IN THE MATTER OF	*	**BEFORE THE**
HOWARD COUNTY	*	**MARYLAND**
GENERAL HOSPITAL	*	**HEALTH CARE**
Docket No. 19-13-CP012	*	**COMMISSION**

*** ***

STAFF REPORT AND RECOMMENDATION

CERTIFICATE OF ONGOING PERFORMANCE FOR PRIMARY PERCUTANEOUS CORONARY INTERVENTION SERVICES

June 18, 2020

I. INTRODUCTION

A. Background

Percutaneous coronary intervention (PCI), commonly known as coronary angioplasty, is a non-surgical procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing. Primary PCI programs provide emergency PCI intervention in the event of a heart attack shortly after it begins. Elective PCI programs provide interventions that revascularize coronary arteries that are substantially blocked but have not yet resulted in an immediate cardiac event.

For many years, only Maryland hospitals with on-site cardiac surgery services could provide PCI. However, in the 1990s, Maryland began allowing some hospitals to perform primary PCI services without cardiac surgery on-site, first as part of research trials evaluating the safety of providing primary PCI at such hospitals and, later, as a regular clinical service, based on the research findings. MHCC issued waivers to the co-location requirement. In the following decade, similar research evaluated the safety of providing elective PCI services at hospitals without on-site cardiac surgery.

The nine Maryland hospitals that obtained waivers to provide elective PCI services participated in a multi-site clinical trial, C-PORT E, a study that was approved by the Commission upon the recommendation of its Research Proposal Review Committee. This non-inferiority study provided evidence that elective PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. In 2012, the Maryland legislature passed a law, categorically regulating the supply and distribution of PCI services and directing the Commission to establish a process and minimum standards for a hospital to obtain and maintain Certificates of Ongoing Performance for the provision of cardiac surgery and PCI. MHCC was directed to establish a Clinical Advisory Group (CAG) to advise the agency on development of regulations to implement the new law.

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter (Cardiac Services Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Services Chapter was subsequently revised and updated in November 2015 and again in January 2019. The primary change in these revisions to the Cardiac Services Chapter that affects PCI programs has been a change to the benchmark used to evaluate hospitals' risk-adjusted mortality rates. Commission staff was unable to obtain benchmark information for risk-adjusted mortality rates consistent with the regulations adopted in November 2015 that reflected the recommendations of the CAG. As a result, the standard addressed by applicants was determined to be inapplicable; however, information on how hospitals performed relative to the newly adopted mortality standard is included in staff reports.

The Cardiac Services Chapter contains standards for evaluating the performance of established PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or both primary and

elective PCI services, for a period of time specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must demonstrate that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide PCI services.

B. Applicant

Howard County General Hospital

Howard County General Hospital (HCGH) is a 225-bed general hospital located in Columbia (Howard County). It is a Johns Hopkins Health System hospital. HCGH does not have a cardiac surgery program on site.

HCGH began providing primary PCI services under a research waiver in September 2003 through participation in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials. Subsequently, the hospital was authorized to provide primary PCI on a regular clinical basis, subject to periodically renewing its qualification for a waiver from the requirement to provide "open heart surgery" as a prerequisite for the provision of PCI services. This waiver was renewed for HCGH over the years based on its compliance with performance requirements established by MHCC. Historically, HCGH has only provided primary PCI services. The hospital was authorized to introduce elective PCI services on April 16, 2020, under MHCC regulations adopted pursuant to the 2012 statutory changes discussed above.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. Howard County is in the Baltimore/Upper Shore region, which also includes Anne Arundel, Baltimore, Baltimore City, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties. Fourteen hospitals in this region provide PCI services. Except for one of the fourteen hospitals, each currently performs both primary and elective PCI services. Five of these hospitals provide both cardiac surgery and PCI services, and one facility in this region has a Certificate of Need to establish a cardiac surgery program.

C. Staff Recommendation

MHCC staff recommends that the Commission approve HCGH's application for a Certificate of Ongoing Performance to continue providing primary PCI services.[1] A description of HCGH's documentation of its performance and the staff's analysis follows.

II. PROCEDURAL HISTORY

HCGH filed a Certificate of Ongoing Performance application on March 22, 2019, in accordance with the review schedule determined by the Commission. MHCC staff requested additional information on February 21, 2020 and April 3, 2020. Additional information was

[1] The next ongoing performance review of HCGH will cover both primary and elective PCI, given that provision of elective PCI by this hospital was authorized in April 2020.

submitted on March 13, 2020 and April 24, 2020. Staff also spoke with representatives of HCGH on May 13, 2020 regarding the review of individual interventionalists.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

HCGH stated that during the review period, there have been no deficiencies in data collection or reporting identified by MHCC staff.

Staff Analysis and Conclusion

HCGH has complied with the submission of data to the American College of Cardiology National Cardiac Data Registry (ACC-NCDR) for CathPCI to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of the ACC-NCDR CathPCI data to validate that hospitals submitted accurate and complete information to the ACC-NCDR. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of HCGH's data reported during the audit period. MHCC staff receives duplicate data as required and concludes that HCGH complies with this standard.

Institutional Resources

10.24.17.07D(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.

HCGH reported that primary PCI services were always available between July 2014 and December 2019. HCGH has maintained two cardiac catheterization laboratories (CCLs) and submitted a log of all downtimes for each CCL for the period June 30, 2013 through December 31, 2019, as shown in Tables 1A, 1B, and 1C. HCGH reported that CCL 1 was down for a total of 260 hours, or 0.7% of the total time period. CCL 2 was down for a total of 274 hours, also 0.7% of the total hours. There were no times when both rooms were simultaneously unavailable.

Table 1A: HCGH CCL Downtime by Location, Date, and Duration, September 2013-March 2016

Location	Date	Hours of Downtime	Reason/Explanation
CCL 1	9/13/13	1.1	Power Issue
CCL 1	2/4/14	4.0	Preventative Maintenance
CCL 1	10/14/14	1.0	Dose Rate Adjustment by Vendor
CCL 1	12/29/14	8.5	Replacement of Uninterruptible Power Supply
CCL 1	2/5/15	4.0	Preventative Maintenance
CCL 1	6/30/15	2.3	Computer Issue
CCL 1	9/25/15	1.0	Unable to Move C-Arm
CCL 2	10/22/15	3.5	C-Arm not Returning to Home Position
CCL 2	11/4/15	1.7	Issue with Handle for Table
CCL 2	12/1/15	4.0	Preventative Maintenance
CCL 2	12/3/15	2.0	Service to Resolve Chiller Issue
CCL 2	10/23/13	4.0	Preventative Maintenance
CCL 2	11/5/13	1.0	Room Locked-Up During a Case
CCL 2	3/6/14	6.0	Chiller Shut-Down on Lateral Head
CCL 2	4/4/14	67.9	Fluoroscopy Not Working; Power Supply Replaced
CCL 2	4/28/14	4.0	Preventative Maintenance
CCL 2	6/20/14	1.0	Error Code and Reboot
CCL 2	8/1/14	8.5	Power Supply Issue Impacting Ability to Move Table
CCL 2	8/5/14	76.0	No Power to Table
CCL 2	11/4/14	4.0	Preventative Maintenance
CCL 2	11/6/14	1.0	Repair Related to Table
CCL 2	11/28/14	2.0	Repair Related to Monitor
CCL 2	12/1/14	1.0	Repair Related to Monitor
CCL 2	12/2/14	22.0	Water Leak From Area Above CCL 2
CCL 2	4/24/15	4.0	Preventative Maintenance
CCL 2	8/17/15	1.5	Repair Related to Monitor
CCL 2	9/22/15	2.5	Repair Related to Problem with Audio
CCL 1	3/17/16	4.0	Preventative Maintenance

Source: HCGH application, pages 2-5.

Table 1B: HCGH Downtime by Location, Date, and, April 2016- December 2018

Location	Date	Hours of Downtime	Reason
CCL 1	4/27/16	18	Repair Related to a Power Issue
CCL 1	9/16/16	8.5	Repair of Broken Foot Switch Cover
CCL 2	4/7/16	4.0	Preventative Maintenance
CCL 2	9/8/16	13.0	Water Leak From Area Above CCL 2
CCL 2	10/10/16	12.0	Water Leak From Area Above CCL 2
CCL 2	11/3/16	4.0	Preventative Maintenance
CCL 2	1/9/17	1.0	AP Ref Monitor Won't Power Up
CCL 1	2/14/2017	184.0	Handle of Table Replaced
CCL 1	2/22/2017	4.0	Preventative Maintenance
CCL 1	3/21/2017	18.0	Replace Fluoroscopy Footswitch
CCL 2	4/11/17	1.3	Chiller Low on Fluid
CCL 2	4/19/17	4.0	Preventative Maintenance
CCL 2	6/23/2017	2.0	Tube and Sensor Errors
CCL 2	7/20/17	8.5	Lose Monitor when Boom is Moved
CCL 2	10/2/17	4.5	Low Air Flow to Cooling Unit
CCL 2	11/13/17	4.0	Preventative Maintenance
CCL 2	1/23/18	1.6	Water Leak From Area Above CCL 2
CCL 2	1/24/18	3.3	Water Leak From Area Above CCL 2
CCL 2	2/7/18	0.5	Tableside Controller for C-arm Failure
CCL 2	2/7/18	1.5	Tableside Controller for C-arm Failure
CCL 2	2/21/18	2.0	Tableside Controller for C-arm Failure
CCL 1	5/11/18	0.5	Loud Beeping in Equipment Room
CCL 1	5/15/18	1.8	Corrective Maintenance
CCL 2	7/9/18	0.4	Lateral Tube Collimator Power Failure
CCL 2	7/9/18	1.3	Lateral Tube Collimator Power Failure
CCL 1	8/11/18	1.0	Reboot Required After Accidental Power Shut-off
CCL 2	9/17/18	3.0	Issues with Frontal Image Display
CCL 2	9/18/18	1.0	Issues with Frontal Image Display
CCL 2	10/11/18	6.5	Preventive Maintenance
CCL 1	11/7/18	1.0	Change Order to Upgrade System
CCL 1	11/29/18	8.0	Preventive Maintenance
CCL 2	12/20/18	1.0	Lateral Chiller Fluid Low
CCL 2	12/20/18	1.0	Lateral Chiller Fluid Low

Source: HCGH application, pages 2-5.

Table 1C: HCGH Downtime by CCL, Date, and Duration, January 2019- December 2019

Location	Date	Hours of Time	Reason
CCL 2	1/3/19	2.8	Cooling Failure; Unit Shut Down
CCL 2	1/31/19	1.0	No Fluoroscopy of Lateral Tube Image
CCL 2	1/31/19	3.0	No Fluoroscopy of Lateral Tube Image
CCL 2	2/12/19	1.5	No Fluoroscopy of Lateral Tube Image
CCL 2	2/15/19	1.6	No Fluoroscopy of Lateral Tube Image
CCL 2	4/9/19	5.5	Preventive Maintenance
CCL 1	5/23/19	3.9	Only Partial Movements of Table Available
CCL 1	6/12/19	6.2	Preventive Maintenance
CCL 2	6/14/19	2.1	Low Coolant
CCL 2	7/25/19	2.3	Low Coolant
CCL 1	9/9/19	2.4	No Power to Table
CCL 2	9/17/19	103.1	Disk Full Message; Cannot Store Images
CCL 2	10/21/19	2.1	Low Coolant
CCL 2	10/22/19	4.4	Preventive Maintenance
CCL 1	11/27/19	8.0	Preventive Maintenance

Source: HCGH application, pages 2-5.

Staff Analysis and Conclusion

MHCC staff reviewed the log of CCL closures for the period of June 30, 2013 to December 31, 2019. There were no times reported where CCL 1 and CCL 2 were both closed simultaneously. HCGH's use of two CCL rooms ensured that a CCL was available for primary PCI 24 hours per day and seven days per week during the period reviewed.

MHCC staff concludes that HCGH complies with this standard.

10.24.17.07D(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 DTB times for transfer cases and evaluate areas for improvement.

HCGH provided a signed statement from Steven C. Snelgrove, President, acknowledging that HCGH is committed to providing primary PCI service as soon as possible following patient arrival, with the aim of providing the service within 90 minutes of arrival at for at least 75% of non-transfer cases. Mr. Snelgrove also states that the hospital will track door-to-balloon time for transfer cases and evaluate areas for improvement. For the requested reporting period, HCGH

stated that it was not a receiving center for transfer patients. HCGH provided door-to-balloon (DTB) times for 2015 through June 2018, as shown in Table 2.

Table 2: HCGH DTB Times by Quarter, Primary PCI Cases (Non-Transfer)

Quarter/End Date for Rolling Eight Quarter Period	Number of PCI Cases with DTB Time <= 90 Minutes	Total PCI Cases	Percent of Cases with DTB of 90 Minutes or Less	
			By Quarter	By Rolling Eight Quarters*
CY2015 Q1	9	16	**56%**	
CY2015 Q2	25	27	93%	
CY2015 Q3	22	29	76%	
CY2015 Q4	20	23	87%	
CY2016 Q1	14	22	**64%**	
CY2016 Q2	17	23	**74%**	
CY2016 Q3	22	27	81%	
CY2016 Q4	23	25	92%	78%
CY2017 Q1	15	24	**63%**	78%
CY2017 Q2	17	21	81%	78%
CY2017 Q3	16	23	**70%**	77%
CY2017 Q4	18	27	**67%**	74%
CY2018 Q1	29	37	78%	76%
CY2018 Q2	15	24	**63%**	75%
CY2018 Q3	15	29	79%	76%
CY2018 Q4	27	32	84%	78%
CY2019 Q1	15	21	**71%**	76%
CY2019 Q2	22	27	81%	77%
Total*	341	457	75%	

Source: HCGH Application, Q4, Updated Q4, *MHCC analysis ACC-NCDR CathPCI for CY 2015-CY 2018 and data provided by HCGH in its application for CY 2019 Q1-Q2.

Staff Analysis and Conclusion

On a quarterly basis, HCGH failed to meet the benchmark DTB standard, that at least 75% of cases have a DTB time of 90 minutes or less, in eight of nineteen quarters. In three of those quarters, the DTB time standard was met for 71 to 74% of cases, just below the standard. MHCC staff verified that these DTB metrics are consistent with data previously reported to the Commission for CY 2015 through CY 2018. MHCC staff also calculated the percentage of cases with a DTB time of 90 minutes or less by rolling eight quarter periods and by calendar year, using the information submitted to MHCC and the ACC-NCDR CathPCI registry by HCGH. This analysis showed that HCGH met the standard when measured over rolling eight-quarter periods, except for the period ending 2017 Q3, when HCGH just missed the standard with 74% of cases meeting the DTB benchmark.

HCGH provided additional details about delays in primary PCI cases. HCGH stated that 58% (n = 28) of these cases had a primary delay at the system level and 42% (n = 20) had a patient-centered reason for delay identified. Of the 28 cases with a DTB of greater than 90 minutes between CY 2015 and CY 2018 where a system-level delay was identified, a majority were walk-

in patients who presented to the Emergency Department without involving an EMS transport service (n = 17).

HCGH provided a list of steps that are underway to improve DTB times for walk-in patients. For example, HCGH reported that the hospital has streamlined electrocardiogram (ECG) testing and interpretation for patients presenting directly to the Emergency Department with chest pain or related complaints (i.e., dyspnea, nausea, abdominal pain). HCGH also reported that this process further improved when HCGH opened its new Emergency Department in February of 2020. Additionally, HCGH conducts community outreach in Howard County to remind the community that calling 911 is safer and more efficient than presenting to the Emergency Department without involving EMS for patients with symptoms of a heart attack or stroke. Finally, HCGH reports that they developed a team to facilitate the transfer of STEMI patients from the Emergency Department to the CCL so that a patient may receive PCI services as soon as possible after the CCL team arrives.

HCGH's analysis of the 20 patients with patient-centered reasons for delay revealed that the most common cause was presentation with cardiac arrest. HCGH responded that patients with cardiac arrest often require stabilization in the Emergency Department (e.g. intubation). Other common causes for delays reported by HCGH were difficulty obtaining vascular access and difficulty crossing the culprit lesion to correctly position the angioplasty equipment.

HCGH stated that if its PCI service program is expanded to include elective PCI services, then an interventional cardiologist will be physically present at HCGH during normal business hours, which will allow for a more rapid performance of primary PCI on patients presenting with STEMI during these times. MHCC approved HCGH's Certificate of Conformance in April 2020 to add elective PCI services.

Given HCGH's performance on the DTB standard, which has not been consistently strong, MHCC staff will track the hospital's performance on the DTB benchmark closely and will follow-up, if HCGH's performance lags on the DTB benchmark. Since the hospital has not received any transfers for primary PCI patients, the final part of this standard is not applicable to HCGH.

MHCC staff recommends that the Commission find that HCGH's performance on this standard is acceptable.

10.24.17.07D(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.

As shown in Table 3, HCGH provided the number of physicians, nurses, and technicians who are able to provide cardiac catheterization services to acute myocardial infarction patients. At the time of the application's filing, HCGH reported that it was in the process of recruiting and hiring two additional full-time equivalent (FTE) nurses and one additional FTE radiologic technician.

Table 3: HCGH CCL Staff

Staff	Number of Staff FTEs	Cross Training (S/C/M*)
Physician	8	
Nurse	4.5	C, M
Technician	3.5	S, M

Source: HCGH Application, Q6a.
*Scrub (S), circulation (C), monitoring (M); N/A means not applicable.

Since filing its application, HCGH reported that it has filled empty positions. The current staffing levels include six nurse FTEs and four technician FTEs. Eight interventionalists are currently performing PCI.

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by HCGH to information reported in 2013 as part of HCGH's application for renewal of its waiver for primary PCI services. In the 2013 application, there were five nursing FTEs reported with three additional available as needed, four technician FTEs reported with one additional available as needed, and seven interventionalists on staff. The volume reported for July 2012 through June 2013 was 87 primary PCI cases.

Staff also compared the recently reported staffing levels for the CCL at HCGH to another existing program with only primary PCI services, MedStar Franklin Square Hospital. MedStar Franklin Square Hospital reported in its application for a Certificate of Ongoing Performance a total of five interventional cardiologists, 5.5 FTE nurses, and four FTE technicians, as of March 15, 2019.

MHCC staff concludes that HCGH has adequately staffed its primary PCI services; HCGH meets this standard.

10.24.17.07D(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 signed statement from Steven C. Snelgrove, President, acknowledging that HCGH is committed to providing primary PCI service as soon as possible and not exceeding 90 minutes from the patient arrival at the hospital for at least 75% of appropriate cases. Mr. Snelgrove also states that the hospital will track door-to-balloon time for transfer cases and evaluate areas for improvement.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of commitment provided and concludes that HCGH meets this standard.

10.24.17.07D(4)(e)The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

HCGH has allocated 0.8 FTEs to the Clinical Data Coordinator position dedicated to PCI program data collection and analysis. One additional staff member is available to assist with data entry during high volume periods and around deadlines for data submission; both of the positions are nursing positions.

Staff Analysis and Conclusion

MHCC staff concludes that HCGH is compliant with this standard.

10.24.17.07D(4)(f) 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.

Peter V. Johnston, M.D., has been the Medical Director of Cardiac Interventional Services at HCGH since July 1, 2010. His work at HCGH is limited to emergency PCIs. He does not routinely see patients at HCGH. He is assisted by a co-director, Eric Schwartz, M.D., who possesses in-depth knowledge of the program at HCGH and is routinely available at the hospital. HCGH submitted a letter from Dr. Johnston stating that he is responsible for defining and implementing credentialing criteria for the CCL and for overall management of the PCI program, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges. HCGH also submitted a job description for Dr. Johnston.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that HCGH is compliant with this standard.

10.24.17.07D(4)(g) The hospital shall design and implement a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

HCGH provided a list of the continuing educational programs offered since the last waiver renewal in September 2013. HCGH also provided additional information about frequency of training required for staff and the credentials required for staff. HCGH hires only technologists who are registered with the American Registry of Radiologic Technologists. This registration is only available to technologists who complete and report twenty-four credits of approved continuing education activities every two years. HCGH's PCI program also only hires nurses who are licensed by the State of Maryland as Registered Nurses (RNs). To be licensed by the State of Maryland, an RN must have completed 1,000 hours of active nursing practice within the previous five years or a Board-approved nursing education program within the previous five years. Effective June 17, 2019, there is a third option: RNs may choose to complete thirty continuing education units to satisfy their requirements for license renewal. HCGH does not have any additional requirements for formal continuing education credits beyond these requirements.

Staff Analysis and Conclusion

MHCC staff's review indicates that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that HCGH meets this requirement.

10.24.17.07D(4)(h) The hospital shall have a formal, written agreement with a tertiary care center that provides for the 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.

Victor Broccolino, the former HCGH President, and Margaret R. Garrett, Senior Legal Counsel, signed and dated an agreement with Johns Hopkins Hospital, a tertiary care center, stating that Johns Hopkins Hospital agrees to receive on an unconditional basis, the transfer of patients from HCGH for any required additional care, including emergent or elective cardiac surgery or PCI.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that HCGH meets this standard.

10.24.17.07D(4)(i) A hospital shall maintain its 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 hospitals performing primary PCI without on-site cardiac surgery.

John Dunn, Administrator of Diagnostic Imaging at HCGH, and James Scheulen, Chief Administrative Officer for Emergency Medicine at Johns Hopkins Medicine, signed and dated an agreement stating that: (1) Johns Hopkins Lifeline is a licensed specialty care ambulance service; (2) Johns Hopkins Lifeline provides air and ground ambulance service to HCGH; and (3) Johns Hopkins Lifeline guarantees the arrival of air or ground ambulance within 30 minutes of a request from HCGH, when clinically necessary.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement provided and concludes that HCGH complies with this standard.

<u>Quality</u>

10.24.17.07D(5)(a) The 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.

HCGH provided attendance records for the multidisciplinary STEMI committee from 2014 through 2018. HCGH described that this committee meets monthly, and the agenda includes both interventional case review and review of all issues related to primary PCI services, identification of problem areas, and development of solutions. Cases identified as needing in-depth review are referred for the quarterly mortality and morbidity conference review or root cause analysis on an as-needed basis.

Staff Analysis and Conclusion

HCGH holds monthly peer case review meetings that have had few cancellations during the 2015 through 2018 period. Meeting cancellations did not cause the meeting frequency to fall below every other month or six times per year.

MHCC staff concludes that HCGH meets this standard.

10.24.17.07D(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.

HCGH provided attendance records for the multidisciplinary STEMI committee meetings during the 2014 through 2018 period. Participants at this meeting include Howard County Department of Fire and Rescue personnel, Emergency Department (ED) nursing and physician leadership, a central venous line (CVL) nursing and technologist representative, CVL physician and administrative leadership, intensive care unit nursing and physician leadership, a cardiac rehabilitation representative, and quality assurance leadership.

Staff Analysis and Conclusion

HCGH reported only three meeting cancellations in 2015 through 2018; the three canceled meetings were scheduled to be held in March 2015, March 2017, and November 2018. The two meeting cancellations in March were due to the NCDR conference taking place, and the meeting in November 2018 was cancelled due to the Thanksgiving holiday.

MHCC staff concludes that HCGH meets this standard.

10.24.17.07D(5)(c) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

(i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or

(ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual

external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08; or

(iii) For a hospital with both primary and elective PCI programs, a quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraphs .07C(4)(c) and .07D(5)(c).

10.24.17.07D(5)(d) The performance review of an interventionalist referenced in Paragraph .07D(5)(c) shall:

(i) Include a review of angiographic images, medical test results, and patients' medical records; and

(ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.

HCGH reported that the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ) arranges for review of at least 10% of the program's PCI cases in each review period. HCGH submitted copies of external reviews for January 2015 through December 2018. The external reviews were completed by MACPAQ, an MHCC-approved external review organization. In addition, at least one case per provider is sent by Dr. Johnston to Johns Hopkins Hospital (JHH) for quality review quarterly. Cases are randomly selected for quality review by JHH, unless a case is flagged due to complications. A case with complications will be selected for review instead of a randomly selected case

HCGH reported that all cases that do not meet the DTB time standard are reviewed at a monthly multidisciplinary STEMI committee meeting and on weekly PCI DTB Time conference calls that are held every Friday afternoon with the CCL leadership and representatives from the Emergency Department. As of March 6, 2020, HCGH instituted an Interventional Radiology and Cardiovascular Services Multidisciplinary Morbidity and Mortality (M&M) Conference that meets quarterly to review complications from any interventional procedures performed in the catheterization laboratory. The conference is attended by the leadership of the CCL, and physicians representing Interventional Cardiology, Interventional Radiology, and Vascular Surgery. Previously any PCI cases with complications were reviewed at regular Catheterization Laboratory Quality and Assurance (QA) meetings. HCGH reported that the multidisciplinary M&M Conference will supplant the QA meetings going forward.

Staff Analysis and Conclusion

COMAR 10.24.17.07D(5)(c) does not require external review of primary PCI cases, and HCGH only performed primary PCI services from the time the program was first established through the end of the review period for its Certificate of Ongoing Performance application. However, HCGH uses external review as part of its evaluation of individual interventionalists. Between zero and 100% of individual interventionalists' cases have been reviewed by the external review agency in each review cycle from 2015 through 2018, as shown in Table 4.

Table 4: Range of Case Volume at HCGH and Percentage of Cases Reviewed Externally for Each Individual Interventionalist, by Review Period

Review Period	Range for Each Individual Interventionalist		
	Primary PCI Volume at HCGH	Percentage of Cases Reviewed	Number of Cases Reviewed
2015 Q1-Q4	10-17 cases	6%-29%	[1,2]
2016 Q1Q2	1-11 cases	0%-50%	[0,2]
2016 Q3Q4	3-11 cases	10%-33%	[1]
2017 Q1Q2	3-12 cases	8%-50%	[1]
2017 Q3Q4	1-13 cases	7%-100%	[1,2]
2018 Q1Q2	3-13 cases	9%-33%	[1,2]
2018 Q3Q4	2-12 cases	9%-50%	[1]

Source: MHCC staff analysis of MACPAQ reports provided by HCGH and ACC NCDR CathPCI data for 2018.

MHCC staff reviewed MACPAQ reports and calculated the percentage of cases for each individual interventionalist that were reviewed through external review in each review period. This percentage ranged from zero to 100%, as shown in Table 4. However, at least 10% of cases appear to have been reviewed annually for individual interventionalists. Due to the high number of interventionalists providing primary PCI services at HCGH relative to the total volume of cases for the program, even one case may represent over 10% of an individual interventionalist's case volume for the year. The semiannual volume of primary PCI cases for individual interventionalists was often five or fewer cases, but ranged from one to thirteen cases, as shown in Table 4.

In order to comply with the standard for individual interventionalist review, HCGH must review the greater of ten cases or 10% of cases for each individual interventionalist, or all cases, if fewer than ten cases were performed, which HCGH states that it did not know to be the case. HCGH program representatives believed that external reviews were required, and the reviews by MACPAQ were sufficient to meet the individual interventionalist review requirements. On an annual basis, for the program overall, MHCC staff calculated that between 10.5% and 18.1% of cases were typically reviewed externally.

HCGH reported an additional four primary PCI cases per year per interventionalist were reviewed at JHH during quarterly quality review. HCGH also reported that additional cases are reviewed as concerns arise, such as a DTB time greater than 90 minutes or complications. MHCC staff concludes that five to seven cases are reviewed per individual interventionalist annually through a combination of internal and external review of cases, with random selection for external reviews, but generally no random selection for internal reviews.

MHCC staff concludes that HCGH's review of individual interventionalists only partially meets the requirements in COMAR 10.24.17.07D(5)(c) because the total volume of cases reviewed is less than the number required. Staff notes that HCGH failed to comply with this standard due to confusion about the standards for individual interventionalist review, and with interventionalists at HCGH providing PCI services at other locations in Maryland, additional cases for these interventionalists are reviewed, which may compensate for the low number of cases reviewed for the HCGH location. Staff also notes that with the addition of an elective PCI program at HCGH, as approved by the Commission on April 21, 2020, the requirements for the review of individual interventionalists change; a program with both elective and primary PCI services may meet the requirement for review of individual interventionalists through a semiannual external review of at least three cases or 10 percent of cases, whichever is greater. MHCC staff recommends that the Commission find that, considering the specific circumstances detailed above, HCGH has met this standard.

10.24.17.07D(5)(e) The chief executive officer of the hospital shall certify annually to the Commission that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in this chapter, including those regarding internal peer review of cases and external review of cases.

HCGH submitted an affidavit from Steven Snelgrove, Chief Executive Officer, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, and annual interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that HCGH complies with this standard.

10.24.17.07D (5)(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review cases.

(i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.

(ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.

(iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

HCGH provided a thorough description of its quality assurance activities. Particularly, HCGH described the case review in monthly STEMI Case Committee meetings, weekly PCI DTB Time conference calls, annual peer review sessions, a review of all cases with missed DTB time

by the HCGH Patient Safety Committee, post-case feedback to HCGH EMS leadership, and annual EKG teaching sessions for Howard County EMS personnel. HCGH submitted detailed information about quality improvement activities that have arisen from the STEMI Case Committee. Examples include the creation of an Innovation and Continuous Improvement (LEAN) team to assist with projects designed to improve patient throughput in the ED and CCL and creation of changes to Code Blue protocols when members recognized that calling a Rapid Response was the quickest way to get a doctor to the bedside. HCGH also submitted minutes for its STEMI Committee Meetings and minutes from its Heart Attack and CQI Committee meetings for 2015 through 2018.

Staff Analysis and Conclusion

MHCC staff reviewed quality assurance activities described by HCGH and meeting minutes submitted and concludes that HCGH complies with this standard.

Patient Outcome Measures

10.24.17.07D(5)(a) A primary PCI program shall meet all performance standards established in statute or in State regulations.

(b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

(c) A hospital with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause 30-day risk-adjusted mortality rate for primary PCI cases.

HCGH submitted risk adjusted mortality by rolling 12-month reporting periods from the ACC-NCDR CathPCI reports for the period 2015 Q1 through 2019 Q2, when available, as shown in Table 5. A report is not available for any hospitals participating in the ACC-NCDR CathPCI registry of the rolling 12-month period of 2017 Q3 through 2018 Q2.

Table 5: HCGH Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI			
	Hospital AMR	95% Confidence Interval (CI)	National AMR	Meets MHCC Standard
2018q3-2019q2	7.02	[1.94, 17.22]	6.38	Yes
2018q2-2019q1	3.15	[0.38,10.97]	6.13	Yes
2018q1-2018q4	3.34	[0.41, 11.72]	6.00	Yes
2017q4-2018q3	2.04	[0, 23.32]	6.54	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry			
2017q2-2018q1	6.04	[0.73, 21.17]	6.91	Yes
2017q1-2017q4	6.78	[0.83, 23.54]	6.86	Yes
2016q4-2017q3	7.45	[1.55, 20.89]	6.75	Yes
2016q3-2017q2	4.37	[0.53, 15.22]	6.64	Yes
2016q2-2017q3	2.4	[0.06, 12.95]	6.77	Yes
2016q1-2017q4	2.39	[0.06, 12.91]	6.82	Yes
2015q4-2016q3	NR	[0, 9.23]	6.71	Yes
2015q3-2016q2	9.11	[2.52, 22.33]	6.66	Yes
2015q2-2016q1	9.92	[3.27, 22.11]	6.45	Yes
2015q1-2015q4	12.12	[4.54, 25.12]	6.26	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and March 2018
Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) included the National AMR or indicated statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) cases. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI cases.

Staff Analysis and Conclusion

This standard is not applicable for the majority of the review period of HCGH's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. The previous standard only referenced a statewide average as the benchmark, and MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. However, MHCC staff has provided information on how HCGH performed over the period between January 2015 and June 2019, as shown in Table 5.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for STEMI cases and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for HCGH for all 12-month reporting periods between 2015 Q1 and 2019 Q2. MHCC staff concludes that HCGH would have met this standard, if it was applicable for the period reviewed. A report for the hospital's performance for the period ending December 2019, the first period for which the current standard applies, is not yet available.

Physician Resources

10.24.17.07D(7)(a)Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24 month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight quarter basis and report the results to the Maryland Health Care Commission on a quarterly basis.

HCGH submitted a log of primary PCI cases at the applicant hospital as well as primary and elective cases at other hospitals by quarter from 2015 through the end of 2018. Drs. Johnston, Hwang, Miller, Padder, Resar, Thiemann, Trost, and Williams each signed and dated affidavits affirming under penalties of perjury that the information contained in the table on the doctor's form is true and correct to the best of the doctor's knowledge.

Staff Analysis and Conclusion

Staff determined that current interventionalists performed at least 100 PCI procedures on a rolling eight quarter basis between 2015 and 2018.

HCGH complies with this standard.

10.24.17.07D(7)(b)Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24 month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

HCGH responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to HCGH. While HCGH does not have on-site cardiac surgery, each physician performing primary PCI at HCGH performed over 50 PCI procedures annually on average for each of the two 24-month periods.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI procedures annually averaged over a 24 month period, who took a leave of absence of less than one year during the 24 month period measured, may resume the provision of primary PCI provided that:

(i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;

(ii) The physician continues to satisfy the hospital's credentialing requirements; and

(iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.

HCGH responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to HCGH. While HCGH does not have on-site cardiac surgery, as previously noted, each physician performing primary PCI at HCGH performed at least 50 PCI procedures annually, averaged over each of the two 24-month periods.

10.24.17.07D(7)(e) Each physician shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or completed their training before 1998 and did not seek board certification before 2003 [or physicians who completed a fellowship in interventional cardiology less than three years ago].

10.24.17.07D(7)(f)Each physician shall obtain board certification within three years of completion of a fellowship in interventional cardiology.

HCGH submitted a signed and dated statement from Dr. Peter Johnston, Medical Director, Cardiac Interventional Services, acknowledging that all physicians performing primary PCI services at HCGH are board certified in interventional cardiology or are exempt from this requirement.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation provided and concludes that HCGH meets this standard.

10.24.17.07D (7)(g) An interventionalist shall complete a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology during every two years of practice.

HCGH submitted signed and dated attestations from Drs. Johnston, Hwang, Miller, Padder, Resar, Thiemann, Trost, and Williams stating that each has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC staff reviewed the statements provided and concludes that HCGH meets this standard.

10.24.17.07D (7)(h) Each physician who performs primary PCI agrees to participate in an on-call schedule.

HCGH submitted a signed statement from the medical director of cardiac interventional services, Dr. Peter Johnston, acknowledging that each physician who has performed primary PCI is participating in the on-call schedule. HCGH also submitted a copy of the on-call schedule for March 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for March 2019 and observed that Drs. Johnston, Hwang, Padder, Miller, Williams, Resar, Trost, and Thiemann were all scheduled to be on-call at different times during the month.

MHCC staff concludes that HCGH meets this standard.

Volume

10.24.17.07D(8)(a) For primary PCI cases, if a program falls below 36 cases for rural PCI providers and 49 cases for non-rural providers, a focused review will be triggered.

HCGH provided the annual total volume of primary PCI cases at HCGH for CY 2015 to CY 2019. As shown in Table 6, HCGH performed between 95 and 98 primary PCI cases in four of the five years and performed 122 cases in 2018.

Table 6: HCGH PCI Volume by Year, CY 2015- CY 2019

Calendar Year	Primary PCI
2015	95
2016	97
2017	95
2018	122
2019	98

Source: MHCC analysis of HCGH Application, updated response to Q4.

Staff Analysis and Conclusion

Between January 2015 and December 2018, MHCC staff's analysis of the ACC-NCDR CathPCI data indicates that, collectively, interventionalists at HCGH performed a total of between 17 and 37 primary PCI cases per quarter. Staff determined that at least 49 primary PCI procedures were completed per year during this period.

MHCC staff concludes that the standard does not apply to HCGH.

10.24.17.07D(8)(b) The target volume for primary PCI operators is 11 or more primary cases annually.

HCGH provided the number of primary PCI cases by interventionalist from January 2015 to December 2018.

Staff Analysis and Conclusion

MHCC staff reviewed the tables submitted by HCGH. These tables show that between July 2014 and December 2018, each interventionalist performed at least 11 primary PCI procedures per year, on a rolling four quarter basis.

Patient Selection

10.24.17.07D(9) A 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/AHS) for Management of Patients with Acute Myocardial Infarction or 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) believes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

(c)Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.

(d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believes that transfer to a tertiary institution may be harmful to the patient.

When asked about the number of PCI patients who received thrombolytic therapy that subsequently failed during the review period, HCGH responded that no PCI patients received thrombolytic therapy that subsequently failed, as described in (c) above, during the review period.

HCGH also reported that no patients received primary PCI services inappropriately, based on an internal or external review of primary PCI cases for the review period.

Staff Analysis and Conclusions

MHCC staff reviewed the external review reports from January 2015 through December 2018. HCGH meets this standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff concludes that HCGH has met all of the requirements for a Certificate of Ongoing Performance. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a Certificate of Ongoing Performance that permits HCGH to continue providing primary and elective percutaneous coronary intervention services for four years.