



**HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY**

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**ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM**

Application Number: # 20-05A  
To be assigned by Agency

Date of Receipt  
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& DEV. AGENCY

**APPLICANT PROFILE**

Project Title: **Establishment of Cardiac Catheterization Services**  
Project Address: **Kapi'olani Medical Center for Women & Children  
1319 Punahou Street, Honolulu, HI 96826**  
Applicant Facility/Organization: **Kapi'olani Medical Center for Women & Children**  
Name of CEO or equivalent: **Martha Smith**  
Title: **Chief Executive Officer & EVP Oahu Operations**  
Address: **1319 Punahou Street, Executive Offices, Honolulu, HI 96826**  
Phone Number: (808) 983-8071 Fax Number: (808) 983-6086

Contact Person for this Application: **Michael Robinson**  
Title: **Vice President, Government Relations & Community Affairs**  
Address: **55 Merchant Street, 26<sup>th</sup> Floor, Honolulu, HI 96813**  
Phone Number: **(808) 535-7124** Fax Number: **(808) 535-7111**

**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  
**Martha Smith**  
\_\_\_\_\_  
Name (please type or print)

\_\_\_\_\_  
Date  
**CEO & EVP Oahu Operations**  
\_\_\_\_\_  
Title (please type or print)

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1. TYPE OF ORGANIZATION: (Please check all applicable)

- Public \_\_\_\_\_
- Private   X
- Non-profit   X
- For-profit \_\_\_\_\_
- Individual \_\_\_\_\_
- Corporation   X
- Partnership \_\_\_\_\_
- Limited Liability Corporation (LLC) \_\_\_\_\_
- Limited Liability Partnership (LLP) \_\_\_\_\_
- Other: \_\_\_\_\_

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2. PROJECT LOCATION INFORMATION

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

- Statewide: \_\_\_\_\_
- O`ahu-wide:   X
- Honolulu: \_\_\_\_\_
- Windward O`ahu: \_\_\_\_\_
- West O`ahu: \_\_\_\_\_
- Maui County: \_\_\_\_\_
- Kaua`i County: \_\_\_\_\_
- Hawai`i County: \_\_\_\_\_

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

- A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent) **N/A**
- 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, State Health Planning & Development Agency
- Building permit

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

-See Attachment A

- D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:
  - Articles of Incorporation: **See Attachment B**
  - By-Laws: **See Attachment C**
  - Partnership Agreements: **Not Applicable**
  - Tax Key Number: **2-8-011-004**

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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.

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

5. **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	Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
N/A	N/A	N/A	N/A
<b>TOTAL</b>			

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6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:

20 MAY -5 A9 20 AMOUNT:

1.	Land Acquisition	N/A
2.	Construction Contract	\$ 2,550,000
3.	Fixed Equipment	\$ 3,500,000
4.	Movable Equipment	\$ 600,000
5.	Financing Costs	N/A
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	N/A
7.	Other: Architectural/Planning	\$ 1,550,000

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**TOTAL PROJECT COST: \$ 8,200,000**

B. Source of Funds

1.	Cash	\$ 5,200,000
2.	State Appropriations	N/A
3.	Other Grants	N/A
4.	Fund Drive	\$ 3,000,000
5.	Debt	N/A
6.	Other: _____	N/A

**TOTAL SOURCE OF FUNDS: \$ 8,200,000**

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7. **CHANGE OF 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 reference the 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.** **28 APR 26 PM 1:25**  
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This project involves the addition of a new location of existing cardiac catheterization services currently performed at Straub Medical Center to be performed at Kapi'olani Medical Center for Women and Children.

8. **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: **N/A**
- b) Dates by which other government approvals/permits will be applied for and received: **November 2020**
- c) Dates by which financing is assured for the project: **N/A**
- d) Date construction will commence: **February 2021**
- e) Length of construction period: **18 Weeks**
- f) Date of completion of the project: **July 2021**
- g) Date of commencement of operation: **July 2021**

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.

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9. **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.

Kapi'olani Medical Center for Women & Children ("Kapi'olani") – an affiliate of Hawai'i Pacific Health – provides specialty pediatric and women's services. Cardiac catheterization services for pediatric and adults with congenital heart defects are currently provided at Kapi'olani's sister facility Straub Medical Center. This proposed project seeks to create a Hybrid OR suite ("Suite") that can be used to perform cardiac catheterization procedures for pediatric patients and a limited population of adults and young adults with congenital heart disease. This suite will also allow for interventional radiology services to be provided to complement other existing pediatric and women's specialty services currently at Kapi'olani Medical Center.

**a) Relationship to the State of Hawaii Health Services and Facilities Plan.**

The proposed project meets the following priorities and objectives of the statewide and regional priorities of SHPDA's Health Services and Facilities Plan (HSFP, 2009).

First, this project is consistent with the goals and objectives of the State of Hawai'i Health Services and Facilities Plan (HSFP) to "increase cost effective access to necessary health care services" and to "promote regionalization of services where appropriate" (Chapter 1, HSFP 2009). This completed project will enable pediatric and adult patients with congenital heart defects as well as pediatric and female patients requiring acute interventional radiology services safer and more efficient access by reducing the transporting of patients and the costs associated with this and avoidable hospitalizations related to having the procedures performed at Straub Medical Center.

Second, providing cardiac catheterization and interventional radiology services is also consistent with the Statewide Health Coordinating Council (SHCC) general principles to "[p]romote and support the long-term viability of the health care delivery system." (Chapter 3, HSFP 2009). The proposed project will ensure that access to critical cardiac catheterization and interventional radiology services are co-located with existing specialized services at Kapi'olani Medical Center and consolidate potentially related services onto the same care site. This project is also in alignment with the SHCC's general principle in support of projects that are "...appropriate for the regional and statewide continuum of care." For more than a century, Kapi'olani has served as Hawai'i's sole maternity, newborn and pediatric specialty hospital. It is also a tertiary care, medical teaching and research facility. Specialty services for patients throughout Hawai'i and the Pacific Region include intensive care for infants and children, 24-hour emergency pediatric and adult care, critical care air transport, and high-risk Perinatal care. The proposed project will strengthen specialized care in the acute care services segment of the continuum of care.

Third, this project is in alignment with the West O'ahu Sub Area Planning Council (SAC) priorities to improve and increase access to acute care, specialty care and emergency care services. The proposed project will provide greater access cardiac catheterization services for patients with congenital heart defects and will meet the acute, specialty, and emergent health care needs of this population.

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The proposed project is aimed at meeting the needs of pediatric and adult congenital heart defect patients requiring cardiac catheterization. Additionally, the Suite will be available to meet the needs of pediatric and adult female patients requiring acute interventional radiology procedures on site.

The recommended HFSP threshold for the establishment of a new adult cardiac catheterization services/unit is that the minimum annual utilization for each provider is 1,000 diagnostic-equivalent procedures per unit and the utilization of the new unit/service is projected to meet the minimum utilization rate by the third year of operation. The recommended HFSP threshold for expansion of an existing adult cardiac catheterization services is 1,200 diagnostic equivalent procedures per year per unit. [[HFSP, page 30 (2009)]. There are no HFSP stated thresholds for the establishment or expansion of pediatric cardiac catheterization services.

The 2018 SHPDA reported cardiac catheterization service utilization for the Honolulu urban market is provided below.

Honolulu Cardiac Catheterization Diagnostic-Equivalent Services Utilization											
2018 SHPDA Reported											
Provider	Number	Units	Diagnostic		Therapeutic		Electrophysiology		Total	Total	
			Adult	Pediatric	Adult	Pediatric	Adult	Pediatric	D/E	D/E Per Unit	
Straub	Actual		656	22	418	29	283	9			
	Diagnostic Equivalent	3	656 [1]	44 [2]	836 [2]	58 [2]	566 [2]	18 [2]	2,178	726	
Kaukuni	Actual		268	0	160	0	60	0			
	Diagnostic Equivalent	2	268 [1]	0	320 [2]	0	120 [2]	0	708	354	
Queens	Actual		1,685	0	825	0	1,291				
	Diagnostic Equivalent	4	1,685 [1]	0	1,650 [2]	0	2,582 [2]	0	5,917	1,479	

[1] Adult diagnostic cardiac catheterization procedures count as 1 diagnostic equivalent (D/E) procedure. [HSFP, page 30]  
 [2] All pediatric, therapeutic, and electrophysiology procedures count as 2 diagnostic-equivalent (D/E) procedures. [HSFP, page 30]

In 2018, Straub Medical Center performed a total of 2,178 diagnostic-equivalent catheterization procedures or 726 per unit per year. The proposed project at Kapi'olani Medical Center projects performing 200 pediatric diagnostic-equivalent procedures and 24 adult diagnostic-equivalent procedures by Year 3. The Suite will also allow for 35 interventional radiology procedures (25 pediatric and 10 adults) to be performed on patients requiring acute interventional radiology services.

There are no guideline HFSP thresholds for pediatric cardiac catheterization services. While the proposed project does not meet the suggested threshold requirements on adult procedures for expansion or establishment of a new service, the project does meet the sub-optimization criteria for suboptimal utilization.

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The HFSP has recognized sub-optimum utilization criteria as stated below.

“It is recognized that some service areas may not meet the required threshold for a health care service. Sub-optimum utilization may be proposed if the benefits clearly outweigh the costs to the community of duplicating or under-using services, facilities or technologies. Benefits are defined as the form or improved access for the services area(s) population with significant improvement in quality and/or significant reduction in cost to the public.” [HFSP, page 31 (2009)].

The HFSP additionally allows for the thresholds to be modified to [HFSP, page 31 (2009)]:

- Incorporate current and best clinical practice.
- Address the documented needs of an actual population rather than basing are design on statistical generalizations.

The HFSP also states that the thresholds serve only as guides in determining the need for the service area and is not used to solely determine the approval or disapproval of a proposed project. Here, the proposed project will meet the sub-optimization criteria stated above and provide benefits which outweigh regional threshold guidelines as stated above.

Congenital heart defects are defects in the structure of the heart or great vessels that are present at birth. Each year, more than 35,000 babies in the United States are born with congenital heart defects. In Hawai'i, that results in approximately 175 babies born each year with a congenital heart defect. The condition can result in life-long specialized cardiac health care needs and challenges that extend childhood into adulthood. Adult congenital heart disease is not uncommon. More than 800,000 adults in the United States have grown into adulthood with congenital heart disease. This number increases by about 20,000 each year. Specially trained pediatric cardiologist will perform catheterization procedures.

This project is aimed at meeting the needs of patients with congenital heart defects - both pediatric and adult – who require specialized care over their lifespan. Currently cardiac catheterization for congenital cardiac patients – both pediatric and adult patients - are performed by specialized pediatric cardiologists. These procedures are currently provided by Kapi'olani Medical Center based physicians who provide these services at Straub Medical Center.

First, delivering cardiac catheterization services onsite at Kapi'olani would benefit both congenital pediatric and adult patients and families as well as health care practitioners by reducing unnecessary transport to Straub Medical Center where those procedures are currently being performed. Presently infants and children are transported to Straub and are having pediatric procedures performed in facilities housed within an adult specialty program. The project would thereby meet the specific needs of newborn infants delivered at Kapi'olani's NICU and pediatric inpatients and their families as it would eliminate the stress and risks associated with transportation of patients between Kapi'olani and Straub Medical Center for these infants and families requiring access to cardiac catheterization services.

Second, the Suite will additionally improve quality and reduce costs to the public by co-locating cardiac services with existing specialty services for women and pediatric patients. For adult women, having access to immediate interventional radiology services on site at Kapi'olani will enable many interventional techniques used to aid obstetricians or gynecologists in caring for their patients to be provided in an acute setting that is supported



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by other women's specialty services. This Suite would be available for clinicians to perform these emergency procedures on women without requiring us to bring them to surgery or transport them to another facility to perform this interventional procedure. The quality of care benefits to women from having this service on-site outweighs the potential costs of duplication or underutilization of services.

Third, the proposed project would also incorporate best clinical practice by avoiding unnecessary transportation of current congenital heart patients from Kapi'olani Medical Center to Straub Medical Center. Additionally, this project would benefit adult female patients who require immediate access to interventional radiology services by eliminated the need to have them transported to Straub Medical Center. For these reasons, the access, safety and quality of care benefits provided to women and pediatric patients resulting from having this service on-site outweigh any potential costs of duplication or underutilization of services experienced at other facilities.

**b) Need and Accessibility**

Congenital heart defects (present at birth) are the most common type of birth defect. They affect approximately one in one hundred newborns. Each year, more than 35,000 babies in the United States are born with congenital heart defects. In Hawai'i, that results in approximately 175 babies born each year with a congenital heart defect. Congenital heart defects result in life-long specialized health care utilization and health care challenges to patients that extend into adulthood. Adult congenital heart disease is not uncommon. More than 800,000 adults in the United States have grown into adulthood with congenital heart disease. This number increases by about 20,000 each year. Specially trained pediatric cardiologist will perform catheterization procedures.

Presently all services for congenital heart catheterizations – both pediatric and adult - are performed by specialized pediatric cardiologists at Straub Medical Center. This project will allow for the services currently provided at Straub Medical Center to be provided at Kapi'olani Medical Center. The Suite will additionally allow for interventional radiology procedures to be performed for female adults requiring acute interventional radiology services.

In 2018, Straub performed 120 diagnostic-equivalent pediatrics procedures and 2,058 diagnostic-equivalent procedures for adults. The Suite will allow for 200 diagnostic-equivalent pediatric procedures and 24 diagnostic-equivalent procedures for adults to be performed at Kapi'olani Medical Center by Year 3. Additionally, the Suite will allow for 35 interventional radiology procedures to be performed for 25 pediatric patients and 10 adults requiring acute interventional procedures on-site by Year 3.

Kapiolani will continue to provide care to all residents of the area including: Medicare, Medicaid, QUEST and all underserved groups and also the elderly, low income persons, racial and ethnic minorities, women, persons with disabilities, and other underserved groups.

**c) Quality of Service/Care**

The proposed project will improve the safety and quality of care provided to children/adults with congenital heart disease and children and women in Hawai'i requiring acute interventional procedures which can be done in the newly built hybrid suite. Kapi'olani has

the comprehensive breadth of services to meet the ongoing needs of the children and women we service. The current arrangement of transferring a sick or unstable child or woman in an ambulance to another facility adds increased risk, resources and puts stress and a burden on the patient and their family.

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Having a dedicated Suite on-site at Kapi'olani will enable immediate access for pediatric and female patients requiring life-saving procedures. Kapiolani also has immediate access to pediatric/women subspecialists when the need arises. Kapi'olani has dedicated nurses and ancillary staff that are trained in the care specifically of children and woman that can provide ongoing care up until discharge. Kapi'olani Medical Center for Women and Children being the only specialty hospital within a 2500 mile radius makes it the best and most suitable place to construct this much needed suite.

The proposed project will also reduce avoidable hospitalization by eliminating transport of pediatric patients admitted to the Straub catheterization lab which now require an overnight stay or additional care for a complication and are transported back to Kapi'olani. This current practice is resource intensive, adds more risk to the procedure and is an additional burden on the child and family. Physicians are also required to travel between each of the facilities to perform the procedure and provide the follow-up care. Having services at one location would decrease risk, improve efficiency and increase satisfaction among patient/families and the multidisciplinary team members. Staff providing care at Straub Catheterization lab are well-trained however do not have immediate access to the breadth of children's services (i.e., pediatric subspecialists, Child Life services) that are available at Kapi'olani Medical Center.

The proposed project will also additionally improve quality and reduce costs for adult female patients by enabling acute interventional radiology procedures be performed in a facility supported by services. For women, having interventional radiology capabilities at Kapi'olani will enable many interventional Radiology techniques for women that can be used to aid obstetricians or gynecologists in caring for their patients in the acute setting. For example, embolization can be lifesaving in the case of postpartum hemorrhage. Bleeding related to cervical cancer or the threat of bleeding from cervical ectopic pregnancy is amenable to embolization as is hemorrhage related to uterine arteriovenous malformations. Postpartum women are also at a uniquely high risk for deep vein thrombosis and pulmonary emboli and may benefit from consultation and treatment by an interventional radiologist. This suite could be used to perform these emergency procedures on women without requiring us to bring them to surgery or transport them to another facility to perform this interventional procedure.

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

The project will have minimal impact on the overall costs of health services in the community as it will be funded from internal resources. The project's financial projections reflect a positive net margin by year 3. Three year revenue/cost projections are provided (see Attachment D).

**e) Relationship to the existing health care system**

The proposed project is expected to strengthen the existing health care system. Kapiolani is the only pediatric tertiary care hospital in the Pacific Basin. Its ability to provide state-of-the-art care will affect the medical outcomes for all women and children in the service area. The

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proposed project will enhance availability for physicians throughout the community ultimately providing greater scheduling convenience for patients throughout the State of Hawaii. The proposed bed changes will also enhance desirable outcomes for the care of obstetric, pediatric and newborn care. The proposed project will also not have a significant impact on the quality of care provided at Straub Medical Center's where the services are currently being performed.

**f) Availability of Resources.**

The proposed project will require the recruitment of 3.0 FTE cardiac technicians and 2.0 Cardiac Lab RNs by Year 3 of operations. Kapi'olani has 2 cardiology physicians plus contracted services to perform the procedures and would have capacity for increased volumes. Kapi'olani has sufficient trained professionals, management, systems and other resources to fully support the proposed project in addition to the expertise provided by its sister facility Straub Medical Center. The project will be funded from both cash and a fund drive. Approximately \$5.2M from philanthropic sources has already been committed to this project. We do not foresee any issues securing additional philanthropic resources to meet the remaining balance of this project.

**10. Eligibility to file for Administrative Review.** This project is eligible to file for Administrative review because: (Check all applicable)

- It involves bed changes, which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.
- It involves service changes which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.
- It is an acquisition of a health care facility or service, which will result in lower annual operating expenses for that facility, or service.
- It is a change of ownership, where the change is from one entity to another substantially related entity.
- It is an additional location of an existing service or facility.
- The applicant believes it will not have a significant impact on the health care system.