

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

LINDA LINGLE
GOVERNOR OF HAWAII

CHIYOME L. FUKINO, M.D.
DIRECTOR OF HEALTH

DAVID T. SAKAMOTO, M.D., M.B.A.
ADMINISTRATOR

1177 Alakea St. #402, Honolulu, HI 96813 Phone: 587-0788 Fax: 587-0783 www.shpda.org

June 20, 2006

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)

CERTIFICATE OF NEED
APPLICATION
NO. 06-05

Pacific Endoscopy Center, LLC)

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. 06-05 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 Certificate of Need Review Panel and the Statewide Health Coordinating 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. 06-05.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of endoscopy services at 1029 Makolu Street, Suites I and J, Pearl City, Hawaii at a capital cost of \$2,753,025.
2. The applicant, Pacific Endoscopy Center, LLC, 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 February 21, 2006, the applicant filed with the Agency a Certificate of Need application for the establishment of endoscopy services at 1029 Makolu Street, Suites I and J, Pearl City, Hawaii at a capital cost of \$2,753,025 (the "Proposal"). On April 4, April 6 and April 24, 2006, the applicant submitted additional information. On May 9, 2006 the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #06-05.
5. The period for Agency review of the application commenced on May 10, 2006, 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 Certificate of Need Review Panel at a public meeting on May 19, 2006. The Panel unanimously recommended approval of this application by a vote of 7 in favor and 0 opposed.
7. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on May 25, 2006. The Council unanimously recommended approval of this application by a vote of 12 in favor and 0 opposed.
8. The Oahuwide Certificate of Need Review Committee Certificate of Need review of the application was waived pursuant to Section 323D-44.6 HRS.
9. This application was reviewed in accordance with Section 11-186-15, HAR.
10. 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 light of the benefits it will provide and its impact on health care costs."
11. 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"**

12. The applicant states that its proposal "...will advance the H2P2's goal to increase the span of healthy life for Hawaii's residents and the objectives of early detection and diagnosis of treatable diseases and of reducing morbidity and pain through timely and accurate treatment by providing additional access to colorectal cancer screening and endoscopic procedures that will identify elements of high risk and performing appropriate endoscopic procedures to diagnose and/or remove pre-cancerous lesions associated with esophageal, gastric and colon cancer."

13. The applicant states that its proposal "... will reduce the effects of chronic disease and prolong health related quality of life by providing accurate and timely diagnosis and treatment of such conditions as gastroesophageal reflux disease and peptic ulcer."

14. The applicant states that "Pacific Endoscopy will improve the cost-effectiveness of Hawaii's health care system by promoting early detection of cancer through the use of screening procedures, thereby eliminating the need for more costly, and often less effective, treatment of late stage colon and rectal cancer."

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

B. **REGARDING NEED AND ACCESSIBILITY CRITERIA**

16. The applicant states that "The facility will be particularly targeted at persons over the age of 50, for whom regular colorectal cancer screening is recommended."

17. The applicant states that "According to the American Cancer Society, only about half of all Hawaii residents aged 50 or older have had a recent colorectal screening test."

18. The applicant states that "Projections developed by the Hawaii Department of Business, Economic Development and Tourism indicate that by 2010, 26.3% of the island's residents will be over 55."

19. The applicant states that "...Solucient, which maintains the nation's largest database of healthcare information, estimates that 17,461,000 GI endoscopy procedures were done in 2001. Based on the United States Census Bureau's estimate that the nation's population in 2001 was 285,107,923, nationally, 61 GI endoscopy procedures per 1000 persons were performed in 2001."

20. The applicant further states that a survey conducted by Ron Ah Loy, M.D. in 2000 "...reported annual utilization rates (Statewide) for 1999-2000 are only 52.5 percent of the 2001 national utilization of these procedures. Oahu did little better, achieving only 55.7 percent of the 2001 national utilization rates. These utilization rates show that Hawaii and Oahu had an unmet need for endoscopy procedures of approximately 29 and 27 per thousand persons, respectively, in 2001."

21. The applicant states that "... the American College of Gastroenterology's recommendations state that 'several lines of evidence suggest that colonoscopy is the most effective colorectal cancer prevention test currently available' and go on to cite colonoscopy every ten years as the preferred screening strategy."

22. The applicant states that "Pacific Endoscopy will be accessible to all the residents of Oahu, including low-income persons, racial and ethnic minorities, women, people with disabilities, the elderly and the medically underserved."

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

C. REGARDING QUALITY AND LICENSURE CRITERIA

24. The applicant states that "The proposal will improve the quality of health care to the target group by (sic) increasing access to colorectal cancer screening and other endoscopic procedures ..."

25. The applicant states that "Pacific Endoscopy will comply with State and Federal regulation for delivery of care, maintenance of equipment and maintenance of the clinical environment. It will be licensed by the Department of Health and certified by Medicare."

26. The applicant states that "Patient care will be provided by physicians licensed by the Department of Health and Board Certified or Board eligible in gastroenterology. All the physicians are on the staff of one or more Oahu hospitals. In the event of a medical emergency, a transfer agreement is in place with Pali Momi."

27. The applicant states that "Physicians will be assisted by registered nurses or licensed practical nurses. Staff competency will be maintained by regular in-service education. A written Quality Management and Improvement Plan will be in place and ongoing quality review will be conducted."

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

D. REGARDING THE COST AND FINANCIAL CRITERIA

29. The applicant states that "Pacific Endoscopy will improve the cost-effectiveness of Hawaii's health care system by promoting early detection of cancer through the use of screening procedures, thereby eliminating the need for more costly, and often less effective, treatment of late stage colon and rectal cancer."

30. The applicant projects that for Year 1 of the proposal, operating revenue will be \$2,609,058 and operating expenses will be \$1,728,565. The applicant projects that for Year 3 of the proposal, operating revenue will be \$3,157,222 and operating expenses will be \$2,047,651.

31. 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

32. The applicant states that according to data developed by the National Center for Chronic Disease Prevention and Health Promotion, for the period 2001-2002 ... "slightly less than one-half of Hawaii's adults over the age of 50 had had recommended colorectal cancer screening... This project will help to fill that gap by making these services more accessible."

33. The applicant states that "Pacific Endoscopy has received a positive response to this project from Kapiolani Medical Center at Pali Momi ("Pali Momi"), the hospital located most closely to the proposed site, and has entered into a transfer agreement with Pali Momi providing for transfer of Pacific Endoscopy patients who develop any medical emergency to Pali Momi's emergency room for treatment."

34. The applicant states that "Commencement of endoscopy procedures at Pacific Endoscopy will allow Pali Momi to avoid the capital investment required for the addition of endoscopic procedure rooms at the hospital and allow space which would have been used for that purpose to be diverted to other needed services."

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

F. REGARDING THE AVAILABILITY OF RESOURCES

36. The applicant states that "The total cost of the proposed project will be approximately \$2,753,025, which will be financed with private funds. The sources of funds include \$80,645 to be provided by Pacific Endoscopy's members and \$1,000,000 to be obtained through a conventional loan from First Hawaiian Bank. ...Equipment for the facility will be obtained through a lease from the manufacturer... The site, which is valued at \$1,043,280, will be acquired by a commercial lease and will be paid for through monthly lease rental."

37. The applicant states that "In addition to the four gastroenterologists who will work at the facility, Pacific Endoscopy will employ 6 RNs/LPNs and one OR technician, and is confident that qualified personnel can be acquired through inquiries and interviews with persons in the community with requisite training and experience."

38. 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. 06-05 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 Certificate of Need Review Panel and the Statewide Health Coordinating 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 Pacific Endoscopy Center, LLC for the proposal described in Certificate Application No. 06-05. The maximum capital expenditure allowed under this approval is \$2,753,025

WRITTEN NOTICE

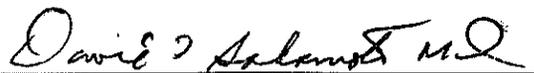
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

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 HAR. 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.

(Note, pursuant to Chapter 323D-47, Hawaii Revised Statutes, a request for reconsideration shall be received by the Agency within ten working days of the state agency decision.)

DATED: June 20, 2006
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



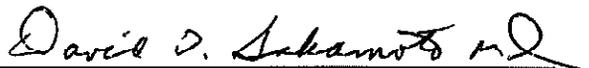
David T. Sakamoto, M.D.
Administrator

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 June 20, 2006.

Darrell Lee, M.D.
Medical Director
Pacific Endoscopy Center, LLC
Pali Momi Medical Office Building
98-1079 Moanalua Road, Suite 620
Aiea, HI 96701

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



David T. Sakamoto, M.D.
Administrator