

November 20, 2015

Eileen Fleck  
Chief, Acute Care Policy and Planning  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, Maryland 21215

**Re: MHCC Questions concerning HCGH's submission for a Certificate of  
Conformance, Primary PCI Services**

Dear Ms. Fleck,

Thank you for the opportunity to respond to the Maryland Health Care Commission's inquiries about Holy Cross Germantown Hospital's application for a Certificate of Conformance, Primary PCI Services. Our response is attached. If you have additional questions, please do not hesitate to contact me at 301-754-7017, or [Kristin.Feliciano@holycrosshealth.org](mailto:Kristin.Feliciano@holycrosshealth.org).

Sincerely,

*Kristin Feliciano* 

Kristin Feliciano,  
Chief Strategy Officer

Cc: Kevin Sexton  
Blair Eig, MD  
Doug Ryder  
Sherri Thompson-Brusca  
Rebecca Vaughan

## **Holy Cross Germantown Hospital Responses to MHCC Questions Concerning its submission for Certificate of Conformance, Primary PCI Services**

### **Quality Measures**

- 1. What is HCGH's assessment of its performance on quality measures that pertain to cardiac care, such as those under the categories heart attack and chest pain, heart failure, and emergency room? Are these measures among those HCGH is tracking closely? If not, please explain.**

Holy Cross Germantown Hospital (HCGH) has developed effective structures and tools to ensure ongoing monitoring and reporting of quality and safety indicators and to evaluate processes on an ongoing basis for both stability and opportunity for improvement. Indicators of performance are shared with staff and leaders and are tracked closely by the hospital-wide Quality and Patient Safety Council and the Quality Committee of the Board of Directors.

Assessment of the care of patients with cardiac conditions begins in the ED and follows the patients through their stay. The Clinical Efficiency Steering Committee monitors patient flow including length of stay and time markers during the ED visit. When there is evidence of a STEMI, the ED uses an activation log to record notification of a PCI facility, EMS arrival and patient transfer. Performance data for patients being transferred show a 10-minute median time to EKG, 100% compliance for ASA, and a median transfer time of 80 minutes.

Holy Cross Germantown Hospital has established a process for the concurrent review of care for all inpatients and observation patients with acute coronary syndrome, AMI or Heart Failure. This process is identical to that in place at Holy Cross Hospital in Silver Spring and leverages a large experienced staff.

Documentation of recommended treatments appropriate to each patient is verified, follow-ups are identified and feedback is provided to caregivers and organizational leadership daily. When an opportunity for improvement is identified, an appropriate action plan is implemented. HCGH is in the process of contracting with NCDR for cardiac data entry. Concurrent review of performance on core cardiac metrics in the first year of operation appears below and on the next page.

**Table 1. HCGH Performance on AMI Measures**

<b>4Q2014 n=20*</b>	
<b>Measure</b>	<b>% Compliance</b>
ASA within 24 hrs	100%
ASA on discharge	100%
ACE/ARB	100%
Smoking Cessation Advice	100%
BB on discharge	100%

<b>1Q2015 n=20*</b>	
<b>Measure</b>	<b>% Compliance</b>
ASA within 24 hrs	100%
ASA on discharge	100%
ACE/ARB (2 of 3)	67%
Smoking Cessation Advice	100%
BB on discharge	100%

<b>2Q2015 n=16*</b>	
<b>Measure</b>	<b>% Compliance</b>
ASA within 24 hrs	92%
ASA on discharge	100%
ACE/ARB	100%
Smoking Cessation Advice	100%
BB on discharge	100%

<b>3Q2015 n=17*</b>	
<b>Measure</b>	<b>% Compliance</b>
ASA within 24 hrs	92%
ASA on discharge	100%
ACE/ARB	n/a
Smoking Cessation Advice	100%
BB on discharge	100%



**Table 2. HCGH Performamance on Heart Failure Measures**

4Q2014 n=93*		2Q2015 n=111*	
Measure	% Compliance	Measure	% Compliance
LVF Assessment	99%	LVF Assessment	98%
ACE/ARB if LVSD	100%	ACE/ARB if LVSD	100%
Smoking Cessation Advice	100%	Smoking Cessation Advice	80%

1Q2015 n=121*		3Q2014 n=114*	
Measure	% Compliance	Measure	% Compliance
LVF Assessment	98%	LVF Assessment	99%
ACE/ARB if LVSD	94%	ACE/ARB if LVSD	100%
Smoking Cessation Advice	95%	Smoking Cessation Advice	100%

\*indicates the number of patients with acute coronary symptoms or AMI and patients with suspected HF or history of HF who were concurrently reviewed

In addition to efficiency and clinical metrics, readmission rates are monitored overall and specifically for AMI and HF in the senior population. The six-month rolling rate for AMI is 0 and for HF is at threshold level at 18.4%. To reduce readmissions, HCGH patients are contacted post discharge to assure they have their medications and physician appointments and to answer questions as needed.

**Table 3. HCGH Readmissions, February – July 2015**

Measure	Six month Rolling Score	Exceptional, Target, Threshold
All cause readmission rate for AMI	0.0%	10.4%, 11.0%, 11.6%
All cause readmission rate for HF	18.4%	14.9%, 15.8%, 19.0%

Finally, HCGH measures many ED statistics including wait times, time to treatment, and time on both red and yellow alert. The last set of measures is one that has received considerable focus, given our large ED volumes (average of 65 patients per day) and the immediate response to the Hospital's presence since opening in October 2014. We are proud to note that during the last quarter (July - September 2015) HCGH was down to 4.40 hours/month on red and 5.38/month on yellow alert. In the month of October 2015 the hospital lowered them further to 3.85 hours on red alert and 0.00 hours on yellow alert.

### **Access to Emergency PCI**

2. Please explain why the reductions in travel times to the nearest MIEMMS designated interventional cardiac center noted in your response to question #10 on the application demonstrates residents in the primary service area of HCGH need access to a primary PCI program at HCGH. For all zip code areas listed in Table 3 of the application, the travel time is less than 30 minutes, the maximum potential reduction in travel time afforded by a primary PCI program at HCGH is 9 minutes, and the average potential travel time minutes saved for all the zip code areas is 4.5 minutes. Is there any basis in the scientific literature indicating that these small travel time gains for a relatively small number of patients necessitate the establishment of an emergency PCI program?

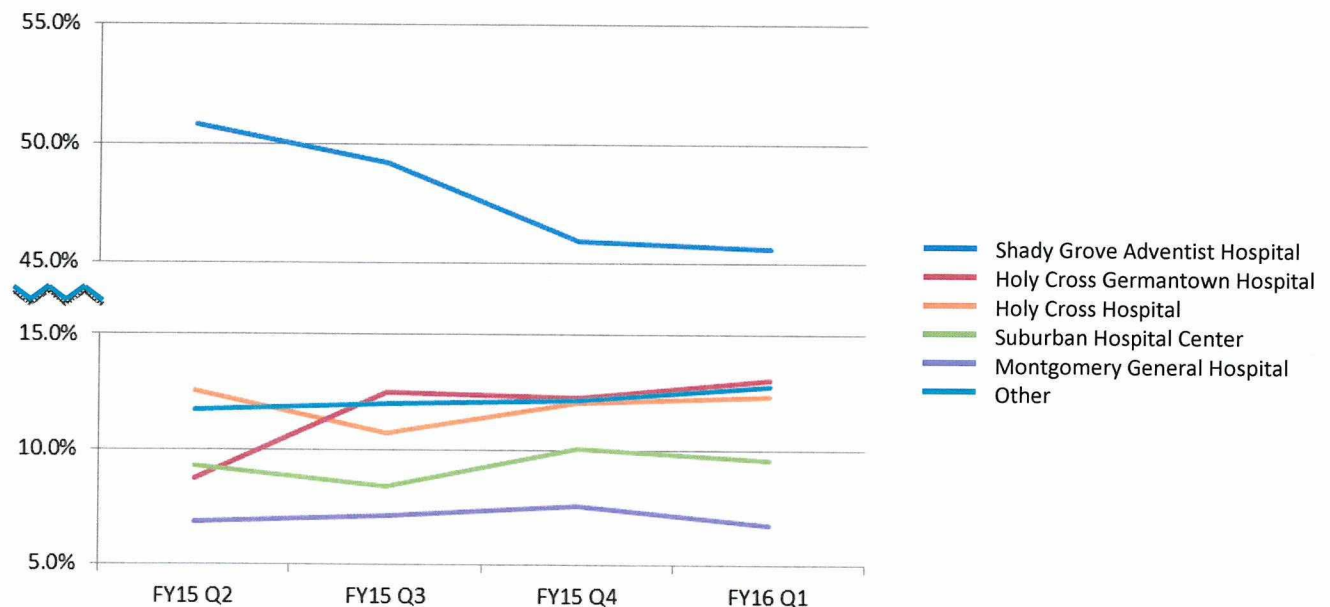
While there is no documentation in the scientific literature indicating that a reduction in travel time of 4.5 – 9 minutes necessitates the establishment of an emergency PCI program, the importance of time to treatment for STEMI, specifically when using primary percutaneous coronary intervention,

has been well documented by multiple organizations including the American Heart Association and the American College of Cardiologists. Many scientific studies, e.g., McNamara RL, Wang Y, Herrin J, et al. in "Effect of Door-to-Balloon Time on Mortality in Patients with ST-Segment Elevation Myocardial Infarction,"<sup>1</sup> have documented the strong association between time to treatment and mortality, i.e., longer times to treatment are correlated with increased mortality. In a situation where, "time is muscle," reducing transport times to facilities certified to perform pPCI shortens the overall time to treatment.

In addition to the literature underscoring the importance of swift treatment times for STEMI, there is support for a primary PCI program at Holy Cross Germantown from both the area Emergency Medical Services and the community at large. Fire Chiefs in Montgomery County and Frederick County provided letters of support for a pPCI program at HCGH with the original application. Community support for services at Holy Cross Germantown Hospital is highlighted by the hospital's continued gain in market share in its service area (see table below – HCGH is the red line). HCGH market share has grown from 8.7% in its first quarter of operation to 13% at the end of its first year of operation.

This increased market share brings with it the responsibility and expectations to offer the community necessary life-saving services such as pPCI. Without the ability to perform this procedure, the critical time element for STEMI patients who choose HCGH is the time from assessment to transfer to arrival at the nearest available cardiac interventional center. The additional time for these patients is a significant factor in receiving life-saving measures that would be performed in a more timely fashion if the services were available at Holy Cross Germantown Hospital.

**Table 4. Market Share in the HCGH Service Area, Q2FY15 – Q1FY16**



3. Does HCGH believe that the small reductions in travel time that may result from the proposed project will produce a measurable benefit in the outcome of PCI? If yes, please provide the basis for this belief.

<sup>1</sup> McNamara RL, Wang Y, Herrin J, et al. Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. Journal of the American College of Cardiology 2006;47:2180-2186



Yes, Holy Cross Germantown Hospital believes that reducing transport time, and hence overall time to treatment, will lead to better outcomes for patients. In a September 2013 article in *The New England Journal of Medicine* on "Door-to-Balloon Time and Mortality among Patients Undergoing PCI," the study authors noted that:

*Door-to-balloon time is one component of total ischemic time; as door-to-balloon time is reduced, it becomes a smaller fraction of total ischemic time, making the time before arrival at a hospital a more important factor. Therefore, efforts with potential to improve outcomes may include increasing patients' awareness of symptoms, reducing the interval from the time of symptom onset to treatment, and shortening the transfer time between medical facilities.<sup>2</sup> (Emphasis added)*

Another way that we can reduce time from onset of symptoms to treatment is to reduce the need to transfer patients out for cardiac intervention. Holy Cross Germantown Hospital serves a large number of walk-in patients who choose us as their preferred provider of emergency care. Without being able to provide pPCI, we limit their access to timely care and extend the time to treatment.

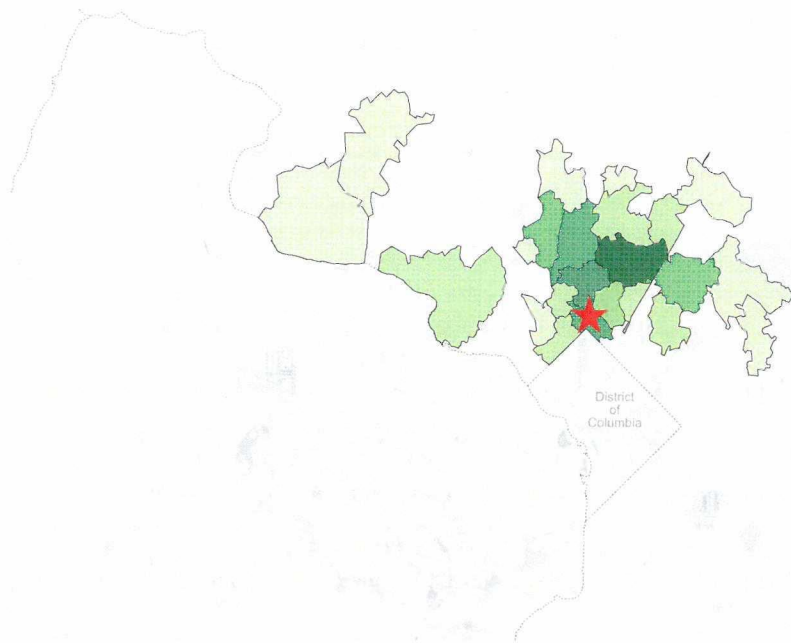
**4. Are the assumptions regarding market share in zip code areas bordering and near HCGH, as shown in Table 4 of the application, consistent with the experience of the primary PCI program at Holy Cross Hospital or other hospitals in Maryland that HCGH may regard as comparable?**

Yes, the assumptions on market share in the HCGH service area are in keeping with the experience of other pPCI programs. Specifically, looking at 2014 pPCI volume by zip code for Holy Cross Hospital, Frederick Memorial Hospital and Shady Grove Adventist Hospital shows that the majority of pPCI cases for each of these institutions come from zip codes that border or are near each of these facilities (see maps below). Excluding pPCI cases for patients with home zip codes outside of Maryland and DC, all three hospitals drew approximately 60% of pPCI cases from the 5 zip codes in and around the zip code where the hospital is located.

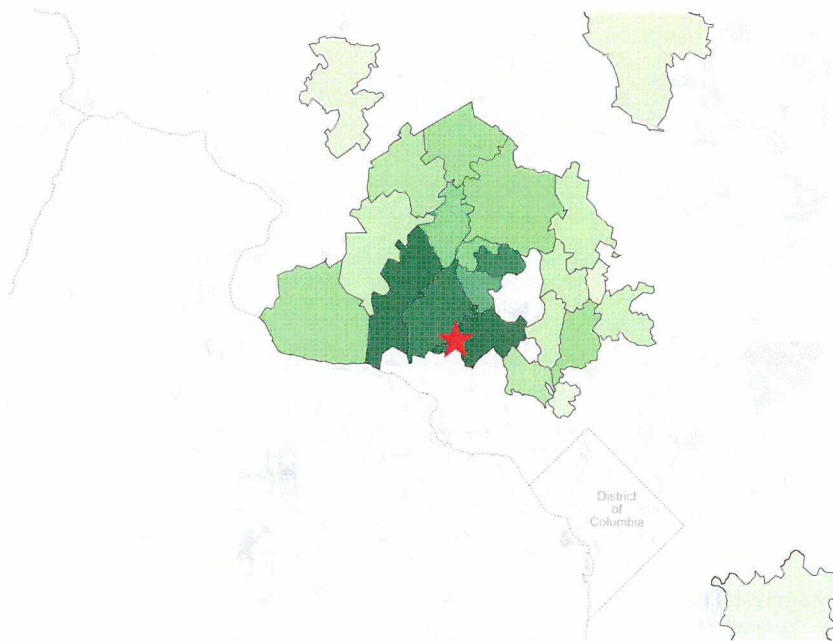
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<sup>2</sup> Door-to-Balloon Time and Mortality among Patients Undergoing Primary PCI; Daniel S. Menees, M.D., Eric D. Peterson, M.D., Yongfei Wang, M.S., Jephtha P. Curtis, M.D., John C. Messenger, M.D., John S. Rumsfeld, M.D., Ph.D., and Hitinder S. Gurm, M.B., B.S.; *New England Journal of Medicine* 2013; 369:901-909, September 5, 2013

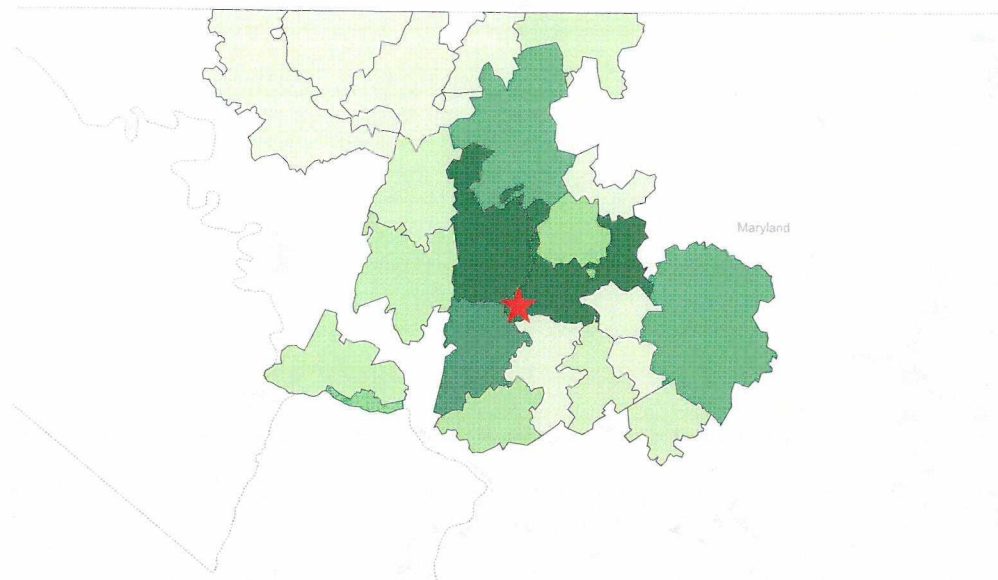
**Map 1. Holy Cross Hospital: 2014 pPCI Cases by Zip Code (MD and DC only)**



**Map 2. Shady Grove Adventist Hospital: 2014 pPCI Cases by Zip Code (MD and DC only)**



**Map 3. Frederick Memorial Hospital: 2014 pPCI Cases by Zip Code (MD and DC only)**



- 5. Please explain why your response to question #12 on the application demonstrates that residents in the primary service area of HCGH are receiving suboptimal therapy for STEMI. Is there any evidence that the hours on diversion resulted in worse patient outcomes for STEMI patients? What were the transports times for the five cases in 2014 and the three cases in 2013, with a transportation time greater than 30 minutes? If known, what factors contributed to excessive transport times in these cases?**

An article published in November 2015 in *Health Affairs*, "Ambulance Diversion Associated with Reduced Access to Cardiac Technology and Increased One-Year Mortality," found that even when controlling for available technology, patients admitted for acute MI during high periods of ED diversion "still experienced a statistically and clinically significant increase (8.2 percent relative increase) in long-term mortality compared to those who did not experience diversion." Further, the study authors posit that "we also recognize that this type of policy that allows exceptions to a hospital's ambulance diversion for a subset of conditions would not completely eliminate the disparities in health outcomes among cardiac patients experiencing different levels of diversion, since delay in treatment is still an important factor influencing patient outcomes."<sup>3</sup>

The chart below summarizes the transport times for the five cases in 2014 and three cases in 2013 where the transport time was greater than 30 minutes. It is not known with any certainty what led to the transport times in excess of 30 minutes. Reviewing the data for these 8 calls does not show any clear patterns as the days of the week and times of day both vary – with only one call, on 5/13/2013 occurring during rush hour.

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<sup>3</sup> Yu-Chu Shen and Renee Y. Hsia; Ambulance Diversion Associated With Reduced Access To Cardiac Technology And Increased One-Year Mortality; *Health Affairs*, 34, no.8 (2015):1273-1280



**Table 5. STEMI Cases with EMS Transport Times in Excess of 30 Minutes, Calendar Years 2013 - 2014, HCGH Primary Service Area**

Chief Complaint	Incident Date	Zip Code	Service Area	Dispatch	On-Scene	Hospital Depart	Hospital Arrival	Transport Time
Chest Pain - STEMI- Yes	5/13/2013	20879	HCGH PSA	4:39 PM	4:45 PM	4:58 PM	5:48 PM	0:49
Cardiac - STEMI- Yes	6/30/2013	20878	HCGH PSA	3:11 PM	3:16 PM	3:32 PM	4:10 PM	0:38
Cardiac - STEMI- Yes	7/4/2013	20877	HCGH PSA	8:18 PM	8:24 PM	8:40 PM	9:16 PM	0:36
Chest Pain - STEMI- Yes	3/17/2014	20872	HCGH SSA	7:40 AM	7:51 AM	8:01 AM	8:52 AM	0:50
Chest Pain - STEMI- Yes	8/18/2014	20872	HCGH SSA	10:35 AM	10:37 AM	10:47 AM	11:34 AM	0:47
Cardiac - STEMI- Yes	10/5/2014	20837	HCGH SSA	9:37 AM	9:50 AM	10:18 AM	10:54 AM	0:36
Chest Pain - STEMI- Yes	12/2/2014	20876	HCGH PSA	2:56 PM	2:59 PM	3:13 PM	3:48 PM	0:34
Chest Pain - STEMI- Yes	10/30/2014	20878	HCGH PSA	5:29 AM	5:37 AM	5:55 AM	6:27 AM	0:32

### **Staffing**

#### **6. Could you confirm the number of Interventionalists included among the four physician FTEs included in your response to question #16?**

There are four Cardiac Interventionalists on staff at HCGH among the four physician FTEs included in our response to question #16:

- Dennis Friedman, M.D.
- Thomas Wang, M.D.
- Greg Fisher, M.D.
- Mike Chen, M.D.

### **Capital Expenditure**

#### **7. The Response to Question 31 was "yes," the introduction of primary PCI will require a capital expenditure. However, Form A was not attached to the application. Please provide Form A. Identify the source of the cost estimate and provide any assumptions needed to validate or interpret the cost estimate.**

Form A appears on the last two pages of this document. We inadvertently omitted it from the application that we submitted to the Commission on October 16, 2015.

The minor capital equipment to be purchased is an ACIST Contrast Injection System - CVi with mobile cart accessory for a total cost of \$26,000.

The ACIST|CVi® Contrast Delivery System is used for controlled infusion of radiopaque contrast media used in pPCI procedures. It simplifies contrast injection for these procedures, from small injections in the coronary arteries, to large volumes in the ventricles and peripheral vasculature. The system has been shown to reduce procedure time and the volume of contrast delivered to the patient by providing precise contrast delivery. It includes an array of advanced, built-in safety features that provide continuous and automated monitoring of all critical systems functions, and can deliver contrast with ease even through 4Fr catheters. By reducing overall procedure time the



ACIST CVi helps to reduce radiation exposure. It is designed and built to streamline procedures and deliver faster case turnaround, while minimizing the use of contrast. <sup>4</sup>

HCGH identified the need for the ACIST system and mobile cart based on consultations with the interventional cardiologists on staff at HCGH and with Holy Cross Hospital Medical Imaging leadership about additional equipment that would be needed to perform pPCI procedures in the HCGH cardiac cath lab. The Supply Chain department obtained the cost estimate from the vendor and then validated the cost based on HPB/Trinity Health contracts; other purchases made by Trinity hospital systems around the United States; and, cost information in MDBuyline. The Supply Chain staff also negotiated directly with the vendor on price. (Holy Cross Health is a health system within Trinity Health)

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<sup>4</sup> [http://acist.com/wp-acist/wp-content/uploads/2015/06/ACIST-CVi-brochure-US\\_2014\\_LR.pdf](http://acist.com/wp-acist/wp-content/uploads/2015/06/ACIST-CVi-brochure-US_2014_LR.pdf), 11/10/2015

I hereby declare and affirm under penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

Kristin Feliciano (P)

Kristin H. Feliciano  
Chief Strategy Officer  
Holy Cross Health

November 20, 2014  
Date

**Form A: PROJECT BUDGET**

**INSTRUCTION:** This form is to be completed if capital expenditures will be necessary for the applicant hospital to provide pPCI services. All estimates for 1.a.-d., 2.a.-h., and 3 are for current costs as of the date of application submission and should include the costs for all intended construction and renovations to be undertaken. DO NOT CHANGE THIS FORM OR ITS LINE ITEMS. IF ADDITIONAL DETAIL OR CLARIFICATION IS NEEDED, ATTACH ADDITIONAL SHEETS.

**A. Use of Funds****1. Capital Costs:**

a.	<u>New Construction</u>	\$	0
(1)	Building		0
(2)	Fixed Equipment (not included in construction)		0
(3)	Land Purchase		0
(4)	Site Preparation		0
(5)	Architect/Engineering Fees		0
(6)	Permits, (Building, Utilities, Etc)		0

**SUBTOTAL** \$ 0

b.	<u>Renovations</u>		
(1)	Building	\$	0
(2)	Fixed Equipment (not included in construction)		0
(3)	Architect/Engineering Fees		0
(4)	Permits, (Building, Utilities, Etc.)		0

**SUBTOTAL** \$ 0

c.	<u>Other Capital Costs</u>		
(1)	Major Movable Equipment		0
(2)	Minor Movable Equipment		26,000
(3)	Contingencies		0
(4)	Other (Specify)		0

**TOTAL CURRENT CAPITAL COSTS** \$ 26,000  
(a - c)

d.	<u>Non Current Capital Cost</u>		
(1)	Interest (Gross)	\$	0
(2)	Inflation (state all assumptions, Including time period and rate)	\$	0

**TOTAL PROPOSED CAPITAL COSTS** \$ 26,000  
(a - d)



2. Financing Cost and Other Cash Requirements:

a.	Loan Placement Fees	\$	0
b.	Bond Discount		0
c.	Legal Fees (CON Related)		0
d.	Legal Fees (Other)		0
e.	Printing		0
f.	Consultant Fees		
	CON Application Assistance		0
	Other (Specify)		0
g.	Liquidation of Existing Debt		0
h.	Debt Service Reserve Fund		0
i.	Principal Amortization		
	Reserve Fund		0
j.	Other (Specify)		0

**TOTAL (a - j)** \$ 0

3. Working Capital Startup Costs \$ 0

**TOTAL USES OF FUNDS (1 - 3)** \$ 26,000

**B. Sources of Funds for Project:**

1.	Cash	26,000
2.	Pledges: Gross 0,	
	less allowance for	
	uncollectables 0	
	= Net	0
3.	Gifts, bequests	0
4.	Interest income (gross)	0
5.	Authorized Bonds	0
6.	Mortgage	0
7.	Working capital loans	0
8.	Grants or Appropriation	
	(a) Federal	0
	(b) State	0
	(c) Local	0
9.	Other (Specify)	0

**TOTAL SOURCES OF FUNDS (1-9)** \$ 26,000

**Lease Costs:**

a.	Land	\$	0	x	0	= \$	0
b.	Building	\$	0	x	0	= \$	0
c.	Major Movable Equipment	\$	0	x	0	= \$	0
d.	Minor Movable Equipment	\$	0	x	0	= \$	0
e.	Other (Specify)	\$	0	x	0	= \$	0