IN THE MATTER OF	*	**BEFORE THE**
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HOLY CROSS GERMANTOWN-HOSPITAL	*	**MARYLAND HEALTH**
	*	
	*	**CARE COMMISSION**
DOCKET NO. CC-15-15-0002	*	

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STAFF REPORT & RECOMMENDATION

APPLICATION FOR CERTIFICATE OF CONFORMANCE TO ESTABLISH PRIMARY PERCUTANEOUS CORONARY INTERVENTION SERVICES

Released March 11, 2016

I. INTRODUCTION

A. Background

The Maryland Health Care Commission (MHCC) began regulating cardiac surgery and percutaneous coronary intervention (PCI) services through a Certificate of Need process in 1990. For many years, only hospitals with cardiac surgery services on-site could provide PCI services. This approach was adopted because emergency cardiac surgery may be required for a complication of, or inability to satisfactorily complete, PCI. Percutaneous coronary intervention, commonly known as coronary angioplasty, is a non-surgical cardiac procedure in which a catheter is used to place a stent to open blood vessels in the heart that have been narrowed or blocked by a buildup of plaque. Early PCI intervention is a critical factor in preserving life and minimizing damage to heart muscle, thereby improving the recovery potential for the patient. Primary PCI (pPCI) programs provide emergency PCI intervention in the event of a heart attack shortly after it begins. Non-primary PCI programs provide elective interventions that re-vascularize coronary arteries that are substantially blocked but have not resulted in an immediate cardiac event requiring emergency treatment.

As cardiologists gained experience with primary PCI and better techniques evolved, the risks of the procedure declined and results improved. Consequently, in 1996, Maryland began allowing some hospitals to perform primary PCI at hospitals without cardiac surgery on-site, through a program in which the MHCC issued waivers to the co-location requirement. In order to obtain and maintain a waiver to perform primary PCI without on-site cardiac surgery services, a hospital had to meet standards adopted by the MHCC.

In its 2004 Cardiac Surgery & PCI Services Chapter of the State Health Plan, the Commission expressed its interest in considering a waiver from the co-location requirement to conduct a well-designed research study that would test the theory that performing non-primary (elective) PCI in a non-surgery-on-site hospital was not inferior to performing the procedure in a hospital with cardiac surgery on site. This change was very controversial. A research proposal by Dr. Thomas Aversano of Johns Hopkins was ultimately approved by the MHCC's Research Proposal Review Committee composed of national and regional experts. Nine Maryland hospitals participated in the C-PORT E research study. In 2012, Dr. Thomas Aversano presented new research from a multi-site clinical trial (C-PORT E) that found elective PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. As a result of these new research findings, in 2012, at the MHCC's request, the Maryland legislature passed a law directing the Commission to adopt new regulations for the oversight of PCI services at hospitals without on-site cardiac surgery. After extensive discussion with a clinical advisory group that developed formal recommendations, MHCC staff developed proposed regulations. The Commission then adopted new regulations for cardiac surgery and PCI services that became effective in August 2014, and which were subsequently updated in November 2015.

COMAR 10.24.17, the State Health Plan chapter for both PCI and cardiac surgery, contains standards for the establishment of new PCI programs and for evaluating performance of established PCI services in Maryland. An applicant's request to establish a new pPCI program,

elective PCI program, or both a pPCI and elective PCI program is considered through a Certificate of Conformance review. A Certificate of Conformance for primary PCI, if granted, authorizes a hospital to provide these services for a specified period of time. At the end of the time period, the hospital must meet requirements in COMAR 10.24.17 to renew its authorization to provide the PCI service by obtaining a Certificate of Ongoing Performance issued by the Maryland Health Care Commission if a hospital demonstrates that it has met quality and performance standards.

B. Applicant

Holy Cross Germantown Hospital (HCGH)

Holy Cross Germantown Hospital (HCGH or the Hospital) is a 93-bed general acute care hospital located in Germantown, Montgomery County, Maryland. The Hospital opened on October 1, 2014 and is part of Holy Cross Health, the Maryland component of Trinity Health, a large, not-for-profit multi-hospital system. Trinity Health owns and operates two Maryland hospitals, HCGH and Holy Cross Hospital of Silver Spring. Holy Cross Health submitted a Certificate of Conformance application on behalf of HCGH to perform pPCI, and it projects a capital cost of $26,000 for this project which is to be used for minor movable cardiac equipment.

Service Area

Montgomery County is Maryland's second most affluent County in terms of per capita income.[1] It is also the largest jurisdiction in the State, with an estimated population of 1,036,002 in 2015.[2] The Maryland Department of Planning projects that Montgomery County's population will increase about 7.1 percent between 2015 and 2025, a growth rate similar to that projected for the State overall. Population growth in Montgomery County is projected to be slightly higher than the Statewide average for the period 2015 through 2030 (11.4 percent compared to 10.0 percent). Between 2015 and 2025, the number of individuals age 65 and older is expected to increase at a much higher rate both in Montgomery County (36.2 percent) and Statewide (37.1 percent).[3]

There are six general hospitals in Montgomery County. Four provide primary PCI services. The closest general hospital to HCGH is Adventist HealthCare Shady Grove Medical Center in Rockville, approximately 7.4 miles from HCGH. It provides both primary and elective PCI services. The next closest general hospital is Suburban Hospital in Bethesda, at a distance of 12.9 miles. It provides cardiac surgery services and both primary and elective PCI. MedStar Montgomery Medical Center is located approximately 16.8 miles from HCGH, in Olney, and does not provide PCI services. Holy Cross Hospital, in Silver Spring, is located approximately 19.3 miles from HCGH and provides primary PCI services. Finally, Washington Adventist

[1] Maryland Department of Planning "Per Capita Personal Income for Maryland's Jurisdictions (in Constant 2009 $) (1/15)" http://www.mdp.state.md.us/msdc/s3_Projection.shtml (Accessed February 18, 2016).
[2] Maryland Department of Planning. "2014 Total Population Projections for Non-Hispanic White and All Other by Age, Sex and Race (7/8/14)." http://www.mdp.state.md.us/msdc/s3_Projection.shtml (Accessed February 18, 2016).
[3] Maryland Department of Planning. "2014 Total Population Projections for Non-Hispanic White and All Other by Age, Sex and Race (7/8/14)." http://www.mdp.state.md.us/msdc/s3_Projection.shtml (Accessed February 18, 2016).

Hospital provides cardiac surgery and both primary and elective PCI services. It is located in Takoma Park, approximately 23.1 miles from HCGH. A relocation of WAH is underway to the White Oak area of Silver Spring. When this hospital is relocated, it will be approximately 22.8 miles from HCGH.

The third closest Maryland hospital to HCGH offering PCI services is located outside of Montgomery County in Frederick. Frederick Memorial Hospital provides both primary and elective PCI services and is located approximately 22 miles from HCGH.

C. Staff Recommendation

MHCC staff recommends that the Commission deny HCGH's application for a Certificate of Conformance to establish a pPCI program because the residents in the proposed service area have adequate access to pPCI services. A description of the evidence presented by HCGH and MHCC staff's analysis of this information follows.

II. PROCEDURAL HISTORY

HCGH filed a Certificate of Conformance application on October 16, 2015. On November 20, 2015, HCGH submitted responses to questions, requests for additional information, and clarifications concerning its application for a Certificate of Conformance for pPCI services.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

10.24.17.06A(1) An applicant seeking a Certificate of Conformance to establish primary PCI services shall address and meet the general standards in COMAR 10.24.10.04A in its application.

The applicable standards from the Acute Care Hospital Services Chapter are shown below in bold.

(1) Information Regarding Charges.

Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

Maryland hospitals are required to make information regarding hospital charges available to the public. HCGH provided a copy of its most recent charge information, as well as the location of this information on the Hospital's web site. As required, this information includes a list of charges for the ten most common inpatient surgical procedures, medical imaging services, and laboratory services. HCGH stated that this list is displayed in the Hospital's registration area and in the cashier's area, in addition to posting the information on the Hospital's website. The list of charges includes the phone number for the Hospital's Financial Counseling Office for individuals seeking charge information on services that are not included on the list. In addition, the list includes phone numbers for inquiries regarding professional fees from physicians and other providers that may bill patients for care. Furthermore, HCGH stated that "[a]ll registration, financial counseling, customer service, cashier and patient accounting staff are trained regarding the availability of charge information and the process for forwarding patient requests for charge estimates to the financial counseling department." (Application, Exh. 1).

Staff Analysis

Based on the information provided in HCGH's application and MHCC staff's ability to locate updated charge information, MHCC staff concludes that HCGH is compliant with this standard.

(2) Charity Care Policy.

Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.

(a) The policy shall provide:

(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.

(ii) Minimum Required Notice of Charity Care Policy.

1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;

2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital;

3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.

(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

HCGH submitted a copy of the Hospital's written policy for patient financial assistance and the policy for the provision of charity care for indigent patients. This document included a statement of Holy Cross Health's mission for making medically necessary care available to individuals in need, and detailed the financial policies of the facilities operated by Holy Cross Health including HCGH as well as dissemination procedures. The applicant stated that its

financial policies are publicized to all patients verbally and are published yearly in the local newspapers. The document is prominently displayed throughout the Hospital and is posted on the Hospital's website. The policy is presented in plain language in English and Spanish and is available in other languages represented by the patient population.

Because HCGH only opened in October 2014, it was not included in the HSCRC's Community Benefit Report for FY 2014, the latest report available. However, HCGH noted that among all Maryland hospitals reporting charity care as a percentage of total operating expenses, the bottom quartile ranged from 0.3% to 2.1%, and HCGH's level of charity care for the period October 1, 2014 through June 30, 2015 was $2,108,744, which comprised 3.1 percent of its total operating expenses of $68,283,993 for the same period. (Application, p. 3). HCGH explained that the level of charity care that it had provided was likely appropriate to the needs of the population in its service area because Montgomery County is one of the most affluent counties in Maryland with an average household income of $94,965 and a high rate of insured residents. (Application, p. 3). HCGH cited the Community Need Index developed by Dignity Health and Truven Analytics to support this conclusion; the Community Need Index shows 4.2% of the population in the Hospital's service are is uninsured compared to 7.2% Statewide. (Application, p. 3). HCGH also noted that its commitment to the underserved is demonstrated by the presence of a Maternity Partnership clinic on the Hospital's campus and a primary care Health Center for adults and children that opened in May 2015 in Germantown, Maryland. (Application, p. 3).

Staff Analysis

MHCC staff verified through data provided by the Maryland Department of Planning that Montgomery County is one of the most affluent counties in Maryland. Based on information provided in HSCRC's Community Benefit Report for FY 2014, MHCC staff calculated the percentage of charity care relative to total operating expenses for the five other acute care general hospitals in Montgomery County: Adventist Shady Grove Medical Center; Suburban Hospital; Holy Cross Silver Spring Hospital; MedStar Montgomery General Hospital; and Washington Adventist Hospital. MHCC staff then compared the results to the level of charity care reported by HCGH. The percentage of charity care for Montgomery County hospitals ranged from 2.0% for Suburban Hospital to 7.9% for Holy Cross Silver Spring. The percentages of charity care provided by SGMC (3.4%) and MedStar Montgomery General Hospital (3.3%) were most similar to the level reported by HCGH (3.1%). Thus, it appears that HCGH provides a level of charity care that is similar to other hospitals located in Montgomery County. MHCC staff concludes that the level of charity care provided by HCGH is appropriate.

MHCC staff notes that HCGH meets the requirements for public distribution of its financial assistance policy. However, MHCC staff concludes that HCGH's financial assistance policy is inadequate because it states that a determination of probable eligibility will be made within two days of a completed application. The requirement for a "completed application" before the Hospital makes a determination of probable eligibility is unacceptable and does not comply with this standard. A determination of probable eligibility must be made based on the information submitted; a determination of final eligibility would be made after the hospital has complete information. If the Commission decides to approve HCGH's application, no Certificate of Conformance should issue until HCGH submits a revised financial assistance

policy that is in compliance with this standard.[4]

(3) Quality of Care.

An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

(i) Licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;

(ii) Accredited by the Joint Commission; and

(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.

(b) A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.

HCGH is a Medicare provider in good standing and has not been sanctioned, barred, or excluded from participating in the Medicare program. HCGH is also currently accredited by the Joint Commission which conducted a two-day site visit in September 2015. Following this site visit, minimal Requirements for Improvement were identified and the Hospital submitted a correction plan of action on October 26, 2015. HCGH noted that the Joint Commission has not denied, limited, or suspended its accreditation status, nor has the Hospital been put on Accreditation Watch by the Joint Commission. (Application, p. 2).

Because HCGH is a new hospital, its performance has not yet been included in the Maryland Hospital Performance Guide, which is based on 12 months of data. HCGH's data collection for quality measures for this guide began with its January 2015 discharges. However, HCGH stated that it has established a concurrent review process that assesses compliance daily with critical quality measures. (Application, p. 4). MHCC staff subsequently requested additional information from HCGH regarding its performance on quality measures that pertain to cardiac care. In correspondence to MHCC staff dated November 20, 2015, HCGC explained that Hospital performance indicators are tracked by the Hospital's Quality and Patient Safety Council and by the Quality Committee of the Board of Directors. HCGH noted that its assessment of care for patients with cardiac conditions begins in the emergency department (ED) with monitoring patient flow including various time markers during an ED visit. When there is evidence of an ST-elevated myocardial infarction (STEMI), a type of heart attack for which primary PCI is often the most appropriate emergency treatment, the ED uses an activation log to record notification of a PCI facility. Additional tracking includes emergency medical service (EMS) arrival and patient transfer, median time to administration of an electrocardiogram (EKG), used to diagnosis the heart attack as a STEMI, the administration of aspirin within 24 hours of arrival, and other measures. HCGH provided documentation of its review of performance on core cardiac metrics for the first year of operation including: performance on acute myocardial infarction (AMI) measures, performance on heart failure measures, and HCGH readmissions for AMI and heart failure, as shown in Tables 1, 2, and 3 below.

[4] If this were a Certificate of Need application, instead of a Certificate of Conformance application, staff would hold a project status conference pursuant to COMAR 10.24.01.092A, after which the hospital could revise its charity care policy and staff could make a recommendation on the application to the Commission.

Table 1: HCGH Performance on AMI Measures by Time Period

Measure	Level of Compliance by Time Period			
	2014Q4	2015Q1	2015Q2	2015Q3
Aspirin within 24 hours	100%	100%	92%	92%
Aspirin on discharge	100%	100%	100%	100%
Angiotensin Converting Enzyme (ACE) or Angiotensin Receptor Block (ARB)	100%	67%	100%	N/A
Smoking Cessation Advice	100%	100%	100%	100%
Beta Blocker on discharge	100%	100%	100%	100%
Total Number of Cases for Each Time Period	20	20	16	17

Source: HCGH November 20, 2015 correspondence with MHCC staff. (Table 1).

Table 2: HCGH Performance on Heart Failure Measures by Time Period

Measure	Level of Compliance by Time Period			
	2014Q4	2015Q1	2015Q2	2015Q3
Left Ventricular Function Assessment	99%	98%	98%	99%
ACE/ARB if Left Ventricular Systolic Dysfunction	100%	94%	100%	100%
Smoking Cessation Advice	100%	95%	80%	100%
Total Number of Cases for Each Time Period	93	121	111	114

Source: HCGH November 20, 2015 correspondence with MHCC staff. (Table 2).

Table 3: HCGH Readmissions, February- July 2015

Measure	Percent Readmissions	Exceptional, Target, Threshold
All Cause Readmission Rate for AMI	0.0%	10.4%,11.0%, 11.6%
All Cause Readmission Rate for Heart Failure	18.4%	14.9%, 15.8%, 19.0%

Source: HCGH November 20, 2015 correspondence with MHCC staff. (Table 3).

Staff Analysis

HCGH reported no readmissions for AMI. HCGH's overall readmission rate is below the Statewide risk-adjusted average for Maryland hospitals, 22.6 (data not shown), for the year ending June 30, 2014 (the range was 21.8 to 29.0).[5] As shown in Tables 1 and 2, HCGH almost always scores at 90% compliance or higher for each quarter. With regard to smoking cessation advice, although compliance was only 80% in the second quarter of 2015, the weighted average for all four quarters is above 90%. For the ACE/ARB measure (Table 1) in the first quarter of 2015, where HCGH reported compliance of only 67%, it noted that only three cases were counted for the measure. In another quarter, the measure did not apply, and in the other two quarters the standard was met with 100% compliance. MHCC staff is unable to calculate a weighted average for all four quarters based on the information provided. However, MHCC staff concludes that HCGH has complied with the quality of care standard based on its high level

[5] MHCC Hospital Guide. "Returning to the hospital after getting care for heart failure." (raw data) https://www.marylandqmdc.org/MarylandHospitalCompare/index.html#/quality-ratings/condition?topic=7&subtopic=21. (Accessed 2/22/16).

of performance in two of three applicable quarters for the ACE/ARB measure and on all other performance measures reported by HCGH for the most recent four quarters of data available.

10.24.17.06A(2)(a) A hospital shall demonstrate that the proposed program is needed for its service area population through an analysis of current utilization patterns of the population for primary PCI services

HCGH provided information on its proposed service area as defined by zip code areas and cities, including the pPCI volume for each zip code area in CY 2013 and CY 2014. (Application, Table 2). As shown in Table 4, HCGH identified 24 zip code areas in its proposed service area, with a total of 122 pPCI cases originating in its proposed service area in CY 2013 and 136 in CY 2014. HCGH attributes the 11% increase in pPCI case volume between CY 2013 and CY 2014 to the upper part of Montgomery County aging faster than the County and State as a whole. HCGH stated that the number of residents over age 65 in the upper part of Montgomery County will double in just 12 years, leading to an increase in the number of PCI cases compared to the rest of the County, which will double in 20 years. (Application, p. 5).

HCGH estimated travel times to current hospitals designated as Cardiac Interventional Centers by the Maryland Institute of Emergency Medical Services Systems (MIEMSS) as PCI Centers for the population in its service area, as shown in Table 4. HCGH reported that, if it established a pPCI program, travel times to HCGH would be shorter for 15 of the zip code areas (62.5%) and that, on average, non-rush hour patient travel to the closest PCI Center would be reduced by 4.5 minutes,. (Application, p. 6).

Table 4: Estimated Travel Times to Nearest Existing pPCI Provider and HCGH by Zip Code Area

Zip Code Area	Nearest Existing pPCI Provider			HCGH	
	Hospital Name*	Mileage	Travel Time (minutes)	Mileage	Travel Time (minutes)
20874	SGMC	8.6	14	5.3	9
20875	SGMC	8.9	14	2.8	7
20876	SGMC	11.4	17	3.6	8
20877	SGMC	4.4	13	5.2	13
20878	SGMC	5.0	11	7.3	13
20879	SGMC	7.3	16	6.4	12
20882	SGMC	13.8	26	10.9	21
20883	SGMC	7.0	13	5.4	10
20884	SGMC	3.8	10	5.0	10
20885	SGMC	4.5	8	4.9	8
20886	SGMC	7.6	14	3.5	10
20898	SGMC	2.2	7	6.8	9
20899	SGMC	4.2	8	3.8	6
20837	SGMC	15.1	24	14.9	23
20838	Frederick Memorial	17.7	20	13.8	17
20839	SGMC	16.6	25	15.6	24
20841	SGMC	11.0	19	6.5	13
20842	SGMC	16.4	26	12.0	19
20850	SGMC	3.1	8	9.0	11
20851	SGMC	5.1	15	11.7	16
20853	SGMC	6.9	14	14.9	17
20855	SGMC	6.3	15	11.1	16
20871	SGMC	13.0	16	6.1	11
20872	SGMC	17.0	23	8.5	16

Source: HCGH application, p. 6.
*Note: SGMC is Adventist HealthCare Shady Grove Medical Center.

HCGH stated that the need for a pPCI program in the upper part of Montgomery County is supported by data provided by the Montgomery County Fire and Rescue Services on the number of walk-in patients with symptoms that suggest possible myocardial infarction or acute STEMI. HCGH noted that 18 walk-in patients had to be transferred to the nearest PCI center in the first year that the Hospital operated and the transfer time adds critical time to the door-to-balloon time for those patients. HCGH's President Doug Ryder quoted paramedics for Montgomery County as saying "time is muscle." (Application, Exh. 2).

In a letter dated November 9, 2015, MHCC staff asked HCGH whether there was any basis in the scientific literature indicating that the small travel time gains cited necessitate the establishment of a pPCI program. HCGH responded in a letter dated November 20, 2015 that,

while there was no documentation in the literature specifically indicating that a reduction in travel time of 4-9 minutes would call for the establishment of a primary PCI program, studies suggest that longer times to treatment are associated with increased mortality. HCGH quoted a study from the September 5, 2013 *New England Journal of Medicine*, "Door-to-Balloon Time and Mortality among Patients Undergoing Primary PCI" as follows:

> 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. (p. 908)

HCGH stated that, by reducing transport time, and thereby overall time to treatment, patients would have better outcomes. HCGH also proposed that another way to reduce the time from onset of symptoms to treatment is to reduce the need to transfer patients for cardiac interventions. HCGH further explained that it serves a large number of walk-in patients who would have less access to timely care if HCGH is unable to provide pPCI services. Lastly, HCGH stated that its "increased market share brings with it the responsibility and expectation to offer the community necessary life-saving services such as pPCI." HCGH provided graph of the market share in the HCGH Service Area, with five of six Montgomery hospitals represented and an "other" category.

HCGH stated that an ED physician would initiate thrombolytic therapy,[6] such as the administration of tissue plasminogen activator (tPA) if it appears that the transfer time will be greater than 30 minutes. (Application, p, 10). It noted, however, that it "has not needed to nor administered tPA for any STEMI patients who needed to be transported to a certified interventional cardiac center. (Application, p. 9).

Staff Analysis

The impact of door-to-balloon time on mortality rates led to the wide adoption of a door-to-balloon time standard of 90 minutes or less, and continues to be the standard, as reflected in the current (2013) guidelines of The American College of Cardiology/American Heart Association for the Management of STEMI patients. As stated in COMAR 10.24.17.07D(4)(b), this standard has been adopted in Maryland for evaluating the quality of PCI programs. Maryland's PCI programs are expected to have a door-to-balloon time of 90 minutes or less for at least 75 percent of patients who receive pPCI, excluding transfer patients. Using the NCDR CathPCI Registry, a large national registry used by participants for quality improvement, MHCC staff investigated whether patients who received pPCI from zip code areas in the service area identified by HCGH met this standard in CY 2014. MHCC staff calculated that 80.5% of all patients had a door-to-balloon time of 90 minutes or less, without excluding transfer patients,

[6] Thrombolytic therapy is a less effective treatment than pPCI for a patient suffering a myocardial infarction or acute STEMI.

consistent with the quality standards adopted by the Commission.

MHCC staff investigated the number of transfer patients who received primary PCI services at Adventist HealthCare Shady Grove Medical Center (SGMC), the nearest hospital for all but one zip code area that HCGH includes in its expected service area. In the last quarter of 2014, there were four transfer patients who reside in the service area identified by HCGH that received primary PCI services. Their door-to-balloon times ranged from 87 to 99 minutes, with only one patient receiving pPCI within the 90 minute standard. In the first two quarters of 2015, there were five transfer patients who reside in the service area identified by HCGH that received primary PCI services, and their door-to-balloon times ranged from 79 to 370 minutes. All of these patients were discharged alive. Unfortunately, MHCC staff was unable to determine the outcomes specifically for the 18 walk-in patients that HCGH indicated were transferred in its first year of operation.

MHCC staff also investigated the outcomes of transfer patients Statewide and for the anticipated service area of HCGH based on data from the American College of Cardiology's National Cardiovascular Data Registry (NCDR), specifically the CathPCI Registry, in CY 2013 and CY 2014. Statewide, in CY 2013, the percentage of patients referred for pPCI who died prior to hospital discharge was 7.0% among patients who had been transferred from another hospital compared to 5.0% mortality among patients who had not been transferred. In CY 2014, the mortality rates increased to 8.9% for transferred patients and 6.1% for patients who were not transferred. The rates differ slightly if data from three hospitals in Delaware and from Washington Hospital Center in the District of Columbia are included in these calculations, as shown in Table 5. Although many factors influence the risk of mortality for patients, and the mortality rates reported here have not been risk adjusted to account for those factors, the rates provide some context for considering the disadvantage of being a transfer patient and whether residents in the service area of HCGH appear to be underserved.

Table 5: In-Hospital Mortality for Transfer and Non-Transfer Patients Referred for pPCI, CY2013- CY2014

Type	Maryland Hospitals CY 2013	Maryland Hospitals CY 2014	Region CY 2013	Region CY 2014
Transfer	7.0%	8.9%	7.0%	8.4%
Non-Transfer	5.0%	6.1%	5.4%	6.4%

Source: MHCC Staff Analysis of NCDR CathPCI Registry Data for CY 2013 and CY 2014.
Note: For approximately 15% of records each year, it is unknown whether the patient was transferred. The Region includes all Maryland Hospitals with pPCI Services, Washington Hospital Center, and three Delaware hospitals designated as Cardiac Interventional Centers by MIEMSS.

Although HCGH indicated that most patients in its service area would likely receive pPCI services at SGMC, the nearest provider in most cases, MHCC staff noted that many transfer patients who resided in HCGH's expected service area were treated at Washington Hospital Center. With regard to patients residing in HCGH's expected service area treated at a Maryland hospital or at Washington Hospital Center, in CY 2013, 16.7 percent of transferred patients referred for PCI died prior to hospital discharge (2 of 12 patients) compared to 3.0% of patients who were not transferred (3 of 100). In CY 2014, the mortality rates for transferred and non-transferred pPCI patients referred for PCI who reside in the service area identified by HCGH

were 5.3% (1 of 19 patients) and 6.7% respectively, as shown in Table 6.

Table 6: In-Hospital Mortality Rates for Transfer and Non-Transfer Patients Referred for pPCI from HCGH's Proposed Service Area, CY 2103- 2014

Type	CY 2013	CY 2014
Transfer	16.7%	5.3%
Non-Transfer	3.0%	6.7%

Source: MHCC Staff Analysis of NCDR CathPCI Registry Data for CY 2013 and CY 2014.

Due to the many factors that may influence the mortality risk for patients and the small number of transfer patients, the mortality rates derived from the NCDR CathPCI Registry should be interpreted with caution. In addition, approximately 15% of records for pPCI patients were missing information on whether a patient had been transferred or not. However, MHCC staff notes that the unadjusted mortality rates do not appear to suggest that access to pPCI services is worse for residents in the service area of HCGH compared to the level of access available to Maryland residents overall.

Although a reduction in the number of walk-in patients transferred for further evaluation of cardiac symptoms would likely substantially benefit those with STEMI who require PCI services by reducing these patients' total ischemic time,[7] there are other mechanisms besides establishing a primary PCI program that could also improve outcomes for these patients. For example, educating the public on the importance of dialing 911 and using ambulance transport when someone may be experiencing a heart attack.

Although HCGH noted that studies suggest that longer times to treatment are associated with increased mortality, the study that it cited did not include analyses of the impact of small reductions in door-to-balloon times or transit time on in-hospital mortality for patients who would otherwise be treated in 90 minutes or less. MHCC staff located two recent studies that address the impact of reductions in door-to-balloon time on in-hospital mortality rates, providing quantitative information on the relationship. A study of STEMI patients who underwent pPCI between January 1, 2005 and December 31, 2011 concluded that for each 10 minute decrease in door-to-balloon time, in-hospital mortality for individual patients decreased by approximately 8% (odds ratio 0.92; 95%; confidence interval 0.91-0.93).[8] A second study that included a meta-analysis of eight studies with 88,723 patients reached very similar conclusions.[9] It concluded that the odds ratio for in-hospital mortality was 1.053 (95% confidence interval 1.036-1.071) for every ten-minute increase in door-to-balloon time and 1.169 (95% confidence interval 1.112-1.229) for every 30-minute increase. These results suggests that in-hospital mortality is increased by approximately 5.3% for every ten-minute increase.

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[7] Solhpour, A., Chang, K., Arain, S.A., Balan, P., Loghin, C., McCarthy, J.J., Anderderson, H.V., and Smalling, R.W. "Ischemic Time is a Better Predictor Than Door-to-Balloon Time for Mortality and Infarct Size in ST-Elevation Myocardial Infarction." Catheterization and Cardiovascular Interventions. (2015) Sept 2.

[8] Nallamothu, B.K., Normand, S.T., Wang, Y., Hofer, T.P., Brush J.E. Jr., Messenger, J.C., Bradley, E.H., Rumbsfeld, J.S., Krumholz, H.M. "Relation between door-to-balloon times and mortality after primary percutaneous coronary intervention over time: a retrospective study." Lancet. 2015 Mar 21;385(9973):1114-22

[9] Chen, Hong-Lin and Liu, Kun. "Effect of door-to-balloon time on in-hospital mortality in patients with myocardial infarction: A meta-analysis." International Journal of Cardiology. 187 (2015) 130-133.

Although the reductions in travel time cited by HCGH, based on its analysis of the nearest treatment locations for patients in its proposed service area, would not be a factor in the measurement of door-to-balloon time, which generally begins with a hospital's door, MHCC staff believes that the estimated reduction in mortality calculated in the two studies reviewed serves as a useful tool to estimate the potential benefit of a small reduction in the time from symptom onset to treatment through reduced travel times. Given the very small impact of a five minute reduction in door-to-balloon time, an estimated four percent reduction in a patient's risk for in-hospital mortality, MHCC staff concludes that the reduced travel times projected by HCGH do not justify the need for an additional pPCI program, when considered in combination with other evidence that the proposed population to be served is not underserved. HCGH reported that no patients transferred from its facility to another hospital for pPCI have been given thrombolytic therapy, a therapy regarded as the next best alternative, when a patient will not likely have access to timely pPCI therapy. In addition, MHCC staff concludes that the patients HCGH proposes to serve are not underserved without adequate access to PCI services based on the high percentage of patients meeting the current door-to-balloon time standard without excluding transfer patients.

MHCC staff requested information from MIEMSS on the likely impact of a pPCI program at HCGH on the EMS system, drive-times, and quality of care. MIEMSS reported that between May 1, 2015 and October 31, 2015, there were a total of 90 patients within a 30 minute drive time to HCGH identified as STEMI and 13 were transported to HCGH, even though the patients likely would then be transferred to a hospital with pPCI services. MIEMSS noted that all other patients, except one, were taken to SGMC or Suburban Hospital. MIEMSS explained that STEMI patients are at risk of cardiac arrest, so decreasing transport time is essential and clinically benefits patients. MIEMSS concluded that "a primary PCI program at HCGH would have a positive effect on the EMS system and patients from the Northern Montgomery County region." (Email from MIEMSS to MHCC staff, December 15, 2015).

Potentially many additional pPCI programs could be justified if even small reductions in travel time or the existence of patients who require transport to another facility for pPCI were regarded as sufficient justification for establishing a pPCI program. Although MIEMSS concludes that a pPCI program at HCGH would have a positive effect on the EMS system and patient care, MHCC staff is concerned about the proliferation of pPCI programs if the threshold for justifying the need for a new program is set too low. Patient outcomes could be worse if resources and PCI volume are spread too thinly, as a result of MHCC approving many new pPCI programs. Consequently, despite community support from Montgomery County Fire and Rescue and Frederick County Government for the establishment of a pPCI program at HCGH, MHCC staff concludes that establishing a pPCI program at HCGH is not justified.

10.24.17.06A(2)(b) At a minimum, an applicant shall document that its proposed program will achieve, by the end of the second year of operation, an annual case volume of at least 36 PCI cases if the hospital is located in a rural area or an annual volume of at least 49 cases if the hospital is located in a non-rural area.

HCGH provided a map depicting the 2014 primary PCI volume for all zip code areas in the HCGH service area. HCGH developed its projections for primary PCI case volume based on several assumptions. HCGH allocated cases between HCGH and the nearest existing facility

(Adventist HealthCare Shady Grove Medical Center) based on 100% of the cases that border only HCGH zip code areas and have a shorter drive time to HCGH. Zip code areas bordering both hospitals that were equidistant were allocated at 50%, and those bordering only SGMC with a shorter drive time to SGMC were allocated 0%. (Application, p. 7).

HCGH provided specific examples to support its market share assumptions, including maps of the 2014 pPCI volume by zip code area for Holy Cross Hospital of Silver Spring, Frederick Memorial Hospital, and Adventist HealthCare Shady Grove Medical Center. (HCGH November 20, 2015 letter to MHCC Staff). Based on its projections, HCGH determined that the baseline volume for the Hospital is 68 PCI cases, with the projected annual volume growing by one case each year from CY 2015 to CY 2019. (Application, p. 8). Thus, HCGH's projected pPCI volume is 69 cases in 2015 and 73 cases in 2019. The projected rate of growth for cardiac medicine was determined to be 0.5% per year, and for catheterization 1.7% per year (Application, page 8).

Staff Analysis

MHCC staff evaluated the information provided by HCGH and concluded that HCGH would likely achieve an annual volume of at least 49 cases as required.

10.24.17.06A(3)(a) An applicant shall present evidence, including emergency transport data and patient-level data that demonstrate that the proposed program's service area population has insufficient access to emergency PCI services and is receiving suboptimal therapy for STEMI.

HCGH cited data from Montgomery County Fire and Rescue on all STEMI calls received in the HCGH primary service area for the calendar years 2013 and 2014 as evidence of insufficient access to pPCI. There were 70 STEMI calls in each year. In 2013, four percent took longer than 30 minutes to transport to the nearest facility authorized to handle pPCI patients. In 2014, this percentage increased to 7%. (Application, p. 9). In follow-up correspondence on November 20, 2015, HCGH provided the transport time for each patient during 2013 and 2014 who had a transport time over 30 minutes; these values ranged from 36 to 49 minutes in 2013 and 32 to 50 minutes in 2014. HCGH also cited a study[10] that concluded that ambulance diversion is associated with reduced access to cardiac technology and increased patient mortality within the subsequent 12 months. HCGH noted that the number of hours HCGH was on diversion between January 1, 2015 and September 30, 2015 was much lower when compared to SGMC, as shown in Table 7 below.

[10] Shen, Yu-Chu and Hsia, Renee Y. "Ambulance Diversion Associated With Reduced Access to Cardiac Technology and Increased One-Year Mortality." Health Affairs. August 2015.

Table 7: Number of Hours on Diversion by Hospital, January 1, 2015 to September 30, 2015

Yellow Diversion	Total Hours	Average Hours/Month	HCGH % Variance From SGMC
HCGH	226.28	25.14	
SGMC	276.84	30.76	-18%
Red Diversion	**Total Hours**	**Average Hours/Month**	**HCGH % Variance From SGMC**
HCGH	170.5	18.94	
SGMC	406.97	45.22	-58%

Source: HCGH Application, page 9.
Note: Red diversion is when a hospital has no ECG monitored beds available and requests that patients who are likely to require this type of care, not be transported to their facility. ECG monitored bed is defined as any adult in-patient critical care bed, including specialty critical care units and telemetry beds. Yellow diversion is when the ED temporarily requests that absolutely no Priority II or III patients are transported to their facility because the ED is experiencing a temporary overwhelming overload such that priority II or III patients may not be managed safely.

HCGH emphasized that the authors of this study concluded that patients admitted for acute myocardial infarction during high periods of ED diversion "still experienced a statistically and clinically significant increase (8.2% relative increase) in long-term mortality compared to those who did not experience diversion."

Staff Analysis

MHCC staff evaluated the study cited by HCGH and noted that, while there was a statistically and clinically significant increase in long term mortality rates for a patient with AMI when the nearest hospital was on diversion for 12 hours or more on the day of the patient's admission, there was not a statistically significant difference in mortality at 30 days, 90 days, or one year, if the number of hours on diversion was less than six hours or between six and 12 hours. The number of hours on diversion that SGMC reported for CY 2015 suggests that each hospital was rarely or never on diversion 12 hours a day, the threshold identified in this study. SGMC was on red diversion for 12 hours or longer on 18 days total or approximately 5% of days in CY 2015 and on yellow diversion for only four days. MHCC staff concludes that HCGH has not demonstrated that the proposed population to be served has insufficient access to pPCI services.

10.24.17.06A(4)(a) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction 24 hours per day, seven days per week.

When handling downtime that may occur due to required equipment maintenance or due to unforeseen circumstances, HCGH stated that it would follow protocols similar to those of Holy Cross Hospital of Silver Spring, which has been a part of the pPCI waiver program since its inception. HCGH states that, if its cardiac catheterization laboratory is unable to function, it will coordinate transfer of STEMI patients to the nearest Cardiac Interventional Center. HCGH also attached hospital transfer agreements from Suburban Hospital and Washington Hospital Center and noted that if it appears that the transfer time will be greater than 30 minutes, the ED

physician will initiate thrombolytic therapy, such as the administration of tissue plasminogen activator (tPA). (Application, p. 10).

Staff Analysis

MHCC staff notes that the protocols in place at Holy Cross Hospital of Silver Spring have been successful and will likely be adequate for HCGH. MHCC staff concludes that HCGH meets this standard.

10.24.17.06A(4)(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

HCGH provided a signed statement from its President, Doug Ryder, in agreement with the above statement. Mr. Ryder stated that HCGH will support the program by providing the leadership and resources necessary to provide pPCI services in accord with the requirements established by the MHCC. (Application, Exhibit 2).

Staff Analysis

MHCC staff concludes that HCGH meets this standard. Staff notes that like other hospitals that provide pPCI service, HCGH would be required to participate in the NCDR Cath PCI Registry and submit duplicate information to MHCC. MHCC staff will have the ability to verify door-to-balloon times for the hospital.

10.24.17.06A(4)(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to patients with acute myocardial infarction 24 hours per day, seven days per week.

HCGH submitted information to MHCC staff showing the proposed staffing pattern, as well as the days and hours of operation and the proposed call rotation. The proposed call rotation included the response time and time to arrival at the hospital. HCGH included the on-call process as well as the backup call plan which is issued every four months. With regard to adequate staffing for the cardiac catheterization laboratory, the following table was also submitted by HCGH as part of its application.

Table 8: Total Current Number of CCL Physician, Nursing, and Technical Staff

Staff Type	Number/FTEs	Cross-Training (S/C/M)*
Physician	4	
Nurse	1.5(FTE) and 1 PRN**	S/C/M
Technician	2.0(FTE)	S/M

Source: HCGH Application, p. 12.
*S/C/M indicates whether the nursing and technical staff are cross-trained to scrub (S), circulate (C), or monitor (M).
**PRN refers to pro re nata or "as needed."

HCGH also submitted the following table showing the number of physicians, nurses, and technicians that it plans to be in place if pPCI services are established at HCGH.

Table 9: Total Proposed Number of CCL Physician, Nursing, and Technical Staff

Staff Type	Number/FTEs	Cross-Training (S/C/M)*
Physician	4	
Nurse	3(FTE) and 3 PRN**	S/C/M
Technician	4(FTE) and 4 PRN**	S/M

Source: HCGH Application, p. 12.
*S/C/M indicates whether the nursing and technical staff are cross-trained to scrub (S), circulate (C), or monitor (M).
** PRN refers to pro re nata or "as needed."

Staff Analysis

MHCC staff reviewed the staffing information submitted by HCGH and compared it to information reported by three existing primary PCI programs during their last Waiver renewals, including MedStar Franklin Square, Holy Cross Silver Spring, and Carroll Hospital Center. The staffing levels reported in Table 9 are consistent with the levels reported by Holy Cross Silver Spring as of September 4, 2013, with respect to the number of full-time equivalent (FTE) nurses and technicians, but fewer physicians are reported (4 versus 6). CHC reported similar staffing levels to HCGH in its last Waiver renewal application; As of June 1, 2013, it reported six technical staff FTEs and five nurse FTEs. Franklin Square Medical Center also reported a similar level of staffing; as of December 31, 2012, it reported approximately six technical staff FTEs and five nurse FTEs. Based on its analysis of the information reported by HCGH, MHCC staff concludes that HCGH meets this standard.

10.24.17.06A(4)(d) The hospital president or Chief Executive Officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.

HCGH provided a letter of commitment regarding the establishment of a pPCI program at the hospital from its President, Doug D. Ryder. In his letter, Mr. Ryder stated that the Board of Directors of Holy Cross Health is committed to providing increased access to health care services to upper Montgomery County. Prior to the opening of the Hospital, Mr. Ryder visited all of the fire houses in upper Montgomery County to ask the paramedics how HCGH could better serve the community. The paramedics responded that a pPCI program was needed. (Application, Exh. 2).

Staff Analysis

MHCC staff concludes that HCGH complies with this standard.

10.24.17.06A(4)(e) The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

HCGH provided a description of the staff that will be dedicated to the program for data collection, management, reporting, and quality improvement efforts. HCGH noted that a cardiac catheterization laboratory registered nurse and technician will devote up to 0.5 FTEs combined to collecting and entering data in the NCDR CathPCI Registry. HCGH also identified five key systems used to achieve ongoing improvement in performance, and the hospital structures and processes which support compliance monitoring and enhanced performance improvement activities. (Application, p. 13).

Staff Analysis

MHCC staff concludes that the staff resources described will be sufficient to collect data and effectively coordinate institutional quality improvement efforts. HCGH complies with this standard.

10.24.17.06A(4)(f) A hospital shall complete a PCI development plan that includes appropriate training for the emergency room, catheterization, laboratory, coronary care unit and if applicable, post-procedure unit. The plan shall include protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure. In addition, there shall be an on-call coverage back-up plan for primary PCI cases, when an on-call interventionalist covers more than one hospital on a given shift, as well as when two simultaneous STEMI patients present at the hospital.

HCGH described the hospital's PCI backup call plan in which an interventional cardiologist is always available to meet the needs of the patients. Its on-call schedule will be developed by the Medical Staff Office and issued every four months. If a primary on-call interventionalist will not be available, HCGH's plan requires the cardiologist to contact the Medical Staff Office with the name of a back-up interventionalist and then a revised schedule is reissued. On-call cardiologists must respond within five minutes of getting a page and must be available via pager or cell phone when not at home. The on-call cardiologist may not be scheduled for pPCI call at another institution simultaneously. (Application, Exh. 1 & 3).

Staff Analysis

MHCC staff concludes that HCGH complies with this standard.

10.24.17.06A(4)(g) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

HCGH President, Doug Ryder, stated that 90 days prior to first use approval, he will provide the name of the physician director of interventional cardiology services who will be responsible for defining and implementing credentialing criteria for the catheterization laboratory and for the overall primary PCI program management. In addition, physician credentials, case

volume, board certification, and the signed on-call schedule will be sent to the MHCC. (Application, Exh. 2).

Staff Analysis

HCGH elected not to submit detailed information regarding physician credentials and the name of the physician director, but it has committed to providing such information at least 90 days prior to first use approval. MHCC staff noted in the application provided to HCGH that the required information only needed to be submitted at least 90 days prior to first use approval. MHCC Staff concludes that HCGH complies with this standard.

10.24.17.06A(4)(h) The hospital shall design and implement a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

HCGH submitted a chart of the continuing medical education program for staff of its cardiac catheterization laboratory, intensive care unit, and Emergency Department. HCGH noted that its intensive care unit also functions as a coronary care unit. The chart HCGH submitted includes the continuing education topic, the dates of the activity, the intended audience, and whether the program is an internal or external program. (Application, pp. 15-16).

Staff Analysis

MHCC staff notes that the continuing medical education program for staff includes appropriate topics and is consistent with the types of activities previously reported by hospitals seeking renewal of their Waivers for pPCI services. MHCC staff concludes that HCGH complies with this standard.

10.24.17.06A(4)(i) The hospital shall have a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

HCGH has a current signed and dated agreement with Suburban Hospital that provides for the unconditional transfer of pPCI patients from HCGH to Suburban Hospital. (Application, Exh. 4). In addition, a second hospital, Washington Hospital Center, is identified as being in the process of signing an additional transfer agreement. HCGH stated that a copy would be forward to the Commission upon receipt (Application, p. 17).

Staff Analysis

MHCC staff concludes that HCGH has met this standard based on the transfer agreement provided for Suburban Hospital. MHCC staff has not received a copy of the transfer agreement with Washington Hospital Center that HCGH anticipated signing.

10.24.17.06A(4)(j) The hospital shall maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air

or ground ambulance within 30 minutes of a request for patient transport by a hospital performing primary PCI without on-site cardiac surgery.

HCGH has a transport agreement with Butler Medical Transport, LLC, which is licensed by the Maryland Institute for Emergency Medical Services System as an advanced cardiac support emergency medical services provider. This agreement guarantees the arrival of the ambulance at HCGH within 30 minutes of a request for pPCI patient transport. (Application, Exh. 5).

Staff Analysis

MHCC staff concludes that HCGH has met this standard based on the transport agreement provided.

10.24.17.06A(5)(a) A hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

In the letter of commitment signed by HCGH President Doug D. Ryder, HCGH acknowledges that it will develop a formal schedule of meetings for interventional case review that will be held at least every other month. He also stated that interventionalists and other physicians, nurses, and technicians who care for pPCI patients will be required to attend these meetings. (Application, Exh. 2).

Staff Analysis

MHCC staff concludes that HCGH meets this standard based on the letter of commitment provided.

10.24.17.06A(5)(b) A hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

In the letter of commitment signed by HCGH President Doug D. Ryder, HCGH commits to the creation of a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area. Mr. Ryder stated that this group will meet monthly to review any and all issues related to the primary PCI program, identifying problem areas and developing solutions. (Application, Exh. 2).

Staff Analysis

MHCC staff concludes that, based on the letter of commitment provided, HCGH meets this standard.

10.24.17.06A(5)(d) A hospital shall evaluate the performance of each interventionalist at least

annually through a review of at least 10 cases or 10 percent of the interventionalist's cases whichever is greater; or if fewer than 10 cases have been performed by the interventionalist, then all cases shall be reviewed. A hospital may choose another review period for evaluating the performance of each interventionalist, if the review will be conducted in a manner that assures that the review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraph .06A(5)(d) and is approved ty the Commission's Executive Director.

In the letter of commitment signed by HCGH President Doug D. Ryder, HCGH acknowledges that at least semi-annually, as determined by the Commission, the hospital will conduct an internal review of at least 10 percent of randomly selected PCI cases performed in the applicable time period. (Application, Exh. 2).

Staff Analysis

MHCC staff concludes that HCGH meets this standard based on the letter of commitment provided.

10.24.17.06A(6) Each physician who performs primary PCI services at a hospital that provides primary PCI without on-site cardiac surgery shall meet the ACCF/AHA/SCAI 2013 update of the Clinical Competence Statement on Coronary Artery Interventional Procedures; and achieve an average annual case volume of 50 or more PCI cases over a two-year period.

In the letter of commitment signed by HCGH President Doug D. Ryder, HCGH acknowledges that each physician who performs primary PCI services at HCGH which is a program without on-site cardiac surgery, will achieve an average annual case volume of 50 or more PCI cases over a two-year period. (Application, Exh. 2).

Staff Analysis

MHCC concludes that HCGH meets this standard, based on the commitment signed by HCGH's President. MHCC staff notes that its collection of the NCDR CathPCI Registry data allows MHCC staff to validate the case volume of interventionalists at Maryland hospitals, Washington Hospital Center, and three Delaware hospitals.

10.24.17.06A(7) The hospital shall commit to providing primary PCI services only for suitable patients. Suitable patients are:

(a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of Patients with Acute Myocardial Infarction or in the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI for Percutaneous Coronary Intervention).

(b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) reasonably conclude may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in a worse outcome.

(c) Patients for whom primary PCI services were not initially available and who received thrombolytic therapy that subsequently failed. Such cases should constitute no more than 10 percent of cases. (d) Patients who experiences a return of spontaneous circulation following cardiac arrest and presents at a hospital without on-site cardiac surgery for treatment, when the COMAR 10.24.17 30 treating physician(s) reasonably conclude that transfer to a tertiary institution may be harmful for the patient.

HCGH provided a signed statement from the Hospital's chief executive officer (CEO) as required (Application, Exh. 2).

Staff Analysis

In addition to a signed statement from the Hospital's CEO, HCGH is required to provide a signed statement from the medical director of cardiac interventional services. HCGH has not determined who will be the medical director, and it does not need to provide such information until at least 90 days prior to first use approval, as directed by MHCC staff in the application for a Certificate of Conformance. MHCC staff concludes that HCGH meets this standard.

10.24.17.06A(21) An applicant shall document that its proposed primary PCI program will achieve financial viability.

HCGH determined that the introduction of pPCI services will require a capital expenditure by the Hospital. The total proposed capital cost is $26,000 which will be used to purchase a Contrast Injection System-CVi with mobile cart accessory (Letter to MHCC staff, November 20, 2015). The Hospital submitted financial projections for part of 2016 through 2019, as shown in Table 10.

Table 10: Projected Revenue and Expenses for HCGH by Time Period

Category	Time Period			
	March-Dec 2016	2017	2018	2019
Revenue				
Gross Revenue	$ 908,628	$ 1,228,811	$ 1,246,118	$ 1,263,426
Adjustments to Revenue				
Bad Debt	$ 2,726	$ 3,686	$ 3,738	$ 3,790
Contractual Allowance	$ 59,061	$ 79,873	$ 80,998	$ 82,123
Charity Care	$ 15,447	$ 20,890	$ 21,184	$ 21,478
Net Patient Services Revenue	$ 77,233	$ 104,449	$ 105,920	$ 107,391
Net Operating Revenue	$ 831,395	$ 1,124,362	$ 1,140,198	$ 1,156,034
Expenses				
Salaries, Wages, Benefits	$ 332,558	$ 449,745	$ 456,079	$ 462,414
Contractual Services	$ 250,444	$ 334,003	$ 334,080	$ 334,158
Current Depreciation	$ 3,900	$ 5,200	$ 5,200	$ 5,200
Supplies	$ 37,800	$ 51,120	$ 51,840	$ 52,560
Other Expenses (Lab, Pharmacy, Radiology)	$ 242,550	$ 328,020	$ 332,640	$ 337,260
Total Operating Expenses	$ 867,252	$ 1,168,087	$ 1,179,839	$ 1,191,591
Income				
Net Income (Loss)	$ (35,857)	$ (43,725)	$ (39,641)	$ (35,557)

Source: HCGH Application, Form B, pp 21-23.

Staff Analysis

The capital investment required for the establishment of pPCI services at HCGH is very small because the major capital investment by HCGH required to provide PCI services, the cardiac catheterization laboratory and its angiographic system was made in 2014, when construction of HCGH was completed. The Hospital's cardiac catheterization laboratory is currently used for diagnostic angiography of the heart. However, if HCGH obtains approval to provide pPCI services, the cardiac catheterization laboratory would also be used for those services.

MHCC staff compared the projected revenue and expenses per pPCI case to those estimated for University of Maryland Upper Chesapeake Medical Center (UCMC) and Carroll Hospital Center (CHC). UCMC and CHC each reported on the actual revenue and expenses as part of an application submitted in 2014 for a Certificate of Conformance to establish an elective PCI program. Both of these programs reported positive net revenue for their pPCI programs. Although UCMC reported a much higher pPCI volume than projected by HCGH over the next three years (128 cases), CHC's reported pPCI volume in FY 2014 was 82 cases, only about 10% more cases than projected by HCGH in its full third fiscal year. The information reported by

CHC suggests net income of approximately $1,200 per case. However, as MHCC staff noted in its report on CHC's and UCMC's Certificate of Conformance applications, CHC took a broad approach to reporting the financial performance of its pPCI Program, looking at revenues and expenses throughout its full range of diagnostic and treatment services and allocating revenues and expenses for all these services for each primary PCI patient that received primary PCI at CHC. MHCC staff notes that a similar approach could result in positive net revenue projection for HCGH. MHCC staff concludes that, in spite of the net loss of revenue projected by HCGH, the program is likely to be financially viable. MHCC staff concludes that HCGH meets this standard.

IV. Recommendation

Based on the above analysis and the record in this review, MHCC staff concludes that HCGH can implement a developmental program for primary PCI that will establish a program that meets the minimal requirements of the State Health Plan. However, HCGH has not demonstrated the need for a primary PCI program at its hospital for the proposed population to be served. Patients in HCGH's proposed service area who require pPCI services are being adequately served by existing pPCI programs, primarily SGMC's program, based on the door-to-balloon times achieved for these patients in CY 2013 and CY 2014. Although HCGH has reported fewer hours on diversion than SGMC, the nearest existing provider of pPCI services, the reported number of hours on diversion in CY 2015 seems unlikely to have had a significant impact on mortality rates for most patients with acute myocardial infarction. In addition, the reduction in travel times, an average of 4.5 minutes, appears unlikely to result in a significant benefit for the population to be served with regard to mortality rates.

MHCC staff is concerned about the precedent that would be set by allowing a new program to be established based on only a small gain in travel time for patients. Just under half of Maryland's general hospitals provide primary PCI services at this time. All of the hospitals that do not provide this service can document that some STEMI patients in their service area could reach their facilities more quickly than the nearest hospital with PCI services. Many of these hospitals could also demonstrate the proposed program is likely to meet the minimum volume of pPCI cases required. However, MHCC staff concludes that spreading the volume of pPCI cases among many additional programs may negatively affect the quality of care for patients and make the provision of this service less economical from a system perspective. For this reason, MHCC staff recommends, as reflected in COMAR 10.24.17, a conservative approach to expanding the supply of pPCI programs.

MHCC staff agrees that reducing the number of STEMI patients who are transferred from a hospital without pPCI services may substantially benefit those patients. However, MHCC staff did not find evidence that the transferred patients from the proposed service area of HCGH are underserved relative to other Maryland residents. Therefore, MHCC staff recommends that the Commission **DENY** HCGH's request for a Certificate of Conformance to establish a pPCI program. MHCC staff notes that this recommendation should not preclude HCGH from reapplying for a Certificate of Conformance at a later date, if HCGH believes that circumstances have changed. MHCC staff also anticipates that the adoption of additional performance

measures over time may be useful to evaluating a future application for a Certificate of Conformance to establish a primary PCI program.