

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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October 12, 2018

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 18-02
Hilo 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. 18-02 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 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.18-02. 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

FINDINGS OF FACT

1. This is an application for a Certificate of Need ("Cert.") for the establishment of interventional cardiac catheterization services, at no capital cost.
2. The applicant, Hilo Medical Center, is a public 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 March 9, 2018 the applicant filed with the Agency, a Certificate of Need application for the establishment of interventional cardiac catheterization services, at no capital cost (the "Proposal"). On April 26, 2018, June 14, 2018 and July 2, 2018, the applicant submitted revisions/additional information. On July 3, 2018, the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #18-02.

5. The period for Agency review of the application commenced on July 17, 2018, the day notice was provided to the public pursuant to HAR 11-186-39.

6. The application was reviewed by the Hawaii County Subarea Health Planning Council at a public meeting on July 24, 2018. The Council voted 5 to 0 in favor of recommending approval of the application.

7. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on September 27, 2018. The Committee voted 11 to 0 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
CERTIFICATE OF NEED CRITERIA

A. REGARDING THE RELATION OF THE PROPOSAL TO THE STATE HEALTH SERVICES AND FACILITIES PLAN CRITERIA

12. The applicant states that "...the addition of PCI services improves access to health care services by adding services not currently available on island."

13. The applicant states that "In the case of an emergency, on island access to PCI services means more care being provided within the "golden hour" to reduce the coronary heart disease death rate and possible increase life expectancy for our expanding and aging community. In emergent cases, emergency air transport can cost upwards of \$30,000. There are also significant financial costs borne by families who must make emergency arrangements to follow their loved ones to O'ahu for what is often a lengthy hospital stay. While harder to quantify, there are also significant cardiac rehabilitation and long-term support costs for those who sustain avoidable heart damage due to the long transport times and a majority of care being provided outside of the "golden hour"."

14. The applicant states that "To support the new interventional catheterization service, Hilo Medical Center plans to hire two additional interventional cardiologists to join our current resident cardiologist to address the provider (workforce) shortage of specialty physicians in the County of Hawai'i. The program will also require the hiring of additional registered nurses, radiology technicians, nurse practitioners and associated support staff."

15. The Agency finds that the Proposal meets the relationship to the state health services and facilities plan criteria.

B. REGARDING THE NEED AND ACCESSIBILITY CRITERIA

16. The applicant states that "As there are currently no interventional cardiac catheterization labs on Hawai'i, the need for implementing the service is clearly indicated. Heart disease continues to be the number one cause of death in Hawai'i, accounting for 23% of all deaths in 2015. (See Hawai'i Data Book, Table 2.17-Causes of Death, By Sex). According to SHPDA, the County of Hawai'i has the highest growth rate of resident population and the highest growth rate of older adults along with the highest coronary heart disease death rates in the state."

17. The applicant states that "The number of heart attacks and cardiac deaths in Hawai'i County is expected to continue and potentially worsen as our local "baby boomer" population ages. The most effective treatment, which stops heart attacks while they are happening, has never been available to residents of the Hawai'i Island in a timely manner due to distance and transportation barriers. Currently, Hawai'i Island residents who experience a heart attack present to the Emergency Room (ER) via Emergency Medical Service (EMS) or by private vehicle. There, the ER physician assesses the patient to determine if they meet specific criteria and, if appropriate, administers medication intended to restore blood flow to the heart. On Hawai'i Island, approximately 51% of patients do not meet the criteria for the drug and the efficacy is unreliable for those who do receive it. It is standard practice for ER staff to call O'ahu hospitals to see if they will accept the patient for transfer. If and when the patient is accepted, emergency air transportation is arranged. During the 3 to 5 hours it takes to complete the transfer to an interventional cardiac catheterization lab on O'ahu, the patient's heart attack continues and the heart is often irreparably damaged. This is a sub-optimal process and it is not the standard of care for the treatment of heart attacks."

18. The applicant states that "Percutaneous Coronary Interventions (PCI), also known as balloon angioplasty with stent placement, offered in a cardiac catheterization lab has been the gold standard for treatment of heart attack for over 25 years. At first, only hospitals that offered open heart surgery would operate these cardiac catheterization labs due to the risk of complications that required surgical intervention. Studies have consistently shown that with technological advances complication rates have dropped significantly over the years and according to a 2012 study published in the New England Journal of Medicine, "Door-to-balloon times may be shorter, and patient outcomes consequently better, if primary PCI is widely available." Many hospitals began offering cardiac catheterizations without on-site cardiac surgery. This trend has continued as treatment and technology have matured and today, many hospitals without on-site cardiac surgery are routinely treating patients for heart attack in their facilities with PCI in cardiac catheterization labs. The most recent publication by the American College of Cardiology "SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup" supported the offering of interventional cardiology for treatment of heart attack as beneficial and safe for isolated population, provided certain guidelines were followed. Hilo Medical Center will adopt and implement the ACC guidelines relevant to facility requirements for PCI Programs without on-site surgery."

19. The applicant states that "Hilo Medical Center services approximately 198,449 Hawai'i residents. As indicated previously, SHPDA's catheterization utilization data indicates that approximately 600 catheterization procedures are performed per 100,000 residents. Therefore, Hilo Medical Center will potentially provide catheterization services to 1,200 individuals. The number of procedures Hilo Medical Center performs will be the product of its current diagnostic catheterization lab combined with the proposed Interventional Cath Lab."

20. The applicant states that "The proposed Interventional Catheterization service will improve our resident's access to lifesaving care in the form of a mechanical means of treating heart attack using percutaneous coronary intervention (PCI). This service will accommodate patients and families who may be unable to afford or do not want to travel significant distances to access emergent and non-emergent care. This service will be available to all patients regardless of income, race, ethnicity, gender, age, disability or ability to pay for emergent cases. As this program aims to serve the entire county's non-emergent interventional needs this service improves accessibility to all residents of the Big Island by eliminating the need to fly to O'ahu, reducing the cost of seeking care and making care more affordable."

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

C. REGARDING QUALITY AND LICENSURE CRITERIA

22. The applicant states that "Due to the limited access East Hawai'i residents have to a full array of treatment options during a heart attack, the establishment of an Interventional Catheterization service will at minimum improve quality of care by increasing on-island treatment options for residents. Having the ability to perform percutaneous coronary intervention (PCI) procedures at Hilo Medical Center means quicker treatment response times. Faster response times means providing lifesaving treatment within the first 90 minutes, resulting in reduced heart muscle loss. Reduced heart muscle damage means shorter hospitalization stays and enhanced outcomes including diminished morbidity and mortality rates."

23. The applicant states that "Hilo Medical Center is accredited by the Joint Commission, licensed by the State of Hawai'i Department of Health, is in good standing with Medicaid and Medicare healthcare programs and is currently recognized as a four star facility by the Centers for Medicaid and Medicare (CMS). Per CMS, four star facilities are in the top 20% of all acute hospitals in the United States [sic]."

24. The applicant states that "Policies and procedures, as well as clinical protocols, will be established for the interventional cardiology service. Staffing ratios are established, and all registered nurses and technologists will meet continuing education requirements. All Cardiologists will be licensed and certified by the American Board of Cardiology."

25. The applicant states that "The most recent publication by the American College of Cardiology "SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup" supported the offering of interventional cardiology for treatment of heart attack as beneficial and safe for isolated population, provided certain guidelines were followed. Hilo Medical Center will adopt and implement the ACC guidelines relevant to facility requirements for PCI Programs without on-site surgery."

26. The applicant states that "Hilo Medical Center has a well-established, proven plan for transfer to cardiac surgical facilities, and will arrange for an expedient transfer in the rare event that cardiac surgery is necessary. Hilo Medical Center is also working with medical air transport providers, scheduling mock drills and additional training for medical staff to ensure we are able to safely transfer patients with balloon pumps to cardiac surgical facilities on O'ahu."

27. The applicant states that "All Cardiologists will be licensed in the State of Hawai'i and certified by the American Board of Cardiology. Previous experience and training in cardiac catheterization will also be required. Technologists will be certified radiological technologists licensed in the State of Hawai'i with additional training in catheterization. Registered nurse will be certified in Advance Cardiac Life Support, Conscious Sedation, and Intraaortic Balloon Pump Operation. In addition, registered nurses will be experienced in Intensive Care unit or Emergency Department nursing. The Lab Technician will have training in Activated Clotting Time Analysis (ACT), and will be MT certified by the American Society for Clinical Pathology (ASCP). 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. Technologists will be certified in Advance Cardiac Life Support."

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

D. REGARDING THE COST AND FINANCIAL CRITERIA

29. The applicant states that "This project will help keep health care costs down and improve quality of care. Currently, interventional catheterization services are only available on the neighbor islands of O'ahu and Maui. Travel time between islands causes unnecessary and dangerous delays in providing emergency care, resulting in higher long term health care costs due heart damage from delayed treatment."

30. The applicant states that "In the first year, anticipated revenues are \$2,863,575 with operating expenses of \$3,132,500 resulting in a net loss of \$268,925. By the third year of operations, Hilo Medical Center projects, a total of 275 interventional procedures or 550 (2 x 275) diagnostic equivalent procedures, and 650 diagnostic procedures for a total of 1,200 procedures (275 x 2 = 550, 550 + 650 = 1,200). Anticipated revenues for the third year are \$3,499,925 with operating expenses of \$2,978,144, resulting in a net gain of \$521,781."

31. 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 CRITERIA

32. The applicant states that "The addition of the proposed Interventional Catheterization service will fill a critical void in the current health care delivery system on Hawai'i Island. Patients suffering from a heart attack currently have only one option of treatment - clot dissolving drugs, and 51% of patients currently seen at Hilo Medical Center do not meet the criteria for the drug and the efficacy is unreliable for those who do receive it."

33. The applicant states that "Currently there are no alternatives to this project. The establishment of a full service Cardiac Catheterization Lab at Hilo Medical Center is the only way to ensure that East Hawai'i residents receive appropriate treatment within the "golden hour". Failure to implement an Interventional Catheterization Lab will result in East Hawai'i residents being denied timely and cost effective access to essential and lifesaving health care services jeopardizing the health and welfare of our residents."

34. The Agency finds that the relationship to the existing healthcare system of the area criteria have been met.

F. REGARDING THE AVAILABILITY OF RESOURCES CRITERIA

35. The applicant states that "An Interventional Cardiologist will be present for all procedures. Hilo Medical Center plans to maintain three Interventional Cardiologists to support this services [sic] for both emergent and non-emergent cases. Currently we have one Interventional Cardiologist who has accepted an offer and we will continue to recruit two additional Interventional Cardiologists."

36. The applicant states that "The proposed service will be staffed with four (4) registered nurses and three (3) radiologic technologists. Hilo Medical Center has three (3) FTE registered nurses and two (2) FTE radiologic technologist on staff in the current catheterization lab. An additional one (1) FTE registered nurse, one (1) FTE radiologic technologist and one (1) FTE lab technician will be recruited and hired. Our current Imaging Manager who is also a radiologic technologist will serve as the Interventional Cath Lab Coordinator. The coordinator will manager day-to day activity in conjunction with technical staff, Cardiology Director, and Hospital Administration. We currently staff our Short Stay/PACU with 11.7 FTE registered nurses and one (1) full time licensed practical nurse. An additional 1.8 registered nurses will be recruited and hired to care for the increased patient volume attributed to interventional catheterization services. The additional RNs will be required to maintain the current 2:1 patient care ratio on Short Stay/PACU."

37. The applicant states that "Hilo Medical Center maintains an ongoing employee recruiting program and it is anticipated that positions will be filled as required."

38. The Agency finds that the availability of resources criteria have been met.

III

CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 18-02 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 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 service; and
- (2) The cost of the service 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 Hilo Medical Center for the Proposal described in Certificate of Need application No.18-02. There is no capital expenditure authorized under this approval.

WRITTEN NOTICE

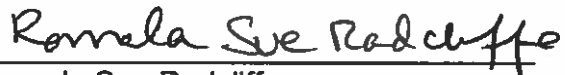
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

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: October 12, 2018
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



Romala Sue Radcliffe
Administrator