

October 7, 2003

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF	)	CERTIFICATE OF NEED
	)	APPLICATION
	)	NO. 03-23
Waimea Endoscopy, L.L.C.	)	
	)	
Applicant	)	
_____	)	DECISION ON THE MERITS

DECISION ON THE MERITS

The State Health Planning and Development Agency (hereinafter "Agency"), having taken into consideration all of the records pertaining to Certificate of Need Application No. 03-23 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Hawaii County Subarea Health Planning Council, the Agency hereby makes its Decision on the Merits, including findings of fact, conclusions of law, order, and written notice on Certificate of Need Application No. 03-23.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of an outpatient endoscopy surgicenter, limited to gastrointestinal procedures at 64-5188 Kinohou St., Waimea, HI at a capital cost of \$1,087,200.
2. The applicant, Waimea Endoscopy, L.L.C. is a limited liability company organized under the laws of the State of Hawaii.

3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).

4. On July 21, 2003, the applicant filed with the Agency a Certificate of Need application for the establishment of an outpatient endoscopy surgicenter, limited to gastrointestinal procedures at 64-5188 Kinohou St., Waimea, HI at a capital cost of \$1,087,200 (the "Proposal"). On July 25, 2003, the applicant submitted additional information. On July 30, 2003 the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #03-23.

5. The period for Agency review of the application commenced on July 31, 2003, the date on which the review schedule for the application appeared in the newspaper of general circulation pursuant to Section 11-186-39 HAR.

6. The application was reviewed by the Hawaii Subarea Health Planning Council at a public meeting on August 6, 2003. The Committee unanimously recommended approval of this application by a vote of 6 in favor and 0 opposed.

7. The Certificate of Need Review Panel and Statewide Health Coordinating Council reviews of the application were waived pursuant to Section 323D-44.6 HRS.

8. This application was reviewed in accordance with Section 11-186-15, HAR.

9. Pursuant to Section 323D-43(b), HRS:

"(b) No Certificate shall be issued unless the Agency has determined that:

- (1) There is a public need for the facility or service; and
- (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs."

10. Burden of proof. Section 11-186-42, HAR, provides:

"The applicant for a certificate of need or for an exemption from certificate of need requirements shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence."

II

**FINDINGS OF FACT**

A. **REGARDING THE RELATION OF THE PROPOSAL TO THE STATE HEALTH SERVICES AND FACILITIES PLAN (HAWAII HEALTH PERFORMANCE PLAN) OR "H2P2"**

*Vision and Guiding Principles (Chapter II)*

11. The applicant states that the Proposal is consistent with many of the objectives of H2P2 such as:

- Early detection and diagnosing of treatable diseases such as esophageal, gastric and colon cancer
- Reducing the effects of chronic disease such as gastroesophageal reflux disease and peptic ulcer disease by properly diagnosing and treating appropriately to minimize short and long-term complications
- Reducing morbidity and pain through timely and appropriate diagnostic and therapeutic intervention such as screening colonoscopies to prevent colon cancer

*Statewide and Regional Priorities (Chapter III)*

12. The applicant states that the Proposal will increase access to cost-effective healthcare services including services that enhance disease prevention and early detection such as cancer detection and prevention by appropriate endoscopic evaluation.

13. The applicant states that the proposed facility "...will establish clinical benchmarks for minimal standards of care for the prevention, detection, management and follow up of disease specific health condition. Examples include evaluating patients with gastrointestinal reflux disease (GERD), performing endoscopy when appropriate and follow up to assess response to treatment."

*Diseases and Conditions (Chapters IV-XI)*

14. The applicant states that the Proposal "...will enhance the detection and management of a variety of infectious agents affecting the gastrointestinal tract and require endoscopic procedures to confirm their presence. These would include esophageal candidiasis, herpes or CMV of the esophagus, stomach or colon and tuberculosis of the GI tract."

15. The applicant states that the Proposal will improve access for the "...evaluation of patients suspected of having esophageal, gastric or colon malignancies, identifying the population at risk who warrant interventions and subsequent surveillance procedures to prevent occurrence or recurrence of a GI malignancy."

16. The applicant states that "Endoscopic services provided by the proposed ASC addresses and includes the reduction of morbidity related to complications of diabetes."

17. The Agency finds that this criterion has been met.

#### B. REGARDING NEED AND ACCESSIBILITY CRITERIA

18. The applicant states that the target group for the Proposal is persons 45 years and older who require gastrointestinal endoscopic procedures. The applicant further states that the population of this age group has increased from 32,000 to 58,000 in the County of Hawaii from 1990 to 2000.

19. The applicant states that "Colorectal cancer ranks third in incidence among men and women and is the second leading cause of death in the United States, accounting for 56,000 deaths annually."

20. The applicant states that "...colonoscopy has emerged as the 'gold standard' because of its superiority over other methods for detecting polyps and cancer..."

21. The applicant states that the Proposal "... will fulfill a need for and increase accessibility to this well recognized tool for early cancer detection."

22. The applicant states that "The proposed endoscopy ASC will provide a need and address the demand for GI specialty services. This is based on local, regional and national utilization rates indicating significant lower utilization rates for ...the north and west side of The Island, eg, 12 procedures per 1000 per year compared with 35 procedures per 1000 persons per year in the Hilo district and 32 procedures per 1000 statewide. "

23. The applicant states that the Proposal "...will be accessible to all residents of the community, in particular, low-income persons, racial and ethnic minorities, women, people with disabilities, other underserved groups, and the elderly."

24. In a memorandum dated August 29, 2003, Juliette Tulang, Chair, Hawaii Subarea Health Planning Council forwarded the Council's recommendation for approval of this application. The recommendation states in pertinent part:

**1. Need and Accessibility:**

Based upon the growth of the target group (patients 45 years of age and older), a need exists for the proposed service. The applicant's proposed service will be available to all residents of the area including all underserved groups.

25. The Agency finds that the need and access criteria have been met.

**C. REGARDING QUALITY AND LICENSURE CRITERIA**

26. The applicant states that the Proposal will comply with federal and state licensing agencies including state licensure as an ambulatory surgery center and certification as a Medicare and Medicaid provider.

27. The applicant states that the owner/applicant "...has over 10 years' experience providing GI specialty care on the Big Island, is Board certified and possesses the necessary technical expertise, knowledge of the community health care needs, and sensitivity to ethnic and cultural diversity that will foster good quality specialty healthcare provided at the proposed endoscopy ASC."

28. The applicant states that its quality assurance program, internal policies and procedures will be utilized to monitor and evaluate the quality of care.

29. In her memorandum dated August 29, 2003, Juliette Tulang, Chair, Hawaii Subarea Health Planning Council states in pertinent part:

**2. Quality of Service/Care:**

The proposed facility will be licensed by the State Department of Health and Medicare certified and has quality assurance procedures in place. The owner is a Board certified gastroenterologist.

30. The applicant states that "the proposed endoscopy ASC will provide for continuing education for all staff members..."

31. The Agency finds that quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

32. The applicant projects that the total capital cost of the Proposal will be \$1,087,200 and that the sources of funding "include personal funds of \$122,000, commercial loan (First Hawaiian Bank) of \$828,000, equipment lease/purchases Olympus Corporation (endoscopy equipment) \$100,000, Physician Sales and Service, Inc (PSS) (monitoring equipment, crash cart, defibrillator) \$37,200."

33. The applicant projects that for Year 1 of the proposal, gross revenue will be \$724,100 and net income from operations will be \$28,500. The applicant projects that for Year 3 of the proposal, gross revenue will be \$1,086,000 and net income from operations will be \$258,000.

34. The applicant states that "The proposed free-standing GI ambulatory surgery center would reduce costs. Currently GI endoscopy procedures are performed in the hospital setting and cost 40% to 50% higher than in an ASC. These higher costs are, in part, the result of a higher overhead cost inherent in operating a functioning well equipped and staffed Operating Room 24 hours a day, which is required to provide a wide array of surgical procedures."

35. In her memorandum dated August 29, 2003, Juliette Tulang, Chair, Hawaii Subarea Health Planning Council states in pertinent part:

**3. Cost and Finances:**

The proposed facility is financially feasible and will result in lower costs by taking advantage of the reduced overhead associated with an outpatient setting.

36. The Agency finds that cost and financial criteria have been met.

E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA

37. The applicant states that the Proposal will improve the existing healthcare system by reducing healthcare costs and by favorably impacting the quality of care in the community.

38. The applicant states that "The shift of services from the hospital setting to the endoscopy ASC will favorably impact quality of care by freeing up the block time two days a week utilized by the applicant for other surgeries to be done. These would include elective, emergency and trauma in the following categories; Ob-Gyn, ENT, Plastic Surgery, Orthopedics, Thoracic Surgery, Ophthalmology, and General Surgery cases, which can now utilize eight extra operating room days per month."

39. The applicant states that "Waimea Endoscopy, LLC will work with existing health services and continue to utilize their needed services and continue to provide gastroenterology services for inpatients and gastroenterology related emergencies. In addition, Waimea Endoscopy, LLC will provide an integral segment of the comprehensive healthcare services needed in the community."

40. In her memorandum dated August 29, 2003, Juliette Tulang, Chair, Hawaii Subarea Health Planning Council states in pertinent part:

**4. Relation to the Existing Health Care System:**

The proposal will enhance the existing healthcare system. North Hawaii Community Hospital and Kona Community Hospital have indicated their support for the proposal.

41. The Agency finds that this criterion has been met.

**F. REGARDING THE AVAILABILITY OF RESOURCES**

42. The applicant states that sources of funding "include personal funds of \$122,000, commercial loan (First Hawaiian Bank) of \$828,000, equipment lease/purchases Olympus Corporation (endoscopy equipment) \$100,000, Physician Sales and Service, Inc (PSS) (monitoring equipment, crash cart, defibrillator) \$37,200."

43. The applicant states that its proposal will require "...two RNs trained in assisting in GI procedures, one surgical/scope technician to assist with procedures and care of endoscopes, one receptionist/business office staff worker to schedule and assist patient and family with information gathering, and one billing clerk to assure proper coding and process claims appropriately."

44. The applicant states that "With information derived from interviews and serious inquiries from people residing in the area, Waimea Endoscopy, LLC is confident needed personnel trained in the field of GI endoscopy and other supportive positions needed for the facility will be acquired."

45. The Agency finds that the applicant has met this criterion.

III

**CONCLUSIONS OF LAW**

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 03-23 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Hawaii Subarea Health Planning Council and based upon the findings of fact contained herein, the Agency concludes as follows:

The applicant has met the requisite burden of proof and has shown by a preponderance of the evidence that the Proposal meets the criteria established in Section 11-186-15, HAR.

Accordingly, the Agency hereby determines that, pursuant to Chapter 323D-43(b):

- (1) There is a public need for this proposal; and
- (2) The cost of the proposal will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

**ORDER**

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a certificate of need to Waimea Endoscopy, L.L.C. for the proposal described in Certificate Application No. 03-23. The maximum capital expenditure allowed under this approval is \$1,087,200.




WRITTEN NOTICE

Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 of the Agency's Certificate of Need Program rules. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

DATED: October 7, 2003  
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY


  
\_\_\_\_\_  
David T. Sakamoto, M.D.  
Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Decision on the Merits, including findings of fact, conclusions of law, order, and written notice, was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on October 7, 2003.

Ron Ah Loy, M.D.  
Administrator  
Waimea Endoscopy, L.L.C  
75-5995 Kuakini Hwy. #315  
Kailua-Kona, HI 96740

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY

  
David T. Sakamoto, M.D.  
Administrator

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