



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

**STANDARD APPLICATION - CERTIFICATE OF NEED PROGRAM**

Application Number: # 18-02 Date of Receipt:  
To be assigned by Agency

**APPLICANT PROFILE**

Project Title: Establishment of Interventional Cardiac Catheterization Services

Project Address: 1190 Waianuenu Avenue

Hilo, Hawaii 96720

Applicant Facility/Organization: Hilo Medical Center

Name of CEO or equivalent: Dan Brinkman

Title: Regional Chief Executive Officer

Address: 1190 Waianuenu Ave., Hilo, Hawaii 96720

Phone Number: 808-932-3100 Fax Number: 808-974-4746

Contact Person for this Application: Mari Horike

Title: Administrative Services Officer

Address: 1190 Waianuenu Ave., Hilo, Hawaii 96720

Phone Number: 808-932-3124 Fax Number: 808-974-4746

**CERTIFICATION BY APPLICANT**

I hereby attest that I reviewed the application and have knowledge of the content and the information contained herein. I declare that the project described and each statement amount and supporting documentation included is true and correct to the best of my knowledge and belief.

Signature [Handwritten Signature]

Date 4/23/18

Dan Brinkman  
Name (please type or print)

CEO  
Title (please type or print)

**1. TYPE OR ORGANIZATION: (Please check all applicable)**

Public	<u>  X  </u>
Private	<u>      </u>
Non-profit	<u>      </u>
For-profit	<u>      </u>
Individual	<u>      </u>
Corporation	<u>  X  </u>
Partnership	<u>      </u>
Limited Liability Corporation (LLC)	<u>      </u>
Limited Liability Partnership (LLP)	<u>      </u>
Other: _____	<u>      </u>

**2. PROJECT LOCATION INFORMATION:**

**A. Primary Service Area(s) of Project: (Please check all applicable)**

Statewide:	<u>      </u>
O`ahu-wide:	<u>      </u>
Honolulu:	<u>      </u>
Windward O`ahu:	<u>      </u>
West O`ahu:	<u>      </u>
Maui County:	<u>      </u>
Ka`ua`i County:	<u>      </u>
Hawai`i County:	<u>  X  </u>

**3. DOCUMENTATION (Please attach the following to your application form):**

**A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)**

*The designated site is located on the Hilo Medical Center campus and is owned by the Hawai`i Health Systems Corporation. There is no site control documentation.*

**B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)**

- Certificate of Need from SHPDA (pending)
- Joint Commission Accreditation (valid 2017 – 2019)

**C. Your governing body: list by names, titles and address/phone numbers**

Year 2018 list included, please see Attachment 1

D. If you have filed a Certification of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:

- Articles of Incorporation  
Not applicable. HHSC formed by statute (HRS Chapter 323F)
- By-Laws  
Please see Attachment 2
- Partnership Agreements  
Not applicable
- Tax Key Number (project's location)  
(2) 3-027-002

4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "x" in the appropriate box.

	Used Medical Equipment (over \$400,000)	New/Upgraded Medical Equip. (over \$1 million)	Other Capital Project (over \$4 million)	Change in ownership	Change in service/establish new service/facility	Change in Beds
Inpatient Facility					X	
Outpatient Facility						
Private Practice						

5. **TOTAL CAPITAL COST:** None

6. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved

<b>TOTAL</b>			

7. **CHANGE IN SERVICE.** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please consult Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

Establishment of interventional cardiac catheterization services.

**8. PROJECT COSTS AND SOURCES OF FUNDS (For Capital Items Only)**

<b>A. List All Project Costs:</b>	<b>AMOUNT:</b>
1. Land Acquisition	_____ \$0 _____
2. Construction Contract	_____ \$0 _____
3. Fixed Equipment	_____ \$0 _____
4. Movable Equipment	_____ \$0 _____
5. Financing Costs	_____ \$0 _____
6. Fair Market Value of assets acquired by lease, rent, donation, etc.	_____
7. Other: _____	_____
<b>TOTAL PROJECT COST:</b>	<b>_____ \$0 _____</b>

**B. Source and Method of Estimation**

Describe how the cost estimates in Item "A" were made, including information and methods used:

Hilo Medical Center does not anticipate any capital costs for this project.

**C. Source of Funds**

**AMOUNT:**

- 1. Cash \_\_\_\_\_
- 2. State Appropriations \_\_\_\_\_
- 3. Other Grants \_\_\_\_\_
- 4. Fund Drive \_\_\_\_\_
- 5. Debt \_\_\_\_\_
- 6. Other: \_\_\_\_\_

**TOTAL SOURCE OF FUNDS:** \_\_\_\_\_

**9. IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

a) Date of site control for the proposed project,

The site designated for the cardiac catheterization services is pre-existing on the campus of Hilo Medical Center. The lab that is currently utilized for our diagnostic cardiac catheterization services (CON Application #07-16A) will also serve as the lab for our interventional cardiac catheterization services.

b) Dates by which other government approvals/permits will be applied for and received,

February 2018 – Complete and submit Certificate of Need Application.

c) Dates by which financing is assured for the project,

Not applicable.

d) Date construction will commence,

Not applicable.

e) Length of construction period,

Not applicable.

f) Date of completion of the project, and

Not applicable.

g) Date of commencement of operation.

Approximately January 2019

*Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the Certificate of Need.*

10. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

According to the Centers for Disease Control and Prevention (CDC), cardiovascular disease is the number one cause of death in the United States, including the State of Hawai'i and the County of Hawai'i. 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.

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.

Hilo Medical Center is committed to providing exceptional and compassionate care for our community. It is our intent to develop a safe and cost-effective program to make this life-saving treatment available to residents and visitors of East Hawai'i and, eventually, the entire Hawai'i Island.

Many of the barriers to offering interventional cardiology for heart attack treatment to Hawai'i Island residents have been reduced or eliminated. As mentioned previously, cardiac surgery is no longer a necessary requirement to provide interventional cardiology at Hilo Medical Center. Thanks to Hawai'i CIP Funds allocated in 2014 and 2015, Hilo Medical Center has acquired and installed state-of-the-art cardiac imaging equipment and software. Additionally, we have new cardiology clinic infrastructure designed for up to three interventional cardiologists and supporting providers. Most importantly, an experienced interventional cardiologist was recruited to Hilo Medical Center to develop this program for our community.

Between 2014 and 2016, 187 confirmed heart attacks presented to the Hilo Medical Center Emergency Department. Of these, 49 % were eligible for treatment with medication. Approximately 126 or 67% were transported via emergency air transport to O'ahu. These patients originated from the Hilo, Puna and Ka'u districts, a service area that composes approximately half of the 200,000 residents of the Hawai'i Island. American College of Cardiology (ACC) and American Heart Association released professional guidelines, confirming that catheterization lab intervention initiated within the first 60 – 90 minutes of the heart Attack (the "golden hour") significantly improves outcomes and reduces chronic heart disease. Nearly 100% of those 60-70 heart attacks per year that presented to Hilo Medical Center would have benefited from timely access to an interventional cardiac cath lab, avoiding damage to their heart or death.

Once an interventional cardiology program is established in East Hawai'i, we predict a gradual expansion of service to most of Hawai'i Island. The completion of the Daniel K. Inouye Highway has greatly shortened ground transportation times and helicopter service is available for inter-facility transport on Hawai'i Island. Despite the size of Hawai'i Island, most patients will be able to receive definitive heart attack care much more quickly with an interventional cardiology program on island, than they would with care provided on O'ahu. Assuming eventual coverage to most of the Hawai'i Island population, the number of patients positively impacted would potentially double. Transport cost reduction would be up to \$3M annually while providing substantially better care.

Many lives can be saved and patient outcomes improved; treatment for heart attack can be performed in a safe and cost effective manner on the Hawai'i Island; transportation costs, hardship on families, and rehabilitation costs can be significantly reduced. Adding interventional cardiology services to the Big Island will be a significant step in reducing the "healthcare penalty" that one incurs for living on a neighbor island.

**a. Relationship to the State of Hawai'i Health Services and Facilities Plan**

The proposed interventional catheterization service will increase the number of specialty physicians on the island. Hilo Medical Center plans to hire two additional interventional cardiologists to join our current resident interventional cardiologist which, will lessen the provider (workforce) shortage of 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.



## **b. Need and Accessibility**

Hilo Medical Center proudly serves approximately 113,000 East Hawai'i residents, this is just under 60% of the population of Hawai'i County. With only diagnostic cardiac catheterization capabilities, Hilo Medical Center is not able to provide interventional cardiac care to those suffering from a heart attack. All of our patients who require interventional treatment must rely on services currently offered on other islands, primarily O'ahu. Delays in treatment due to off island travel, increases the risk for adverse clinical outcomes.

The service area for the proposed project would generally be the entire island of Hawai'i (for non-emergent cases) or 198,000 residents, more specifically the East Hawai'i Region for both emergent and non-emergent cases.

Considering Hilo Medical Center's location and position as the sole full-service acute catheterization lab in the County of Hawai'i, the proposed Interventional Cath Lab is expected to reach a utilization of 225 interventional procedures in its first year of operation and 275 by the third year.

## **c. Quality of Service/Care**

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. In the case that cardiac surgery is necessary, Hilo Medical Center has a well-established, proven plan for patient transfers to cardiac surgical facilities, and will arrange for an expedient transfer.

Policies and procedures, as well as clinical protocols, will be established for the interventional cardiology service. Staffing ratios are already established, and all registered nurses and technologists will meet continuing education requirements.

The Imaging Department has an established Quality Improvement Program that conducts internal quality assessments and implements improvements, following the American College of Cardiology Standards and Quality Improvement Program. The Cardiology Quality Committee oversight is provided by the Division of Medicine and the Quality Management Committee of the organized medical staff. Outcomes are reported through these channels to the Quality and Patient Safety committee of the East Hawai'i Regional Board.

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). Four star facilities are ranked in the top 20% of acute hospitals in the United States.

**d. Cost and Finances (include revenue/cost projections for the first and third year of operation)**

Hilo Medical Center currently has three (3) FTE registered nurses and two (2) FTE radiologic technologist on staff in the current catheterization lab. The proposed Interventional Catheterization Lab will require a total of four (4) registered nurses and three (3) radiologic technologists. The current catheterization lab personnel costs the organization \$560,000 annually. The Interventional Catheterization Service also requires a Laboratory Technician which, will be recruited and hired at an additional personnel cost of \$90,000.

The proposed interventional catheterization lab is estimated to have minimal costs. In the first year of operations, Hilo Medical Center projects a total of 225 interventional procedures or 450 (2 x 225) equivalent procedures and 550 diagnostic procedures for a total of 1,000 diagnostic equivalent procedures (225 x 2 = 450, 450 + 550 = 1,000). 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.

**e. Relationship to the Existing Health Care System**

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. The proposed Interventional Catheterization service will help Hilo Medical Center's Emergency Service respond to heart attacks within the "golden hour" time frame, as patients will have access to a mechanical means (PCI) of treating heart attack within the "golden hour."

PCI has been shown to improve quality of life for patients when performed electively in appropriate patients. There are currently no interventional catheterization services available to residents in Hawai'i County – all residents currently seek non-emergent treatment on other islands. As we have no current Interventional Catheterization service on island, this new service will not have any effect on the utilization of other on island facilities. We do not expect a significant impact in the utilization of Interventional Catheterization services on O'ahu. The increased access to life saving treatment for residents on Hawai'i Island should outweigh any minor decrease experienced in the utilization of services on other islands.

**f. Availability of Resources**

Both the financial and personal resources needed to implement the proposal are currently available to implement the interventional cardiac catheterization program here at Hilo Medical Center.