



# STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

NEIL ABERCROMBIE  
GOVERNOR OF HAWAII

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June 1, 2011

## CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF	)	CERTIFICATE OF NEED
	)	APPLICATION
	)	NO. 11-06
MIS Endoscopy, 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. 11-06 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 Oahuwide Certificate of Need Review Committee 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. 11-06. Where appropriate, Findings of Fact shall operate as Conclusions of Law, and Conclusions of Law shall operate as Findings of Fact. As many of the criteria for CON are interrelated, each of the criteria and subheadings within the Findings of Fact shall be deemed to incorporate and include all other Findings of Fact to the extent relevant.

I

## BACKGROUND

1. This is an application for a Certificate of Need ("Cert") for the establishment of Ambulatory Surgery Center services, limited to endoscopy procedures, at 1401 South Beretania Street, 2<sup>nd</sup> Floor, Honolulu, Hawaii, at a capital cost of \$5,414,308.

2. The applicant, MIS Endoscopy, LLC, is a limited liability corporation.
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 14, 2011, the applicant filed with the Agency, a Certificate of Need application for the establishment of Ambulatory Surgery Center services, limited to endoscopy procedures, at 1401 South Beretania Street, 2<sup>nd</sup> Floor, Honolulu, Hawaii, at a capital cost of \$5,414,308 (the "Proposal"). On March 10, 2011, the applicant submitted additional information. On April 11, 2011, the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #11-06.
5. The period for Agency review of the application commenced on April 12, 2011, the day notice was provided to the public pursuant to 11-186-39 HAR.
6. The application was reviewed by the Oahuwide Certificate of Need Review Committee at a public meeting on April 19, 2011. The Committee voted 3 to 0 with one abstention in favor of recommending approval of the application.
7. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on April 28, 2011. The Council voted 8 to 0 with one abstention in favor of recommending approval of the application.
8. The Certificate of Need Review Panel 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. Section 323D-43(b), HRS states:  
  
    “(b) No certificate of need shall be issued unless the state 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.”
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**

12. The applicant states that "Chapter 2 of the Hawaii Health Services and Facilities Plan ("HHSFP") does not establish quantitative utilization thresholds for new freestanding ambulatory surgery centers, including endoscopy centers. Instead, the HHSFP states:

A collaborative arrangement shall be made with an existing acute care hospital in the county. This collaboration shall, without limitation:

- a. Include a transfer agreement
- b. Commit to support all training and recruitment of health care personnel for the benefit of the area
- c. Commit to enhance the EMS and trauma care systems of the area by using the ASC, when necessary, for cases such as natural disasters or pandemic."

13. The applicant states that "MIS will enter into the required collaborative agreement with Kuakini Medical Center and, in the event that one of its patients requires hospitalization, the center's personnel will coordinate the patient's transfer to Kuakini."

14. The applicant states "Chapter 3 of the HHSFP states that the Statewide Health Coordinating Council's ('SHCC') priorities are based on general principles, which include (1) encouraging and supporting education, promotion and preventive initiatives and (2) expanding and retaining the healthcare workforce to enable access to the appropriate level of care in a timely manner."

15. The applicant states that "The proposed endoscopy center will encourage preventive initiatives by providing additional access to colorectal cancer screening and endoscopic procedures that will identify individuals at high risk of developing colorectal cancer and by performing appropriate endoscopic procedures to diagnose and/or remove pre-cancerous lesions associated with esophageal, gastric and colon cancer. It will aid in expanding and retaining physicians qualified to perform colorectal cancer screening by providing general surgeons an opportunity to enhance their endoscopy skills; and thereby assist in

ensuring capacity and access to primary care by making colorectal cancer screening accessible in a more timely manner on Oahu."

16. The applicant states that "By facilitating early detection and treatment of gastroenterological diseases, the center will also advance the Honolulu SAC's goal of controlling the rising costs of senior care."

17. The applicant states that "MIS will help control the costs of senior care by promoting early detection of cancer through the use screening procedures, thereby eliminating the need for more costly, and often less effective, treatment of late stage colon and rectal cancer."

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

#### **B. REGARDING NEED AND ACCESSIBILITY CRITERIA**

19. The applicant states that "The facility will be open to anyone referred for endoscopy services. However, the primary target population will be persons over age 50, who are in need of screening for colorectal cancer. The average age of Oahu residents increased from 34.7 to 36.9 years between April 1, 2000 and July 1, 2009, and the percentage of persons over age 50 increased from 28.5% to 32.5%... This percentage is expected to continue to increase as the baby boomers age. By 2035, DBEDT estimates that persons age 50 and older will comprise about 40% of Hawaii's population."

20. The applicant states that "The American College of Gastroenterology's recommendations state that colonoscopy is the most effective colorectal cancer prevention test currently available and encourage colonoscopy every ten years as the preferred screening strategy. Consistent with this recommendation, effective July 1, 2001, Medicare expanded benefits available for colorectal screening exams. Screening colonoscopies are now reimbursable by Medicare every ten years for average risk patients and every two years for high risk patients. In 2010, the Hawaii legislature passed Act 157, which requires health insurers in Hawaii to provide coverage for colorectal cancer screening in accordance with the recommendations of United States Preventive Services Task Force, which advises that adults over the age of 50 should have regular colorectal screening. As a result, the demand for the procedures will increase dramatically among the state's growing over-50 population."

21. The applicant states that "The CDC reports that, currently, only slightly more than half of the persons in Hawaii over the age of 50 have received colorectal cancer screening."

22. The applicant states that "...MIS estimates that the unmet need for endoscopy procedures on Oahu is approximately 25,000 procedures annually. The unmet demand can only increase with growth in population, generally, and in the percentage of the population over the age of 50, and as expanding insurance coverage for screening colonoscopy makes the procedure affordable to more and more people."

23. The applicant states that "Among other things, MIS's collaborative arrangement with Kuakini requires it to accept all patients properly referred to the center, without regard to payer type... MIS 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."

24. The Agency finds that the need and accessibility criteria have been met.

#### C. REGARDING QUALITY AND LICENSURE CRITERIA

25. The applicant states that "MIS will be certified by Medicare, and licensed by the Hawaii Department of Health. The center will comply with all State and Federal regulations for delivery of care, maintenance of service equipment and maintenance of the clinical environment."

26. The applicant states that "MIS will conduct ongoing quality review on a regular basis, as well as performance reviews of employees at least annually. The reviews will be used to identify strengths and areas for improvement, document professional performance, and gather data as a guide for employment related actions."

27. The applicant states that "All MIS physicians will be Board Certified or Board eligible in gastroenterology or surgery. All of center's physicians will be on the active medical staff of one or more Honolulu hospitals, as well as being associated with various professional organizations."

28. The applicant states that "Staff competency will be maintained at the level required to meet community standards of care and patients' needs. All staff of the proposed center will be given specialty training at the time of hire. Regular in-service education will be conducted on an ongoing basis."

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

#### D. REGARDING THE COST AND FINANCIAL CRITERIA

30. The applicant states that "This project is expected to reduce overall health care costs, as early detection and treatment of colorectal cancer and other gastroenterologic conditions reduce the need for the extensive surgery and

chemotherapy that is necessary for treatment of late stage cancer."

31. The applicant projects that "The operating revenue for the first year of operation is projected at \$2,746,303 and operating expenses for the same period are projected at \$2,484,626, resulting in net income of \$254,228 in Year One. By the third year of operation, operating revenue is expected to increase to \$2,960,344, with total expenses projected at \$2,552,186, resulting in net income of \$400,130."

32. The applicant states that "The sources of funds include \$840,000 to be provided by MIS's members, a commercial loan of \$2,095,455 from American Savings Bank and a \$1,069,050 tenant improvement allowance. Equipment for the facility will be obtained through a lease from the manufacturer, the bank loan or some combination thereof. The site, which is valued at \$1,409,803, will be acquired by a commercial lease and will be paid for through monthly lease rental."

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

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

34. The applicant states that "According to data developed by the National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, in 2006, slightly more 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, both by providing a dedicated facility and by increasing professional capacity to perform the procedure."

35. The applicant states that "MIS will enter into a collaborative agreement with Kuakini Hospital that will include a transfer agreement providing for transfer of MIS patients who develop any medical emergency to Kuakini's emergency room for treatment. MIS's operations will also be compatible with the developing medical home model. MIS will use electronic medical records ("EMR") technology that will enable it to communicate quickly and efficiently with its patients' primary care physicians to facilitate scheduling and data sharing."

36. The Agency finds that these criteria have been met.

**F. REGARDING THE AVAILABILITY OF RESOURCES**

37. The applicant states that "The sources of funds include \$840,000 to be provided by MIS's members, a commercial loan of \$2,095,455 from American

Savings Bank and a \$1,069,050 tenant improvement allowance. Equipment for the facility will be obtained through a lease from the manufacturer, the bank loan or some combination thereof. The site, which is valued at \$1,409,803, will be acquired by a commercial lease and will be paid for through monthly lease rental."

38. The applicant states that "MIS is confident that it can hire the relatively small number of nursing personnel needed for its operation. There are currently many schools in Hawaii offering nursing programs that are constantly producing staff for all types of health care facilities in the area. These include University of Phoenix-Hawaii, Hawaii Community College, Hawaii Pacific University, Kapiolani Community College, University of Hawaii at Hilo, University of Hawaii at Manoa, University of Hawaii (Maui Community College), and University of Hawaii (Kauai Community College). Moreover, many qualified nurses are not currently active because, in many practice settings, nurses are required to work long and irregular hours that are incompatible with family life. By offering flexible schedules during set hours -- and eliminating call coverage MIS will draw these unutilized nurses back into the workforce to staff the center without compromising the staff of other health care providers."

39. 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. 11-06 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 Oahuwide Certificate of Need Review Committee 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 MIS Endoscopy, LLC for the Proposal described in Certificate of Need application No. 11-06. The maximum capital expenditure allowed under this approval is \$5,414,308.

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 1, 2011  
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY

  
Romala Sue Radcliffe  
Administrator