



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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May 17, 2005

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 05-04
Castle Medical Center)	
)	
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. 05-04 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, 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. 05-04.

I

BACKGROUND

1. This is an application for a Certificate of Need ("Cert.") for the establishment of an interventional cardiac catheterization service at Castle Medical Center, 640 Ulukahiki Street, Kailua, Hawaii, at no capital cost.
2. The applicant, Castle Medical Center, is a non-profit 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 4, 2005, the applicant filed with the Agency a Certificate of Need application for the establishment of an interventional cardiac catheterization service at Castle Medical Center, 640 Ulukahiki Street, Kailua, Hawaii, at no capital cost (the "Proposal"). On March 15, 2005 and April 4, 2005, the applicant submitted additional information. On April 4, 2005 the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #05-04.
5. The period for Agency review of the application commenced on April 8, 2005, 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 18, 2005. The Council voted 5 to 0 in favor of recommending approval of this application
7. The application was reviewed by the Certificate of Need Review Panel at a public meeting on April 21, 2005. The Council voted 8 to 0 in favor of recommending approval of this application. During member discussion, the Panel discussed the staffing for the proposal and requested the applicant to provide a three year staffing resources analysis for Castle Medical Center's proposal, including an analysis as to how staffing resources will be adjusted to match utilization throughout the period. The applicant provided this information to the Agency on April 27, 2005.
8. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on April 28, 2005. The Council voted 12 to 0 in favor of recommending approval of this application
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 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 (HAWAII HEALTH PERFORMANCE PLAN) OR "H2P2"

12. With respect to the H2P2 goal of reducing health disparities among Hawai'i's residents, the applicant states that the Proposal will allow Windward residents better access to medical procedures used to treat heart attacks.
13. The applicant states that the Proposal will further the H2P2 desired characteristic of focusing on health performance outcomes for evaluating and planning for health care services.
14. The applicant states that "Research reported from the ACC [American College of Cardiology] demonstrates that there are improved outcomes and reduction of chronic heart disease when interventional catheterization is utilized. In June 2001, the American Heart Association ('AHA') and the ACC concluded that there are significantly improved outcomes and reduction of chronic heart disease when catheterization lab intervention occurs within 60 to 90 minutes of a heart attack (the 'golden hour'). Furthermore, the ACC has stated that interventional cardiac catheterizations could and should be performed in interventional catheterization labs even where open heart surgery is not performed, where catheterization lab angioplasty balloon procedures are available."
15. The applicant states that "A recent study suggests that catheterization should not be performed for reasons other than immediate treatment of heart attack where on site surgery is not available. (See David E. Wennberg, F. Lee Lucas, Andrea E. Siewers, Merle A. Kellett, David J. Malenka, *Outcomes of Percutaneous Coronary Interventions Performed at Centers Without and With Onsite Coronary Artery Bypass Graft Surgery*, Journal of American Medical

Association (Oct. 27, 2004)... The study acknowledges that '[t]his increase in mortality was primarily confined to hospitals performing 50 or less Medicare PCIs per year.' ...Castle intends to perform significantly more than 50 catheterizations per year...Therefore, any potential risk associated with performing less than 50 procedures per year will be non-existent."

16. The applicant states that "It has been demonstrated that medical centers without on-site cardiac surgery performing >100 PCI per year had similar or lower mortality associated with PCI than hospitals with on-site cardiac surgery. (JAMA. 2004; 292:1961-1968)"

17. The applicant projects that it will perform 135 interventional procedures in its first year of operation and 210 interventional procedures by its third year of operation.

18. With respect to the H2P2 critical element of continuity of care, the applicant states the following:

"Continuity of care involves providing the right care, at the right time, and in the right setting...Interventional catheterization is an important tool, which helps physicians in determining the right care for a patient. For interventional catheterizations to be effective, however, the services must be available on a timely basis or there may be a delay in the diagnosis and, consequently, in providing the appropriate treatment...The proposed Interventional Cath Lab will alleviate any existing waiting time for interventional catheterization procedures at Castle Medical Center and allow for timely diagnosis and treatment of heart attacks."

19. With respect to H2P2 Chapter III, *Statewide and Regional Priorities*, the applicant states:

"In addition, Chapter III of H2P2 provides that the recommended regional priorities for modifying the health care delivery system in Windward O'ahu include the diagnosis and treatment of heart conditions. With regard to cardiovascular diseases, interventional catheterizations will be used for angioplasty and similar procedures where a heart attack is imminent or occurring. Therefore, an Interventional Cardiac Catheterization Lab would fill critical needs for Windward Oahu."

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

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

21. The applicant states that "The ACC and the AHA released new professional guidelines in November of 2004, confirming their previous conclusions that cath lab intervention initiated within 60 to 90 minutes of the heart attack (the 'golden hour') significantly improves outcomes and reduces chronic heart disease."

22. The applicant states that "Castle is the only major medical facility in Windward Oahu. As shown in Table B1, all other cath labs are in downtown Honolulu. Castle's primary service area is separated from other cardiac catheterization labs on Oahu by the Koolau Mountain Range. Travel time for Windward residents through or around the mountains is as much as 60 minutes each way, depending on traffic."

23. The applicant states that "This travel time reduces the accessibility of other cardiac catheterization labs to Windward Oahu residents and cuts into the ability of Windward residents to receive interventional catheterization services within the 'golden hour.' "

24. The applicant states that "An interventional Cath Lab at Castle will greatly increase the likelihood that a heart attack patient on Windward Oahu will receive treatment within the 'golden hour' time period."

25. The applicant states that "...heart disease is the number one cause of death in Hawaii, accounting for 35 percent of all deaths in Hawaii in 2002. (See Hawaii Data Book, Table 2.15-Cause of Death, by Sex). Chapter VII of H2P2 states that '[i]t is believed that the occurrence of heart disease and stroke will continue at or above the present level. Therefore, cardiovascular admissions, procedures and healthcare expenditures will increase...' (H2P2, page VII-2)."

26. The applicant states that "Castle is the only major health care facility servicing the Windward Communities of Kailua, Kanoeha, Waimanalo, Hauula, Laie, Kahuku, and Kaaawa, which currently account for approximately 130,000 Oahu residents. Patients both within the primary service area and the 'golden hour' area will be able to utilize Castle for interventional cardiology services if this project is approved."

27. The applicant states that "Approximately 130,000 persons reside in Castle's service area. This translates into approximately 1,300 cardiac catheterization cases per year, based on SHPDA's utilization reports. Based on projections from its existing diagnostic cath lab service, however, Castle expects to perform 764 interventional and diagnostic equivalent procedures by its third year of operations."

28. The applicant states that "Considering Castle's location and position as the foremost medical facility in Windward Oahu, the proposed interventional Cath lab is expected to reach a utilization of 135 interventional procedures in its first year of operations. By its third year of operation, as a result of marketing and an increased awareness of the program, Castle expects the Interventional Cath Lab to reach a utilization of 210 interventional procedures."

29. The applicant states that "Castle will further ensure that the proposed Interventional Cath Lab will be accessible to all persons, 'in particular low income persons, racial and ethnic minorities, women, people with disabilities, other underserved groups, and the elderly.' "

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

C. REGARDING QUALITY AND LICENSURE CRITERIA

31. The applicant states that "The ACC and the AHA released new professional guidelines in November of 2004, confirming their previous conclusions that cath lab intervention initiated within 60 to 90 minutes of the heart attack (the 'golden hour') significantly improves outcomes and reduces chronic heart disease. The guidelines also stated that this cardiac intervention could be performed in labs without heart surgery capability."

32. The applicant states that "Castle Medical Center will adhere to the guidelines as promulgated in the ACC standards."

33. The applicant states that "In addition, Castle has already implemented, or will implement as necessary, all policies and procedures necessary to ensure the least amount of risk possible. Among other factors, Castle will have a very highly skilled and well-trained staff of cardiologists, nurses and radiological technicians to ensure safety. Consulting surgeons will also be available before and after procedures are performed. Finally, Castle has well established, proven plan for transfer to cardiac surgical facilities, and will arrange for an expedient transfer in the rare event that such surgery is necessary. Castle has signed written agreements with cardiac surgical facilities that ensure timely transfer and acceptance of patients in the event of a crisis."

34. The applicant states that "All cardiologists will be licensed in the State of Hawaii and certified by the American Board of Cardiology. Technologists will be certified radiological technologists licensed in the State of Hawaii with additional training in catheterization...Registered Radiologic Technologists will have advanced training in angiographic and interventional procedures. In addition,

radiologic technologists will have specific competencies in electrocardiography and hemodynamic monitoring."

35. The applicant states that "Registered nurses will be certified in Advanced Cardiac Life Support, Conscious Sedation, Intraaortic Balloon Pump Operation, and Activated Clotting Time Analysis. In addition, registered nurses will be experienced in Intensive Care Unit or Emergency Department nursing."

36. The applicant states that "Castle's internal policies are either consistent with or exceed standards set forth by the following organizations with respect to interventional catheterization: American College of Cardiology; Joint Commission on Accreditation of Healthcare Organizations; Medical Consultants Network Inc.; National Guidelines Clearing House (U.S. Department of Health & Human Services); The Cochrane Library."

37. The applicant states that "Castle has been accredited by JCAHO as an acute care hospital ...In addition, Castle is listed by the American Heart Association as a "Get With The Guidelines" facility and it is the only hospital in Hawaii listed by the "Leapfrog Group" as meeting quality criteria for safety."

38. The applicant states "As this is a service designed to treat sudden heart attacks, staffing hours will be twenty four hours a day, seven days a week. One cardiologist will be present for all procedures. Elective PCI will be done according to strict selection and exclusion criteria... based on ACC guidelines on a scheduled basis to augment numbers of procedures to ensure professional staff competency. It has been demonstrated that medical centers without on-site cardiac surgery performing >100 PCI per year had similar or lower mortality associated with PCI than hospitals with on-site cardiac surgery. (JAMA. 2004; 292:1961-1968)"

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

D. REGARDING THE COST AND FINANCIAL CRITERIA

40. The applicant states that there is no capital cost associated with the Proposal and that all capital equipment is currently in place.

41. The applicant projects that for Year 1 of the Proposal, anticipated revenues will be \$3,586,359 and operating expenses will be \$1,711,833. The applicant projects that for Year 3 of the Proposal, anticipated revenues will be \$4,484,808 and operating expenses will be \$2,092,805.

42. 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

43. The applicant states that "The addition of the proposed Interventional Cath Lab will fill a critical void in the current health care delivery system on Oahu. Currently, no interventional catheterization services are available in Windward Oahu."

44. The applicant states that "There are no known alternatives to this project. The establishment of a full service cardiac catheterization lab at Castle is the only way to ensure that Windward residents receive appropriate treatment within the 'golden hour.' "

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

F. REGARDING THE AVAILABILITY OF RESOURCES

46. The applicant states that " All capital equipment is currently in place. Additional supplies may be added to inventory to assure the cardiologist and team have all possible options to perform state-of-the-art interventional cardiology. These additional supplies will be paid for in cash."

47. The applicant states that "The proposed Interventional Cath lab will staff 3 FTE registered nurses and 4 FTE radiologic technologists. The current diagnostic catheterization lab staffs 1.5 FTE registered nurses and 2 FTE radiologic technologists; these employees will continue to staff the proposed Interventional Cath Lab. An additional 1.5 FTE registered nurses and 2 FTE radiologic technologists will be recruited and hired."

48. The applicant states that "Castle presently employs 35 technologists and 10 ancillary personnel. Castle maintains an ongoing employee recruiting program and it is anticipated that positions will be filled as required."

49. 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. 05-04 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, 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 Castle Medical Center for the proposal described in Certificate Application No. 05-04. There is no capital cost authorized under this approval.

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: May 17, 2005
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 May 17, 2005.

Kevin Roberts
President/CEO
Castle Medical Center
640 Ulukahiki Street
Kailua, HI 96734

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



David T. Sakamoto, M.D.
Administrator