IN THE MATTER OF	*	
	*	
ESTABLISHMENT OF ELECTIVE	*	
	*	**BEFORE THE**
PERCUTANEOUS CORONARY	*	
	*	
INTERVENTION SERVICES BY	*	
	*	**MARYLAND HEALTH**
HOWARD COUNTY GENERAL	*	
	*	
HOSPITAL	*	
	*	**CARE COMMISSION**
MATTER NO. 19-13-CC008	*	
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Staff Report and Recommendation

April 16, 2020

I. INTRODUCTION

A. Background

In 2012, Maryland established a new regulatory model for percutaneous coronary intervention (PCI) and cardiac surgery services. PCI is a procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve narrowing of the artery and includes rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents, and other catheter devices for treatment of coronary atherosclerosis.

Under the 2012 law, PCI became a service explicitly regulated by the Maryland Health Care Commission (MHCC) rather than indirectly regulated through regulation of "open heart surgery." Establishment of new PCI programs are now considered through a process called Certificate of Conformance review, with all providers of PCI services now subject to revalidation and authorization through periodic on-going performance reviews.

Two categories of PCI programs are addressed in the Certificate of Conformance regulations found in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Coronary Intervention Services chapter (Chapter) of the State Health Plan, which became effective August 18, 2014: (1) emergency, or primary, PCI programs, that provide only emergent PCI intervention in a heart attack shortly after it begins, and; (2) programs that provide both emergency/primary PCI services and elective/non-primary, PCI services. Elective PCI is non-emergent and involves intervention to revascularize coronary arteries that are substantially blocked but have not resulted in an immediate cardiac event requiring emergency treatment.

Most PCI cases in Maryland are performed in the ten hospitals that provide cardiac surgery and both types of PCI services. However, in the last two decades, research studies have shown that both emergency and elective PCI services can be provided in hospitals without on-site cardiac surgery and achieve levels of patient safety, with respect to mortality and complication rates, comparable to the performance achieved in cardiac surgery hospitals. The initial research study, in which Maryland hospitals participated, showed that in hospitals without cardiac surgery on site (SOS), the provision of primary PCI to certain heart attack patients provided better outcomes than thrombolytic therapy, which previously had been standard care for heart attack patients in non-SOS hospitals. For this reason, the Commission permitted non-SOS hospitals that could meet certain volume and quality standards to provide primary PCI services. Ultimately, 13 such programs were established, more than doubling the number of Maryland sites at which primary PCI can be performed, with the benefit of enabling better emergency interventions to occur more quickly following the onset of a heart attack, Early intervention is a critical factor in preserving life and minimizing the damage to heart muscle, improving the recovery potential for the patient.

More recently, the changing science in heart disease treatment showed that the provision of elective PCI in non-SOS hospitals was not inferior to the provision of elective PCI in hospitals with cardiac surgery on-site. As a result, the Commission granted authority to provide elective PCI services to eight of the 13 non-SOS hospitals that were providing primary PCI. The potential benefit of allowing a hospital with only primary PCI services to provide elective PCI programming

is that a more active program with more PCI cases may support the sustainability of the hospital's provision of needed primary PCI services, a life-saving procedure. These eight hospitals all experienced a regulated and monitored sequence of first operating their elective PCI programs as research "waiver"[1] hospitals, graduating to "registry waiver"[2] status at the conclusion of the active research phase and now, through the 2012 legislation and resulting MHCC action, as regular clinical providers of both primary and elective PCI, subject to on-going performance reviews by MHCC.

Three Maryland hospitals are currently only authorized to provide emergency PCI services. These hospitals include Howard County General Hospital, MedStar Franklin Square Medical Center, and Holy Cross Germantown Hospital.

Additional background on the evolution of PCI regulation in Maryland can be found in Section .02 of the Chapter, which can be accessed through the following link:
http://www.dsd.state.md.us/artwork/10241701.pdf

B. Applicant

Howard County General Hospital (HCGH)

Howard County General Hospital is a 225-bed general hospital located in Columbia, in Howard County, and is the only hospital located within this jurisdiction. It is part of the Johns Hopkins Health System.

To implement this project, HCGH has indicated that there are no capital costs for the proposed project. This is consistent with prior applications reviewed by MHCC staff for hospitals with a primary PCI program that requested approval to add an elective PCI program. Either no capital costs were associated with the project or a small expense associated with the purchase of equipment.

[1] Authorized to provide the service under the control and protocols of a clinical trial examining the safety of elective PCI in hospitals without cardiac surgery back-up.
[2]Authorized to provide the service with mandatory American College of Cardiology National Cardiac Data Registry (NCDR) reporting requirements for performance monitoring.

Service Area Population Characteristics

The most recent population forecast of the Maryland Department of Planning projects that Howard County's population will increase about nine percent between 2020 and 2030. Projected population growth in this jurisdiction is higher than that for Maryland overall (six percent between 2020 and 2030). Howard County is projected to see growth over the next decade in its elderly population, age 65 and over, of approximately 43 percent. Statewide, projected growth in this elderly population is lower, at 33.4 percent.

Table 1: Projected Population and Population Change: Howard County and Maryland Statewide, 2020-2030

	2020		2030		Percent Change	
Jurisdiction	Total Pop.	Age 65+	Total Pop.	Age 65+	Total Pop.	Age 65+
Howard County	336,921	50,525	366,814	72,284	8.9%	43.1%
Statewide	6,141,808	982,672	6,518,798	1,310,434	6.1%	33.4%

Source: MHCC staff analysis of Maryland Dept. of Planning, population projection series (August, 2017).

Compliance With Primary PCI Waiver Requirements

Howard County General Hospital obtained its initial one-year waiver to provide primary PCI services in May 2006. HCGH qualifies to submit a Certificate of Conformance application to add elective PCI because HCGH has been providing primary PCI in accordance with established standards for more than two years, as provided in Health-General 19-120.1(g)(2)(vii) and COMAR 10.24.17.04A(2)(b). HCGH has received three "waiver" renewals of two years duration, reflecting compliance with the performance standards used by MHCC for primary PCI waivers prior to the 2012 law. The waiver for HCGH was last renewed in December 2013.

HCGH was asked to address its current compliance with the standards for primary PCI in this review. HCGH's filings indicate that the hospital continues to meet the standards for primary PCI. The following information highlights the recent experience of the HCGH with respect to the primary PCI standards in the Chapter.

HCGH maintains the necessary on-call facilities and staffing to be able to perform primary PCI 24 hours per day, seven days per week on short notice with acceptable levels of downtime for cardiac catheterization laboratories. HCGH reports one additional physician performing primary PCI services at the hospital, compared to the staffing level at its 2013 waiver renewal and slightly fewer FTEs for nurses and technical staff, with half an FTE less for both nurses and technical staff.

Table 2: Total Number of Cardiac Catheterization Laboratory Physicians, Nurses, and Technical Staff, May 24, 2019

Staff Type	Number/ Full-Time Equivalents	Cross-Training
Physicians	8	
Nurses	6/4.5 FTE	circulate
Technical Staff	7/3.5 FTE	scrub/monitoring

Source: HCGH application, May 2019, page 11.

HCGH is achieving acceptable case volume and door-to-balloon (DTB) times for primary PCI cases. Although HCGH did not meet the DTB time standard in each quarter, it did meet the standard, for all but one period, when measured over rolling eight-quarter periods between January 2015 and June 2019. MHCC staff conducted its own analysis of the NCDR registry data submitted to MHCC through December 2018, and this analysis is consistent with the information submitted by HCGH, except that it appears that HCGH missed the standard in one rolling eight-quarter period ending CY 2017Q4; only 73% of cases met the DTB standard, which is slightly below the requirement that at least 75% of primary PCI cases have a DTB of 90 minutes or less. The volume of primary PCI cases at HCGH exceeded the minimum program volume standard of 49 cases per year for CY 2015 through CY 2018.

Table 3: Percentage of Cases Meeting D2B Standard for Rolling 8-Quarter Periods at HCGH, CY 2015 to CY 2018

Quarter Ending	Number of STEMI Patients	Number of STEMI Patients Receiving primary PCI	STEMI Patients with DTB Times <= 90 Minutes		
			Number	Percent by Quarter	Percent for Rolling 8 Quarters
CY15 Q1	18	18	10	56%	
CY15 Q2	28	28	25	89%	
CY15 Q3	29	27	21	78%	
CY15 Q4	24	24	22	92%	
CY16 Q1	22	22	14	64%	
CY16 Q2	21	21	14	67%	
CY16 Q3	29	28	22	79%	
CY16 Q4	27	27	25	93%	78%
CY17 Q1	23	23	14	61%	79%
CY17 Q2	22	19	17	89%	78%
CY17 Q3	25	25	18	72%	77%
CY17 Q4	24	22	16	73%	75%
CY18 Q1	42	40	30	75%	76%
CY18 Q2	24	24	15	63%	75%
CY18 Q3	18	19	15	79%	75%
CY18 Q4	32	32	27	84%	75%
CY19 Q1	22	22	16	73%	76%
CY19 Q2	15	15	13	87%	75%

Source: HCGH application, Attachment L, May 2019

The cardiologists at HCGH report PCI caseloads that are well above the minimum requirement, for each interventionalist, of 50 PCI procedures annually averaged over a 24-month period. The annual caseloads reported for the HCGH cardiologists between CY 2015 and CY 2018 ranged from 66 to 229 cases. The majority of cardiologists at HCGH reported performance of over 100 cases annually for this period.

HCGH was also asked to address the three general review standards that are posed to all general hospitals filing Certificate of Need applications for any type of project, under COMAR 10.24.10. These standards address information regarding charges, the hospital's charity care

policy, and quality of care.

HCGH has demonstrated that it complied with the charge information standard. This standard requires availability of a defined "representative list of charges" that is updated at least quarterly and made available on the hospital's website.

The hospital fell within the third quartile in the most recent ranking of Maryland hospitals, ordered by highest to lowest level of charity care provided, with the level of charity care defined as a percentage of total expenses. HCGH meets the charity care standard because it does not fall in the bottom quartile for the level of charity care provided, and the charity care policy of HCGH meets the determination of eligibility and notice requirements.

HCGH also complied with the quality of care standard. HCGH has all necessary licenses, certifications, and accreditations. This standard also requires that a hospital document each action taken to improve its performance on each quality measure included in the current Hospital Performance Evaluation Guide when the hospital performs in the bottom quartile relative to other Maryland hospitals, unless the hospital has achieved 90% compliance or better. The performance measures have changed, and this standard is outdated. Instead, when a hospital performs below average on a performance measure, the hospital explains the actions that it has taken to improve on the performance measures. HCGH explained the actions it has taken to improve on all performance metrics where it performed below the statewide average, except in one case. Specifically, the percentage of patients who had low-risk surgery and received a heart-related test, such as an MRI, at least 30 days prior to their surgery though "they do not have a heart condition" was 6.6% at HCGH, which is worse than the statewide average for Maryland hospitals.

HCGH explained that there is a high level of scrutiny for approval of the heart test referenced in the performance standard. For example, Novitis Solutions Incorporated, Medicare's Administrative Contractor for the region that includes HCGH, has issued guidance on coverage for the procedure that requires medical necessity be demonstrated. In addition, the Johns Hopkins Health System's Corporate Compliance Program requires hospitals to review test orders relative to local coverage decisions to ensure that services are medically necessary and billable. Due to the level of scrutiny applied prior to this test, HCGH chose not to focus on it as an area for improvement. Staff agrees that HCGH has provides a reasonable explanation for not focusing on improvement in this area.

II. PROCEDURAL HISTORY

HCGH filed a Certificate of Conformance application on May 31, 2019. Subsequently, in response to requests for additional information and clarification, HCGH submitted additional filings on October 31, 2019, January 24, 2020, and March 27, 2020.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

A. <u>Commission Program Policies, COMAR 10.24[3].17.04A(2)</u>

Consideration of New Programs.

(2) Elective Percutaneous Intervention
(a) A hospital shall obtain a Certificate of Conformance to establish elective PCI services, unless the hospital is exempt from this requirement under Health General §19-120.1(d).

HCGH is not exempt from this requirement.

(b) A hospital shall have been providing primary PCI services for at least two years before seeking a Certificate of Conformance to provide elective PCI services, unless the hospital is located in a part of Maryland that does not have sufficient access to emergency PCI services. In such cases, sufficiency of access will be evaluated by the Commission based on a review of evidence presented by the applicant and collected by Commission staff. An applicant shall show that the population in the service area of the proposed program is receiving suboptimal therapy for STEMI. This review shall include an analysis of emergency transport data and patient-level outcome data.

HCGH has been providing primary PCI services for more than two years.

(c) A review schedule for the establishment of elective PCI programs will be published in the *Maryland Register* at least annually for each health planning region where there is at least one hospital that provides only primary PCI services. An application to establish primary PCI and elective PCI services based on insufficient access pursuant to .04A(2)(b) of this regulation may be filed at any time.

The three hospitals that currently provide only primary PCI were eligible to file in this Certificate of Conformance review cycle for elective PCI. Only HCGH filed an application.

Certificate of Conformance Review Standards, COMAR 10.24.17.06

B. Elective PCI Services.

A hospital issued a Certificate of Conformance to establish an elective PCI service shall agree to voluntarily relinquish its authority to provide elective PCI services if it fails to meet the applicable standards for a Certificate of Conformance.

Acknowledgment of this agreement was part of HCGH's affidavit concluding its Certificate of Conformance application, which was signed by John M. Dunn, Administrator for Diagnostic Imaging.

An applicant seeking to establish elective PCI services shall meet all applicable criteria for a

[3] HCGH Response to MHCC Questions, March 27, 2020, page 3.

Certificate of Conformance for a primary PCI program[4], and shall meet the following additional requirements

(1) Need

The hospital shall demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.

HCGH reported that the nearest alternative primary PCI program to HCGH is located at Saint Agnes Hospital, in Baltimore City, and travel times from Howard County to Saint Agnes Hospital vary from 30 to 50 minutes, depending on the time of day and location in Howard County. HCGH identified the primary population to be served as those residing in the following sixteen zip code areas: 21042, 21043, 21044, 21045, 21045, 21075, 20723, 20707, 21041, 21150, 20725, 20726, 21036, 20763, 20759, and 21737. HCGH provided information on the percentage of patients from these zip code areas who received primary PCI at HCGH between October 1, 2016 and September 30, 2019. A total of 286 cases were included, and HCGH reported a range for the drive time from each zip code area to alternative hospitals that provide primary PCI services, based on Google maps and a time of 4:30 p.m. on a weekday.

MHCC staff subsequently requested that HCGH provide detailed information on the transport times for patients in its primary service area (PSA) to alternative hospitals, based on the pattern of arrivals and volume of arrivals by hour. The zip code areas in HCGH's PSA, the alternative hospitals for transporting primary patients, the number of miles to these hospitals, and the volume of cases for each zip code area in HCGH's PSA are shown in Table 4. Information on the arrival times for primary PCI patients currently served by HCGH and the estimated travel times to alternative hospitals that provide primary PCI services is shown in Table 5.

Table 4: Closest Alternative Hospital for Primary PCI Services and Percentage of PCI Volume by Zip Code Areas in HCGH's PSA

Zip Code Area	21042	21044	21043	21045	20723	21075	20707	21046	20759	20763
Alternative Hospital for primary PCI	Saint Agnes	Saint Agnes	Saint Agnes	Saint Agnes	WAH	Saint Agnes	WAH	WAH	WAH	WAH
Miles to Alternative	20	19	12	15	13	7	8	15	9	15
Percent of HCGH PSA Cases	20%	16%	15%	15%	12%	8%	5%	4%	3%	1%

Source: HCGH Response to MHCC Questions, January 24, 2020, page 4.
Notes: WAH refers to Washington Adventist Hospital, which relocated and changed its name in August 2019 to Adventist HealthCare White Oak Medical Center. The percentage of PCI cases is based on a review in October 2019 of HCGH PCI cases from the HCGH PSA during the period between 10/1/16 and 9/30/19.

[4] This requirement was addressed in the preceding Section I.B. of this report, *supra,* pages 3-5.

Table 5: Travel Time to Alternative Cardiac Intervention Centers from Zip Codes Areas in the Primary Service Area of HCGH

Hour of the Day	Percent of Total Cases	Travel Time (minutes)									
		Zip Code Areas in HCGH's Primary Service Area									
		21042	21044	21043	21045	20723	21075	20707	21046	20759	20763
12-1:00 am	2%	29	25	16	21	22	14	16	22	18	20
1-2:00 am	3%	29	25	16	20	22	14	16	21	18	20
2-3:00 am	2%	29	25	17	20	22	14	14	21	18	20
3-4:00 am	3%	29	25	16	20	22	14	14	21	18	20
4-5:00 am	3%	28	25	16	20	22	14	14	20	16	20
5-6:00 am	3%	28	23	16	19	21	14	15	21	18	21
6-7:00 am	4%	34	25	17	21	24	14	16	22	20	23
7-8:00 am	4%	40	29	20	23	28	16	17	30	21	30
8-9:00 am	4%	43	32	17	23	29	18	19	31	24	30
9-10:00 am	5%	28	26	19	22	28	16	17	28	21	26
10-11:00 am	5%	34	26	18	22	24	16	16	23	21	23
11-12:00pm	4%	33	26	18	22	24	16	16	22	21	22
12-1:00 pm	6%	33	26	18	22	24	16	16	23	21	23
1- 2:00 pm	6%	33	26	18	22	24	16	17	23	21	23
2- 3:00 pm	6%	34	29	18	22	25	16	17	23	21	23
3- 4:00 pm	7%	36	32	18	24	25	17	17	23	22	23
4- 5:00 pm	5%	36	32	20	28	28	17	17	24	22	27
5- 6:00 pm	4%	39	39	24	34	28	20	19	28	22	28
6-7:00 pm	5%	36	32	20	28	28	24	19	28	23	28
7- 8:00 pm	4%	31	26	18	23	25	16	18	23	21	23
8- 9:00 pm	4%	31	26	18	22	24	15	16	22	20	22
9- 10:00 pm	6%	31	26	17	22	24	15	17	22	20	22
10-11:00 pm	3%	31	26	18	20	23	15	16	21	19	21
11-12:00 am	3%	28	25	18	21	23	15	16	21	18	21

Source: HCGH Response to MHCC Questions, January 24, 2020, page 4.
Notes: The percent of cases for each hour of arrival is based on a review in October 2019 of HCGH PCI cases from HCGH PSA between 10/1/16 and 1/21/20 by J. Dunn.

HCGH emphasized that while a majority of residents in its PSA will have a travel time of less than 30 minutes to an alternative location for primary PCI, the travel time benchmark that is used to define adequate access to PCI services, other critical factors should be considered. For some residents, the estimated travel time to another hospital for primary PCI services would be over 20 minutes longer on average than the current travel time. During traffic congestion, the extra travel time would be even longer. HCGH stated that,

> [i]n caring for patients with STEMI, every minute is critical. An unnecessary, 22-minute delay in care could well be the difference between life and death, and

certainly has the potential to cause catastrophic harm to heart attack patients.

HCGH also stated that travel times do not account for the time it make take for EMS to arrive after a 911 call, for a patient to be evaluated in the field, and for a patient to be stabilized, before transport to a hospital. HCGH asserted that bypassing HCGH to take patients to another hospital would add unnecessary delay to care that is time-critical.

HCGH stated that its primary PCI program is not sustainable alone due to several challenges, including difficulty with the recruitment and retention of cardiac catheterization laboratory staff and the lack of an interventional cardiologist on-site during daytime hours. HCGH stated that both the quality of care and timeliness of care would likely be improved by the addition of an elective program. For example, the presence of an interventional cardiologist on-site will result in shorter door-to-balloon times. HCGH also explained that the lack of an elective PCI program makes it more difficult to attract and retain skilled nursing and technologists who would prefer to be in positions where they fully utilize their skills for cardiovascular procedures. It is also more difficult to train new staff because of the unpredictable frequency of primary PCI patients.

MHCC staff requested additional information on staff turnover at the cardiac catheterization laboratory for HCGH and how it compares to other PCI programs in the Johns Hopkins Health System (JHHS). As shown in Table 6, there is higher turnover among nurses and technologists for each fiscal year (FY). The turnover at HCGH ranged from 19% to 30%, and the average turnover rate for FY 2017- FY 2019 was 23%. The average turnover rate for this three-year period at three other PCI programs in JHHS ranged from 4% to 17%.

Table 6: JHHS Staff Turnover Rates for Cardiac Catheterization Laboratory Technologists and Nurses, FY 2017-19

Location	Percent Turnover			
	Fiscal Year			Three-Year Average
	2017	2018	2019	
Johns Hopkins Hospital	20%	18%	12%	17%
Johns Hopkins Bayview Medical Center	0%	0%	46%	15%
Howard County General Hospital	20%	30%	19%	23%
Suburban Hospital	13%	0%	0%	4%

Source: HCGH Response to MHCC Staff's Questions, January 24, 2020, page 3.

Staff Analysis

Staff reviewed the travel times using Google Maps from zip code areas included in HCGH's primary service area with greater than zero patients served between October 1, 2016 and September 30, 2019 for the day March 2, 2020 for each of 24 one-hour time blocks, as shown in Appendix 1. Staff included in Appendix 1, the shortest estimated travel time if multiple routes were suggested by Google Maps. If a range was provided by Google Maps, rather than a single value, staff included the average for the end points of the range provided; if multiple ranges were suggested for multiple routes, staff included the average for the end points of the most optimistic range. Staff concluded that the applicant's detailed hourly estimated travel time analysis is

consistent with staff's analysis.

Staff also developed estimates of travel times with Google Maps, using assumptions about the distribution of arrival of patients consistent with those provided by HCGH in order to compare the magnitude of change in travel times for residents in the PSA of HCGH, if the primary PCI program at HCGH were to close. The detailed hourly analysis, provided in Appendix 1, relied upon the same assumptions as the applicant, with respect to the distribution of patients by zip code area and time of travel. The weighted average for estimated travel times for patients in the primary service area of HCGH is shown in Table 7, and these results are consistent with calculations based on HCGH's analysis in Table 5 and calculations based on the analysis of MHCC staff included in Appendix 1.

Table 7: Average Estimated Travel Time to Closest Alternative Hospitals for Zip Code Areas in the PSA of HCGH

Zip Code Area	21042	21044	21043	21045	20723	21075	20707	21046	20759	20763
Average Travel Time (minutes)	33	28	18	23	25	16	17	24	21	24

Source: MHCC staff analysis of information provided in HCGH response to MHCC questions, January 24, 2020, page 4.
Notes: The average estimated travel time is a weighted average that incorporates the estimated volume of primary PCI cases for a zip code area for 1-hour time blocks.

As shown in Table 5, the vast majority of patients in the HCGH primary service area would have an estimated travel time of 30 minutes or less for primary PCI services, even if the primary PCI program at HCGH closed. A travel time of 30 minutes is considered reasonable access to primary PCI at alternative locations, as indicated in the SHP chapter for cardiac surgery and PCI services. Only one of the ten zip code areas in the PSA of HCGH had an average travel time over 30 minutes for primary PCI. For this zip code area (21042), the average travel time was 33 minutes. The estimated travel time range for residents in this zip code area was 28-43 minutes, and residents in this zip code area comprise approximately 20 percent of the volume of primary PCI cases for HCGH, as reported by HCGH. The percentage of residents age 65 and over in this zip code area (19%), relative to the total population age 65 and over in the PSA of HCGH, is almost proportional with the share of primary PCI volume in the PSA of HCGH, based on MHCC staff's analysis of population estimates for zip code areas in Maryland.[5]

For seven of the zip code areas in the PSA of HCGH, the estimated travel time never exceeded 30 minutes, as shown in Table 5. For one zip code area (21045), the estimated travel time exceeded 30 minutes only during the hour of 5:00 pm to 6:00 pm, when the estimated travel time was 34 minutes. For another zip code area (21044), the estimated travel time only exceeded 30 minutes during five one-hour arrival time blocks. However, the estimated average travel time is 28 minutes, and the increase in travel time, if the primary PCI program at HCGH did not exist,

[5] MHCC staff analyzed 2019 population estimates for zip code areas in Maryland. The population estimate data set was acquired from Nielsen Claritas.

would be approximately 21 minutes longer (7 minutes versus 28 minutes), which is a substantial increase, and this zip code area is the second largest contributor to the PSA for HCGH. Staff also notes that the high end for the range of estimated travel times was over 30 minutes, generally 35-40 minutes, for seven of the ten zip code areas in the PSA of HCGH for some time blocks. Staff concludes that access to primary PCI would be significantly longer for approximately 36% of the population residing in the PSA for HCGH, based on the information provided by HCGH regarding its service area and MHCC's analysis of travel times to alternative hospitals. As HCGH noted in its application, timely care is critical for STEMI patients, and the importance of timely care, as established by research, is the basis for having a door-to-balloon time standard.

Staff notes that while a door-to-balloon time standard of 90 minutes or less is the benchmark used to evaluate hospitals for Certificates of Ongoing Performance, the 2013 guidelines of the American College of Cardiology Foundation/American Heart Association for STEMI patients include a recommendation that the goal for first medical contact (FMC)-to-device time be 90 minutes. For STEMI patients who are transported to a hospital by ambulance, the first medical contact would likely be with emergency medical system personnel, and the time to travel to a hospital would be part of the calculation of FMC-to-device time for those patients. The change in the guidelines for treatment of STEMI patients, which emphasizes FMC-to-device time and sets a higher ideal standard of care for STEMI patients, suggests that reducing travel time for STEMI patients is an important component to improving outcomes for some STEMI patients. This lends further support to Staff's conclusion that the primary PCI program at HCGH is needed to preserve timely access to primary PCI services for the population in HCGH's PSA.

Recommendation

Despite the close proximity of alternative hospitals with primary PCI programs, the primary PCI program at HCGH is essential to preserve timely access. Although approximately 80% of the population residing in zip code areas that are part of the PSA for HCGH would be expected to have a travel time of 30 minutes or less, the benchmark recognized in COMAR 10.24.17 for timely access, the substantially worse access anticipated for some residents in the PSA of HCGH merits consideration, when a primary PCI program has already been established at a hospital. The diminished access for residents in zip code area 21044, which comprises 16% of the PSA for HCGH, is over 20 minutes, an amount of time that, as noted by HCGH, has the potential to be the difference between life and death. For those residents, instead of an average travel time of 7 minutes, the average travel time would be 28 minutes, just slightly under the 30-minute benchmark used for determining if a population has timely access to primary PCI services. Without a primary PCI program at HCGH, 20% of the population in the primary service area of HCGH would have a travel time longer than 30 minutes, and for an additional 16% of the population in the PSA of HCGH travel time would increase to an extent that will hinder timely access.

HCGH, although currently showing a positive account of revenue and expenses, predicts that its PCI program will erode unless it is granted authority to perform elective PCI due to problems with staff retention, and HCGH provided evidence to support the problems with staff retention. MHCC staff has concluded that HCGH presented credible evidence that its program may erode without an elective PCI program, and patients will likely obtain higher quality care with

the addition of an elective PCI program. Staff recommends that the Commission find that HCGH has demonstrated that its proposed elective PCI program is needed to preserve timely access to primary PCI services for the population to be served.

(2) Volume

The hospital shall demonstrate its proposed elective PCI program will achieve a volume of 200 or more total PCI cases (elective and emergency) by the end of the second year of providing elective PCI services.

HCGH stated that it anticipates a volume of 100 primary PCI cases in future years, based on the average number of procedures performed for fiscal years 2013 through 2018. HCGH also identified patients who were transferred from HCGH to Johns Hopkins Hospital over a recent one year period (January 31, 2018 to January 31, 2019) and the number who would have likely remained at HCGH, if an elective PCI program were in place. On an annual basis, this number is 174 inpatients, and HCGH anticipates that at least 39 would receive elective PCI at HCGH rather than at Johns Hopkins Hospital. HCGH also analyzed PCI among patients in the PSA for HCGH and the number who had their outpatient elective PCI procedures at Johns Hopkins Hospital and concluded from this analysis that an additional 81 patients would receive elective PCI at HCGH each year. According to HCGH, among 237 patients in the PSA for HCGH who had elective PCI services, 101 had the procedure performed at Johns Hopkins Hospital.

HCGH identified its PSA as ten zip code areas, based on its review of discharge data from the Health Services Cost Review Commission for elective PCI procedures for records with a zip code area in the HCGH PSA during FY 2016. The PSA is defined as the contiguous zip codes from which the first 75% of inpatient discharges (excluding normal newborns arise.) HCGH estimates a total of at least 120 elective PCI cases will be performed at its hospital, if an elective PCI program is approved. In combination with the projected primary PCI volume for HCGH, 100 cases annually, HCGH projects a total volume of 220 cases, which is above the minimum target case volume of 200 PCI cases.

Using NCDR CathPCI registry data sets, MHCC staff reviewed the zip code areas from which HCGH draws primary PCI patients over the period CY 2016 through CY 2018, and found the zip code areas included in HCGH's PSA to be consistent with the analysis. Staff also found the volume of cases performed at Johns Hopkins Hospital for residents in the PSA of HCGH to be consistent for CY 2017 and CY 2018. Johns Hopkins Hospital has the greatest market share overlap with the PSA of HCGH. The two hospitals that captured the next highest proportion of patients from the PSA of HCGH for elective PCI cases were the former Adventist HealthCare Washington Adventist Hospital and Saint Agnes Hospital. Together, those two hospitals and Johns Hopkins Hospital captured approximately 80% of the market share for elective PCI cases in the PSA for HCGH in CY 2017 and CY 2018, as shown in Table 8.

Table 8: Overlap with PSA of HCGH for Elective PCI Cases by Hospital, CY 2017-2018

Location	CY 2017			CY 2018*		
	Total Elective Cases	Cases in PSA of HCGH	Percent of Market Share	Total Elective Cases	Cases in PSA of HCGH	Percent of Market Share
Johns Hopkins Hospital	639	132	45.1%	531	107	40.7%
Saint Agnes Hospital	328	32	10.9%	331	30	11.4%
Adventist HealthCare Washington Adventist Hospital	632	67	22.9%	632	74	28.1%
MedStar Union Memorial Hospital	954	14	4.8%	861	9	3.4%
Other Hospitals**	5,696	48	16.4%	6,047	43	16.3%
Total	8,117	293	N/A	8,295	263	N/A

Source: MHCC staff analysis of NCDR CathPCI Registry data, CY 2017-18.

*Zip code area information was missing in CY 2018 for almost 9% of the elective PCI cases in the NCDR CathPCI Registry data, including almost 1/3 of cases for Saint Agnes Hospital; for CY 2017, 1% of elective PCI cases had missing zip code area information. Hospitals included in counts are Maryland hospitals and MedStar Washington Medical Center.

**Hospitals in the "Other" category are those that performed less than ten elective PCI cases that overlap with the PSA of HCGH for both CY 2017 and CY 2018.

MHCC staff's analysis of the NCDR CathPCI registry data suggests that the total volume of elective PCI cases for the PSA of HCGH is about 300 cases. HCGH, with its projection of 120 elective PCI cases annually, expects to capture approximately 40% of the elective PCI market share for its PSA. This is consistent with the percentage of market share achieved by Johns Hopkins Hospital, based on the CY 2017 and CY 2018 NCDR CathPCI registry data.

The service area overlap analysis suggests that most elective PCI cases for a program at HCGH will be those currently performed at Johns Hopkins Hospital, consistent with HCGH's analysis of the source of its projected elective PCI cases. Although potentially other hospitals could experience some loss of elective PCI case volume through the addition of this service at HCGH, especially Saint Agnes Hospital and Adventist HealthCare at White Oak Medical Center, the hospital that replaced Washington Adventist Hospital in 2019, the likely level of impact on these programs would not reduce the volume of any of these existing PCI program to levels inconsistent with the State Health Plan requirements because the volumes achieved by Johns Hopkins Hospital, Saint Agnes Hospital, and Washington Adventist Hospital were well above 200 cases.

Recommendation

Staff recommends that the Commission find that HCGH has demonstrated that its proposed elective PCI program is likely to achieve a volume of 200 or more total PCI cases (elective and emergency) by the end of the second year of providing elective PCI services. This case volume can be achieved without reducing the volume at existing elective PCI programs unacceptably.

(3) Financial Viability

The Commission may waive the volume requirement in subsection (2) if the applicant demonstrates that adding an elective PCI program to its existing primary PCI program at its likely projected annual case volume will permit the hospital's overall PCI services to achieve financial viability.

HCGH is not seeking a waiver of the volume requirement in subsection (2) that permits an applicant to demonstrate that the addition of elective PCI services will permit the PCI program to achieve financial viability. HCGH provided a financial schedule for revenues and expenses that show income generation from delivery of primary PCI in FY 2018 and FY 2019, and in future years, with the exception of the first year of implementation anticipated, FY 2020. Less revenue is projected for the first year of implementation, FY 2020, based on an assumed 50% reduction of charges for the elective PCI volume shifted away from other hospitals. This assumption is consistent with the Health Services Cost Review Commission's policies with respect to revenue adjustments for observed market shifts in a service from one or more hospitals to another hospital.

Table 9: Revenues and Expenses, Primary PCI Services at HCGH

	FY 2018	FY 2019
Gross Patient Services Revenue	$2,404,653	$2,452,747
Bad Debt, Contractual Allowances, Charity Care	($168,326)	($171,692)
Net Patient Services Revenue	$2,236,328	$2,281,054
Salaries, Wages, and Benefits	$318,257	$324,622
Contractual Services	-	-
Current Depreciation	-	-
Supplies	$347,405	$354,353
Existing Variable Expenses	$112,215	$114,459
Other Fixed Expenses	$872,548	$889,999
Total Operating Expenses	$1,650,525	$1,683,434
Income from Operations	$585,903	$597,621

Source: HCGH Response to MHCC Questions, January 24, 2019, page 5.

Table 10: Projected Revenues and Expenses, Primary and Elective PCI Services at HCGH

	FY 2020	FY 2021	FY 2022	FY 2023
Gross Patient Services Revenue Baseline	$2,502,801	$2,552,838	$2,602,874	$2,654,932
Inpatient Services- incremental	$327,176	$1,063,876	$1,156,556	$1,252,516
Outpatient Services	$108,879	$450,420	$471,888	$494,035
Bad Debt, Contractual Allowances, Charity Care	($205,650)	($284,629)	($296,192)	($308,104)
Net Patient Services Revenue	$2,732,207	$3,781,506	$3,935,126	$4,093,379
Salaries, Wages, and Benefits	$751,323	$1,150,248	$1,201,175	$1,253,678
Contractual Services	--	--	--	--
Current Depreciation	--	--	--	--
Project Depreciation	--	--	--	--
Supplies and Drugs	$701,444	$1,013,468	$1,064,216	$1,116,588
Other Variable Expenses	$138,202	$140,966	$143,785	$146,661
New Variable Expenses	$88,370	$186,392	$199,965	$214,006
Total Fixed Expenses	$1,097,943	$1,119,902	$1,142,300	$1,165,146
Total Operating Expenses	$2,777,282	$3,610,976	$3,751,440	$3,896,079
Income from Operations	($45,075)	$170,530	$183,686	$197,301

Source: HCGH Response to MHCC Questions, January 24, 2019, page 5.

Recommendation

This standard is inapplicable to the review of the HCGH proposal because the hospital is not requesting a waiver from the minimum volume standard on the basis of its ability to achieve financial viability through the addition of elective PCI. Staff concludes that HCGH can provide primary and elective PCI services on a financially viable basis.

(4) Quality

A hospital shall demonstrate that it provided high quality emergency PCI services over a period of two years or longer, unless the hospital is not required to obtain a Certificate of Conformance to establish emergency PCI services before establishing elective PCI services.

As previously noted, HCGH was first authorized to provide primary PCI services in 2006 and has received three renewals of its "waiver" to continue providing the service. Before issuing each of the waiver renewals, the Commission found that the program met the applicable quality standards. HCGH has submitted its application for a Certificate of Ongoing Performance, and MHCC staff has reviewed this information and requested some additional information. Based on the information submitted, MHCC staff is aware of no reason for concern about the quality of HCGH's primary PCI program.

(5) Preference

A hospital that was providing primary PCI services on January 1, 2012 will be given preference over another hospital that was not providing primary PCI services on January 1, 2012, when the two hospitals have service areas that overlap and only one additional PCI program is needed to provide adequate geographic access for the population in the service areas of both hospitals.

HCGH provided primary PCI services on January 1, 2012. It is not in a competitive review with a hospital seeking to establish elective PCI services that was not providing primary PCI services on January 1, 2012. Thus, this standard is not applicable in this review**.**

(6) Patient Selection
The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

(a) Patients described as appropriate for elective 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) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk are not suitable for elective PCI, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.

HCGH provided the required commitment, in writing, in its Certificate of Conformance application filing.

IV. SUMMARY AND RECOMMENDATION

The information considered in this review indicates that HCGH provides a distinct advantage for geographic accessibility to primary PCI services for approximately a third of the residents in its primary service area. HCGH's existing primary PCI program has continued to be in conformance with the standards established by MHCC for primary PCI in the non-cardiac surgery hospital setting, and a total PCI volume of over 200 cases is likely to be met, if HCGH introduces elective PCI services. Staff recommends that the Commission approve the request of Howard County General Hospital for a Certificate of Conformance to establish elective PCI services. The hospital has demonstrated that timely access to primary PCI services will be jeopardized without the addition of an elective PCI program.

IN THE MATTER OF THE	*	
	*	
ESTABLISHMENT OF ELECTIVE	*	
	*	**BEFORE THE**
PERCUTANEOUS CORONARY	*	
	*	
INTERVENTION SERVICES BY	*	
	*	**MARYLAND HEALTH**
HOWARD COUNTY GENERAL	*	
	*	
HOSPITAL	*	
	*	**CARE COMMISSION**
MATTER NO. 19-13-CC008	*	
	*	

* *

FINAL ORDER

Based on the analysis and recommendations in the Staff Report and the record in this review, it is, this 16th day of April, 2020, **ORDERED**:

That in accordance with and subject to the applicable requirements in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Intervention Services Chapter of the State Health Plan, the application filed by Howard County General Hospital for a Certificate of Conformance to establish elective, or non-primary, PCI services is hereby **APPROVED**,

MARYLAND HEALTH CARE COMMISSION

Appendix 1: MHCC Staff Analysis of Travel Time to Alternative Cardiac Intervention Centers from the Zip Code Areas in the HCGH PSA

Hour of the Day	Percent of Cases	Travel Time (minutes)									
		Zip Code Areas in HCGH's Primary Service Area & Closest Alternative Hospital									
		21042	21044	21043	21045	20723	21075	20707	21046	20759	20763
		St. Agnes	St. Agnes	St. Agnes	St. Agnes	AHC-WOMC	St. Agnes	AHC-WOMC	AHC-WOMC	AHC-WOMC	AHC-WOMC
12-1am	2%	29	24	16	20	22	16	14	20	17	20
1-2 am	3%	30	24	16	20	22	16	14	20	16	20
2-3 am	2%	28	24	16	20	22	16	14	20	16	20
3-4 am	3%	28	25	17	20	20	16	14	20	16	20
4-5 am	3%	28	24	16	20	20	16	14	20	16	20
5-6 am	3%	30	23	16	20	21	16	16	21	18	21
6-7 am	4%	34	26	16	22	23	18	16	22	20	23
7-8 am	4%	38	33	16	25	25	19	16	25	21	24
8-9 am	4%	38	30	17	22	25	19	16	23	20	23
9-10 am	5%	34	26	17	22	22	18	16	22	20	22
10-11 am	5%	33	26	17	22	23	18	15	22	20	22
11-12pm	4%	33	26	18	23	22	19	16	22	20	22
12- 1 pm	6%	33	26	18	23	23	19	16	23	21	23
1- 2 pm	6%	33	26	18	22	22	19	16	22	20	22
2- 3 pm	6%	34	29	18	22	24	19	16	23	20	25
3- 4 pm	7%	37	30	17	22	24	22	16	23	21	23
4- 5 pm	5%	37	33	18	22	24	22	16	23	21	24
5- 6 pm	4%	37	33	18	22	25	22	17	25	22	25
6-7 pm	5%	34	29	18	22	24	19	16	23	21	23
7- 8 pm	4%	31	26	18	22	23	18	16	22	20	22
8- 9 pm	4%	31	26	17	22	23	18	16	22	19	21
9- 10 pm	6%	31	26	17	22	23	18	16	21	19	21
10- 11pm	3%	30	26	17	21	22	18	16	21	18	21
11-12 pm	3%	28	26	17	21	22	17	14	21	18	20

Source: MHCC staff analysis of estimated travel times from zip code areas in the PSA of HCGH to the closest alternative hospitals with primary PCI programs, Saint Agnes Hospital and Adventist HealthCare at White Oak Medical Center (AHC-WOMC), using Google Maps for the date March 2, 2020.