HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number 02-05A

Applicant: Hilo Medical Center

Project Title: Replacement of Peripheral Angiography Equipment

Project Address: 1190 Waianuenue Avenue, Hilo HI

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

Public	__X__
Private	_____
Non-profit	__X__
For-profit	_____
Individual	_____
Corporation	__X__
Partnership	_____
Limited Liability Corporation (LLC)	_____
Limited Liability Partnership (LLP)	_____
Other: _____	_____

2. **PROJECT LOCATION INFORMATION**

A. Project will be located in:

State Senate District Number: ___2__

State House District Number: ___2__

County Council District Number: ___2_

Neighborhood Board District Number (O`ahu only): _____

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

Statewide:	_____
O`ahu-wide:	_____
Honolulu:	_____
Windward O`ahu:	_____
West O`ahu:	_____
Maui County:	_____
Kaua`i County:	_____
Hawai`i County:	__X__

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.) N/A
C. Your governing body: list by names, titles and address/phone numbers Tab 1
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 N/A
   - By-Laws Tab 2
   - Partnership Agreements N/A
   - Tax Key Number (project's location) 2-3-27:2

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 Service	Change in Beds
Inpatient Facility		X			
Outpatient Facility					
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.

N/A

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

6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:		AMOUNT:
1.	Land Acquisition	
2.	Construction Contract	550,000
3.	Fixed Equipment	950,000
4.	Movable Equipment	
5.	Financing Costs	
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	
7.	Other: _____	
	TOTAL PROJECT COST:	1,500,000

B. Source of Funds		
1.	Cash	
2.	State Appropriations	
3.	Other Grants	
4.	Fund Drive	
5.	Debt	1,500,000
6.	Other: _____	
	TOTAL SOURCE OF FUNDS:	1,500,000

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.

___N/A_____

_____

_____

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:

Refer to page 7.

a) Date of site control for the proposed project,
b) Dates by which other government approvals/permits will be applied for and received,
c) Dates by which financing is assured for the project,
d) Date construction will commence,
e) Length of construction period,
f) Date of completion of the project,
g) Date of commencement of operation

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.

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.

Refer to pages 8 – 15.

a) Relationship to the Hawai`i Health Performance Plan (H2P2), also known as the State of Hawai`i Health Services and Facilities Plan.
b) Need and Accessibility
c) Quality of Service/Care
d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
e) Relationship to the existing health care system
f) Availability of Resources.

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.

__X__ The applicant believes it will not have a significant impact on the health care system.

PERIPHERAL ANGIOGRAPHY EQUIPMENT PURCHASE
PROJECTED TIMELINE

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	N/A
c) Dates by which financing is assured for the project	4-26-02
d) Dates for RFOP	
(1) RFP for equipment completed and sent	5-10-02
(2) RFP for equipment awarded	6-10-02
e) Date construction will commence	
(1) Completion of drafting of construction plans	7-10-02
(2) Construction bids awarded/ ordering materials/ permits acquired	7-17-02
(3) Construction begins	10-16-02
f) Length of construction period	
(1) Room renovation completed	1-15-03
(2) New equipment installation	1-17-03
g) Date of completion of the project/ testing	2-13-03
h) Date of commencement of operation	3-03-03

9. Executive Summary

Introduction

Hilo Medical Center (HMC), part of the Hawaii Health Systems Corporation (HHSC), is replacing the peripheral angiography equipment that was purchased in 1994. The angiography unit was a refurbished unit from the University of Washington. About one year ago, the occurrence of mechanical malfunctions became a concern and efforts began for a possible replacement. Mechanical malfunction downtimes have now increased and recently, HMC experienced five downtimes within a four-week period. One of the recent malfunctions occurred while a patient was having a procedure performed. Arrangements were made with the operating room to borrow their mobile C-arm and the procedure, with many adjustments, was safely completed. As of this writing, the angiography equipment has malfunctioned again and repair is expected to be about 1 to 2 weeks in length. This equipment is at the end of its expected working life and within a very short time, it will no longer be operable in a safe manner. Being that this is the only peripheral angiography unit on the Big Island, the entire island is currently without angiography services and will be without angiography service if Hilo does not replace its unit soon.

The estimated costs of the new replacement angiography equipment project are $950,000 for the equipment and $550,000 for the room renovation cost, with a sum of $1,500,000. The actual room renovation cost is unknown at this time because the design plans have not been drawn and the project has not gone out for bidding. Hilo Medical Center has the only angiography unit for the Big Island and we want to continue to provide that service for our community.

A. Relationship to the H2P2

This proposal relates well to the provisions of the H2P2. HMC is a full service, tertiary care facility and as such must continue to have a full service Imaging Department, including angiography services for inpatients, outpatients and emergency patients.

The critical elements of a health care delivery system, as defined in the H2P2, are access, quality management, cost-effectiveness, continuity of care and constituent participation. All of these are addressed through the provision of angiography services at HMC.

- Access to angiography services is assured to all patients, including inpatients, outpatients and emergency patients.

- Quality is assured through the hospital's quality control programs, as well as through the history and experience of the technical and professional angiography staff.
- Cost-effectiveness is assured through the provision of a necessary diagnostic service to patients who reside on the Big Island, in a facility with a wide range of therapeutic services appropriate to the diagnosis.
- Continuity of care is assured through the provision of the service at Hilo's only medical center and only angiography unit on the island, with a wide range of medical professionals and inpatient and outpatient services.
- Constituent participation is assured through the input of various consumer and provider groups in the functioning of the medical center.

The proposal also relates well to the values and priorities of the Hawaii County Subarea Health Planning Council, as identified on pages III-12 to III-16 of the H2P2.

B. Need and Accessibility

The proposal relates well to these criteria. The County of Hawaii, which encompasses the entire Big Island of Hawaii, covers over 4,000 square miles, and has a population of almost 150,000[1]. Being a safety net hospital for the Big Island, we accept all income categories for services. We also accept patients of all ages, all racial and ethnic groups, all genders, and all disability types that need peripheral angiography services.

The availability of comprehensive healthcare for this Big Island community is very clear. Reimbursement for the vast majority (70%) of HMC's patients is provided through Medicare, Medicaid, or Quest. (Refer to Tab 3.) These population groups tend to be the more vulnerable ones as they are elderly and/or are of low income. Prior to the availability of angiography services on the Big Island, residents, regardless of financial resources, were forced to make the difficult decision of whether they could afford to go off-island for the procedure, remain on-island for less-than-optimal care, or not have the procedure at all.

The angiography services at HMC has provided the following number of procedures in recent years:

- 1996 - 171 procedures (start of services)
- 1997 - 179 procedures ↑ 8 procedures or 5% from previous year
- 1998 - 261 procedures ↑ 82 procedures or 44% from previous year
- 1999 - 290 procedures ↑ 19 procedures or 71% from previous year
- 2000 - 347 procedures ↑ 57 procedures or 19% from previous year

[1] U.S. Census Bureau, Census 2000

- 2001 - 401 procedures ↑ 54 procedures or 15% from previous year

The numbers of procedures have increased on the average of 17% over the past six years that angiography services have been available on the Big Island. The large increases in 1998 and 1999 occurred because a new vascular surgeon started practicing in Hilo. All of these Big Island patients have received angiography services in a less costly environment for themselves and their families.

Of the number of procedures performed in 2001, about 120 of them were for hemodialysis grafting, which is performed as an outpatient procedure. After undergoing this procedure, a patient is now able to receive hemodialysis treatments. If HMC did not have angiography services, the hemodialysis grafts would either need to be performed as an ambulatory surgical procedure, an inpatient surgical procedure, or the patient would need to fly off-island. Each of these three alternatives is respectively more costly for the patient and the family member(s) who usually accompanies them, and can be costly for the entire health system when an inpatient procedure is performed where an outpatient procedure could have been performed.

Also, with the new equipment replacement, HMC hopes to offer more and improved vascular services to include:

- Transjugular Intrahepatic Portosystemic Shunt (TIPS) – The current image intensifier is not able to visualize the patient's anatomy very well for this procedure. Patients who may need to have this procedure are having problems with their liver. The new image intensifier can more accurately view the venous system of the liver, thereby making this procedure possible.
- Rotational angiography - The image intensifier can move around the patient in a smooth arc and the intensifier could be on the entire time. The current equipment only takes views in a single angle and plane. This rotational equipment characteristic in both the image intensifier and the table is extremely helpful because arteries and veins do not travel only in a straight line and in only one plane. The new equipment will be able "to go with the flow" of the arteries and veins, have a much more realistic and accurate view of what is occurring, and therefore give more accurate diagnosis and perform more appropriate treatments.
- Stent-grafts – Peripheral stent-grafts will be possible now because of both the rotational capabilities of the equipment and the larger image intensifier. Stent-grafts are grafts that will allow the vascular system to flow better because the procedure will either open the vein/artery, plug a hole in the vein/artery, or divert the flow to a different vein/artery. Individuals who may need stent-grafts will

include those with different types of aneurysms, those with clogged/occluded arteries/veins, or those with abnormal vascular flow (vessel stenosis).

- CO2 Angiography – The new equipment will have software and hardware that will be able to inject carbon dioxide as an alternative contrast agent if needed. This is not as effective but it is much safer for some patients. Also, the use of carbon dioxide also means less possibility of damage to the patient's kidneys

The angiography unit will be placed in a different room within the Imaging Department but the same department will still manage the service and the room change will not affect the accessibility of any patient. (Refer to Tab 4.)

Having peripheral angiography services directly here on the Big Island means that this population will continue to have accessible services to those in all income levels, all ages, any racial or ethnic groups, any gender type, or any disability type. With the new equipment, it means that new and more types of individuals will also be able receive accessible peripheral angiography services.

C. Quality of Service/Care

The proposal relates well to these criteria. HMC is accredited by the Joint Commission of Accreditation of Healthcare Organizations (JCAHO), is so licensed by the Department the Health/Medicare certified. (Refer to Tab 5.)

The Imaging Department participates in HMC's Quality Improvement process. The angiography department within Imaging, has an annual quality calendar with quality assurance studies that are regularly performed and is working on at least one departmental performance improvement project. The information attached shows that trending of angiography data indicates that service improvements are working to increase quality and patient safety. (Refer to Tab 5.)

The staff of HMC and the radiologists from Hawaii Radiologic Associates, Inc. (HRA) have a history of providing quality angiography service, and this quality of care will continue. The interventional radiologists and the vascular surgeon are certified interventional specialists, the angiography nurses have 40 years of combined intensive care/ cardiac care/ angiography experience, and the angiography technologists have 35 years of combined angiography work experience, with one of the angiography technologists certified as a Certified Interventional Technologist. The department also has another Certified Interventional

Technologist who is currently not performing any angiography services but would be available if needed.

The current angiography equipment has a small image intensifier or camera, which means there is a small field of view. A small view field means that small area is where the interventional radiologist or the vascular surgeon can work at one time. During this time, the nurse or the technologist is injecting contrast material for that small area, the angiography equipment is on, taking pictures, and is emitting radiation to the patient and all the staff in the room. Each change in the position of the image intensifier has some overlap with the one before. This means that some of the contrast material and area being exposed to radiation, does receive a double exposure. This process to repeated for as many times as necessary to perform a peripheral angiography procedure. The longer it takes to complete an angiography procedure means that more radiation is probably being emitted. Therefore, having small fields of view is not optimal in peripheral angiography procedures.

The new replacement angiography equipment will produce a higher quality procedure and will create a much safer environment for the patient and the staff. This will be accomplished by:

- A larger view area because of the larger image intensifier.
- The interventional radiologist or the vascular surgeon ordering less contrast material to be injected which means less chance of a patient's kidneys being damaged.
- Having fewer position changes of the image intensifier therefore, less patient area receiving double exposure to radiation.
- More appropriate collimators to limit the scatter and extent of the radiation beam to also decrease radiation exposure.
- More appropriate filters to reduce radiation exposure.
- Performing the procedure quicker, meaning less radiation exposure for the patient and the staff.

The equipment that HMC is hopeful in obtaining is one that has the image intensifier on a ceiling mount for rotational capabilities and where the table is able to move slowly and smoothly back and forth and also rotationally as necessary. The lens of the image intensifier will be about 15", rather than our current 12". The images will have the capability to be sent over phone lines for telemedicine as well as be able to have regular hard copy film views.

The new replacement peripheral angiography equipment means less time involved for each procedure with higher quality service, in a much safer patient and staff environment.

Being accredited by JCAHO means that HMC must keep up with any new standard revision or addition. Just recently, JCAHO added new standards that relate to patient safety. These new standards have also meant new interpretations of existing standards as they relate to patient safety. The new angiography equipment will assist HMC in further meeting the intent of the patient safety standard because of the reasons stated above.

The Request for Oral Proposal (RFOP) to purchase the equipment is currently being completed. This RFOP is asking for bids on angiography equipment with specific criteria that HMC has established and will be completed by May 10, 2002. The vendors being considered are Philips, Seimens, and GE. The Philips and Seimens equipment specifications are attached but GE's specifications are not available at this time. The GE specifications and pricing is expected to be similar to the ones initially presented by Philips and Seimans. (Refer to Tabs 6 and 7.) The vendor contract will hopefully be awarded by June 10, 2002. Drafting of the construction plans completed by July 10,2002. Contract construction awarded with the construction materials ordered and permits acquired by July 17, 2002. Construction begins by October 16, 2002 and ends on January 15, 2003. Equipment installation and testing will be completed by February 13, 2003. The new equipment will be operational by March 3, 2003. (Refer to page 7.)

Without the new equipment, higher quality current and new types of angiography procedures in a safer environment will not be available to both the East and West sides of the Big Island.

D. Cost and Finances

This service does not generate enough revenue for HMC to be profitable at this time, as shown in the attached performa. (Refer to Tab 8.) However, this service, like most OB nursing units of smaller hospitals that are also not profitable, is necessary for a full service community hospital even if it does not pay for itself. Hilo uses revenues from other services in the Imaging Department to offset the losses in this service.

HMC will not be increasing the charge for angiography procedures at this time. Rate changes for HHSC occurs as a grouping with other procedures and services and in combination with a financial analysis of the HHSC systems.

Hilo Medical Center currently performs about four to five angiography procedures daily, Monday through Friday. It is also available for emergency use during evening and night hours as well as on weekends and holidays by an on-call team.

With new, state-of-the-art equipment, HMC anticipates a very conservative 10% increase in volume each year for the first two years, and then a declining increase in the succeeding years. The performa shows a loss that accumulates over a seven-year period of about $211,000. This is a loss that HMC is hoping to decrease by promoting the new types of procedures the equipment will be able to perform and to gain back any business that is currently going to Oahu. If HMC projected the average 17% increase for each of the years in a performa, the ending seven-year revenue would be about $5,912,000. Subtracting the total expenses (no percentage increase added) gives an increase (profit) in the seven-years of about $1,394,000. Hilo Medical Center is of the opinion that the actual figure will be somewhere in between the $211,000 loss and the $1,394,000 profit, reflecting the most conservative and a liberal estimate respectively.

What this performa does **not** show, is the loss of revenue for HMC and the Big Island community if Hilo's only vascular surgeon must leave because he does not have the necessary equipment for his practice. This revenue loss would be in decreased angiography figures as well as in "spin-off" business such as the surgical service revenues and surgical care unit revenues (reduction in patient care days). Another complicating factor is that this vascular surgeon happens to be married to another physician who is a practicing OB/GYN. HMC and the Hilo community would also lose the income that she generates and the services that she provides. She is also the only female OB/GYN in the Hilo community. Both of these physicians leaving our rural community would create a significant gap in specialty services for the Big Island.

The performa also does **not** show the loss of revenue for HMC and the Big Island community if one or more of the interventional radiologists decides to leave because the equipment is not replaced and the peripheral angiography services no longer exist. This possible loss would have great ramifications not only for the angiography service, but also for all of the other imaging services for this island. Fewer radiologists for the Big Island mean fewer imaging services. This is not acceptable for the Big Island.

Sometimes, projects need to be positively considered for the good of the community even though they do not generate enough income to offset its expenses. HMC believes that this angiography equipment replacement project is one of these projects.

E. Relationship to the Existing Health Care System

The proposal relates well to these criteria. HMC is the major health care facility on the Big Island, the only one with an angiography unit, and its

patients (inpatients, outpatient and emergency) need angiography services to be readily available. The only other alternative would be to fly off-island for the service.

F. Availability of Resources

The proposal meets these criteria. The necessary capital resources will be with funds borrowed from Academic Capital. (Refer to Tab 9.) The operating expenses will be funded from HMC's general fund. The physicans utilizing the equipment are already here on the island. The angiography nurses and technologists are also already on staff at the medical center. No new staff are expected to be needed/hired.