as a result of a diagnosis of cancer. The facility believes that participation as a Medicare and Medicaid participating facility will reduce the financial barriers to receiving radiation therapy treatment that presently exists when family members and patients are forced to leave the island of Kauai to receive treatment as is presently the case.

### C. Quality criteria.

The applicant is committed to providing the same high-quality service in Kauai as is currently available in those radiation facilities that the principals have been involved with on the mainland. All three physicians are board certified and specialize in radiation therapy. The facility will hire registered radiation therapy technologists. Physics services

will be provided by an experienced medical physicist, licensed on the mainland, if one is not available locally.

08 JUL -Quality of care.

- a. The proposed project will improve the quality of care being delivered to the target population by being delivered on state-of-the-art equipment, utilizing a 120-leaf collimator. In addition, three-dimensional computerized treatment plans as well as IMRT radiation therapy will ensure that patients receiving services at the facility have the maximum dose accurately delivered to a tumor with a minimal radiation dose delivered to the surrounding tissue. In addition, the proposed project will allow patients to be taken care of without leaving the island, which should improve the quality of life to the patient being treated associated with those providing adjunctive care to the patient.
- b. Each radiation therapy facility has internal policies and procedures that are utilized to monitor the quality of care being provided. These policies and procedures involve physicists checking the calculations on patients' treatment plans for radiation dosage as well as physician review of physicist calculations. Both the physicist and physician supervise the radiation therapy technologists and the delivery of radiation to patients. A sample of the internal quality assurance plan is attached as Exhibit A.
- c. The principals comprising Kauai Oncology, LLC, have operated facilities on the mainland. Dr. Mahmood operates facilities in Jacksonville, Illinois, and Litchfield, Illinois. He also has a facility under construction in Macomb, Illinois. Dr. Ansari has operated a facility located within the hospital in Centralia, Illinois. Dr. Beat has provided radiation therapy services at the St. Louis Cancer Institute. All these facilities have maintained Medicare certification throughout their operation and none of the three principals have ever been reprimanded or sanctioned by Medicare. All physicians are applicants in good standing at the respective hospitals where they have medical staff privileges. All applicants



are board certified by the American Board of Medical Specialties.

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- a. The patient care staff will consist of registered radiation therapy technologists, a dosimetrist, as well as a physician specializing in radiation therapy. The facility will be linked to one of the existing facilities operated by Dr. Saleem Mahmood via Internet to provide 3D computerized treatment plans as well as conventional treatment plans that patients may require during their course of radiation therapy. The facility will also have a medical secretary to assist the radiation therapy technologists in escorting patients to the dressing area, assisting them in positioning on the linear accelerator, as well as assisting the patient post radiation therapy treatment. A physicist will check radiation treatment plans and dose calculations. Port films are taken weekly to check the response of the tumor to the radiation being delivered to the tumor.
- b. The special qualifications of the staff include registry as a radiation therapy technologist and board certification as a physician as well as licensure as a medical physicist by the applicable state in which the physicist is licensed.
- c. As board-certified physicians and registered radiation therapy technologists, continuing education is required in order to maintain licensure and/or certification. Continuing medical education ensures that state-of-the-art care will continue to be delivered to patients who require radiation therapy both now as well as in the future. The facility will also engage in an effort to educate the residents of Kauai as well as neighboring islands regarding the type of radiation therapy services that are available at the facility. In addition to the external beam radiation therapy available in the facility, physicians may offer brachytherapy services to patients in the operating room of Wilcox Hospital pending privileges being granted for brachytherapy. Brachytherapy involves implanting radioactive material into the patient's tissue in order to deliver a dose of radiation to a tumor and the surrounding tissue

instead of utilization of an external beam of radiation.

3. Licensures and certificates.

The licensures and certificates that are required for the proposed project include Certificate-of-Need approval from the State of Hawaii as well as Medicare approval from the Centers for Medicare and Medicaid Services. Other licenses associated with building permits and land use will also be required for this proposed project as well as registration of the equipment that will produce radiation and certification of the vault design to ensure that radiation is contained within the vault where the linear accelerator will be located.

4. Memberships and affiliations.

As previously mentioned, physicians are certified by the American Board of Medical Specialties. Copies of board certifications are attached as Exhibit B. In addition, radiation therapists are registered and licensed by the states in which they provide services and copies of radiation therapy technologists who have indicated in interest in providing services for Kauai Oncology Institute are also attached. Also attached as Exhibit B is the curriculum vitae of the physicist who will initially be providing physics services to Kauai Oncology.

5. Medicare reports.

As a new facility, Kauai Oncology does not have any Medicare surveys indicating any statements of deficiency and/or plans of correction.

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## D. COST AND FINANCES

The proposed project is intended to treat the population in Kauai County who will require radiation therapy during their course of medical treatment after a diagnosis of cancer is made. Based upon the current population of Kauai County as well as an aging population that is growing, the proposed project anticipates that, in the first year of operation in 2010-2011, the project will serve approximately 120 patients out of an estimated patient pool of approximately 150 patients. This estimate is based upon the current cancer incidence rate of approximately 250 patients per year for Kauai County. Based upon the incidence of major types of cancer as well as the race/ethnic makeup in Kauai County, certain assumptions were made regarding the mix of patient treatments that would be provided as well as calculations of the 2008 fee schedules for both Medicare and Medicaid patients. Based upon the projected payer mix and the present fee schedules, the following revenue and cost projections were made for the first through third year of operation:

The projections show that a small operating margin will exist in all three years. As a result, it appears that the proposed project will be able to be supported through the utilization of the service by patients in Kauai County.

## E. RELATIONSHIP TO THE EXISTING HEALTHCARE SYSTEM

The proposed project will fill a gap that currently exists in the present healthcare system, since radiation therapy is not currently available on the Island of Kauai. The proposed project will meet one of the priorities of the Kauai Subarea Council Plan, as stated in the Hawaii Health Performance Plan, that priority should be given to establishing radiation therapy on the Island of Kauai. The proposed project will establish radiation therapy services in Lihue in a centralized location that is convenient to the support services available at Wilcox Memorial Hospital. The proposed project does not intend to duplicate any services that are presently available at Wilcox Memorial Hospital and should, indeed, increase the utilization of laboratory services and diagnostic services that cancer patients require during their course of treatment as well as post treatment. It is the position of the applicant that the proposed project will improve the existing healthcare system.

## F. AVAILABILITY OF RESOURCES

The applicant has identified land suitable for building a radiation therapy center in a central location on the Island of Kauai in Lihue. Three board-certified radiation oncologists have joined forces to establish the proposed radiation therapy center. Dr. Saleem Mahmood has recently hired an additional radiation oncologist to assist him in operating the centers that he presently operates. This will allow Dr. Mahmood the time necessary to implement the proposed project. Dr. Mahmood will initially serve as the project medical director and, if necessary, he will recruit additional medical oncologists to either staff operations in Illinois or on Kauai. Two of the three principal radiation oncologists are licensed to practice in Hawaii, Dr. Michael Beat and Dr. Saleem Mahmood. One of the existing radiation therapy technologists has also received licensure to function as a radiation therapist in Hawaii. Dr. Mahmood has discussed this project with existing personnel working at his other facilities in Illinois and does not anticipate any problem filling the positions that will be necessary to operate Kauai Oncology LLC. Kauai Oncology Institute, LLC, has a financial commitment letter from the Bank of Edwardsville regarding the proposed project that will ensure adequate financial resources are available to complete the project. Kauai Oncology Institute, LLC will enter into a long term lease for the ground, building and capital equipment with the operating entity, Kauai Oncology, LLC. It is the applicant's preference to hire local individuals, if they are available, for the positions of medical secretary, radiation therapy technologist, and medical physicist. However, if local personnel are unavailable, personnel will be recruited from the existing radiation therapy centers operated by Dr. Mahmood. As such, the applicant believes that adequate financial resources, human resources, geographic resources, and patients will be readily available to ensure successful implementation of the project and continued operation of the radiation therapy center proposed.

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