

**IN THE MATTER OF
JOHNS HOPKINS BAYVIEW
MEDICAL CENTER**

*** BEFORE THE
* MARYLAND
* HEALTH CARE
* COMMISSION**

Docket No.: 24-24-CP045

**STAFF REPORT AND RECOMMENDATION
CERTIFICATE OF ONGOING PERFORMANCE
FOR PRIMARY & ELECTIVE PERCUTANEOUS CORONARY INTERVENTION
SERVICES**

October 17, 2024

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 (or emergency) PCI programs provide emergency PCI intervention in the event of a heart attack shortly after it begins. Elective (or non-primary) 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. The Maryland Health Care Commission (MHCC or Commission) issued waivers to hospitals to exempt them from the requirement for co-location of primary PCI services with cardiac surgery. 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 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. The legislation required the Commission to establish a Clinical Advisory Group (CAG) to advise the agency on 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 Surgery Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Surgery Chapter was subsequently revised in November 2015 and again in January 2019. The main change in these revisions that affect PCI programs has been a change to the benchmark used to evaluate hospitals' risk-adjusted mortality rates. Commission staff were 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 Surgery Chapter contains standards for evaluating the performance of established cardiac surgery and 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 (non-primary) PCI services, for a time specified by the Commission that

cannot exceed five years, unless an extension is granted by the Executive Director. At the end of the period, the hospital must demonstrate that it continues to meet the requirements in the Cardiac Services Chapter in order for the Commission to renew the hospital's authorization for a Certificate of Ongoing Performance.

In between renewals for a Certificate of Ongoing Performance, if a hospital is not in compliance with certain standards, a focused review must be conducted. Staff also have the authority to conduct a focused review based on reported patient safety concerns, aberrations in data identified by Commission staff, or failure to meet quality standards established in State and federal regulations.¹ A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance must receive a detailed list of deficiencies identified in the focused review and submit a plan of correction to Commission staff within 30 days of receipt of the list of deficiencies.² If a hospital does not submit a plan of correction that addresses deficiencies cited or successfully complete a plan of correction, the hospital shall upon notice of the Executive Director of the Commission, voluntarily relinquish its authority to perform cardiac surgery or emergency or elective PCI services, as applicable.³

B. Applicant

Johns Hopkins Bayview Medical Center

Johns Hopkins Bayview Medical Center (JHBMC) is a 363-bed general hospital located in Baltimore (Baltimore City). It is part of the Johns Hopkins Hospital System and does not have a cardiac surgery program on-site.

JHBMC received its first waiver for primary PCI services on May 18, 2006. This waiver was subsequently renewed on June 21, 2007, December 17, 2009, December 15, 2011, and December 17, 2013. JHBMC received its first waiver for elective PCI services June 18, 2009. It was subsequently renewed twice. JHBMC received its first Certificate of Ongoing Performance for primary and elective PCI services on June 18, 2020. This is JHBMC's first renewal of its Certificate of Ongoing Performance for PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in the Cardiac Services Chapter. JHBMC is located in the Baltimore/Upper Shore health planning region. This region includes Baltimore City and Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot counties. Fourteen hospitals in this health planning region provide PCI services. Six of these hospitals provide both cardiac surgery and PCI services. Eight hospitals provide only PCI services.

¹ COMAR 10.24.17.07B(2)(a), .07C(2)(a), and .07D(2)(a).

² COMAR 10.24.17.07B(2)(c), .07C(2)(c), and .07D(2)(c).

³ COMAR 10.24.17.07B(2)(e), .07C(2)(e), and .07D(2)(e).

C. Staff Recommendation

MHCC staff recommends that the Commission approve JHBMC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services with one condition. A description of JHBMC's documentation of its performance and the staff's analysis follows.

II. PROCEDURAL HISTORY

On January 10, 2024, JHBMC filed for renewal of its Certificate of Ongoing Performance application to continue providing primary and elective PCI services. MHCC staff requested additional information on February 7, 2024, July 2, 2024, August 23, 2024, August 29, 2024, September 23, 2024, and October 1, 2024. JHBMC submitted additional information on February 26, 2024, July 9, 2024, August 29, 2024, September 4, 2024, September 23, 2024, October 3, 2024, and October 4, 2024.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07C(3) and .07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACC-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.

JHBMC's application stated that there were no deficiencies in data collection. The hospital's data coordinator collects and submits data to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI as well as MHCC staff on a quarterly basis.

Staff Analysis and Conclusion

JHBMC has complied with the submission of ACC-NCDR data to MHCC in accordance with the established schedule. MHCC staff concludes that JHBMC 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.

JHBMC has had one cardiac catheterization laboratory (CCL) since 2020. JHBMC provided a comprehensive CCL downtime report covering the period from March 3, 2020, to

December 11, 2023. JHBMC also provided documentation indicating that the Maryland Institute for Emergency Medical Services Systems (MIEMSS) was notified of downtimes as applicable.

JHBMC reported that when faced with equipment failure on December 13, 2023, two STEMI cases were successfully transferred to Johns Hopkins Hospital (JHH). In one instance, a STEMI patient received thrombolytic therapy prior to being transported to JHH. Another STEMI patient was transferred to JHH on June 11, 2023, due to intraprocedural equipment failure. Additionally, on February 25, 2021, another STEMI case was diverted to JHH because of downtime caused by equipment issues at JHBMC. The CCL downtime is summarized below in Table 1.

Table 1: JHBMC's CCL Downtime, March 2020 – December 2023

Date / Time Start	Date / Time End	Reason	Reroute	Hours
3/3/2020 14:00pm	3/3/2020 18:00	Camera issue	Yes	4.00
3/10/2020 9:30am	3/11/2020 0:00	Replace tube	Yes	14.50
5/26/2020 8:00am	5/26/2020 12:00pm	Preventive maintenance	Yes	4.00
10/6/2020 15:30pm	10/6/20 20:30	Preventive	Yes	5.00
12/17/2020 16:00pm	12/17/20 18:00	Preventive	Yes	2.00
01/08/2021 15:00pm	1/11/20 13:00	New lab opening/moving of equipment, testing, training	Yes	70.00
2/25/2021 11:25am	2/25/21 15:00	Equipment issue	Yes	3.50
3/10/2021 7:00am	3/10/21 13:00	Run new cable in lab	Yes	6.00
3/31/2021 8:00am	3/31/21/13:00	Replace tv screen in lab	Yes	5.00
6/7/2021 15:20pm	6/7/21 17:30	Phillips PM	Yes	2.00
7/20/2021 8:00am	7/20/21 10:00	Phillips equipment repair	Yes	2.00
12/2/2021 8:00am	12/2/21 12:00	Phillips PM	Yes	4.00
3/15/2022 8:00am	3/15/22 11:30	Phillips PM	Yes	3.50
8/31/2022 8:00am	8/31/22 13:30	Phillips PM	Yes	5.50
9/1/2022 8:00am	9/1/22 13:30	Emergent Phillips repair	Yes	5.50
3/1/2023 8:00am	3/1/23 10:45	Phillips PM	No	2.75
6/11/2023 17:44pm	6/14/23 10:00	Equipment malfunction	Yes	64.25
8/16/2023 8:00am	8/16/23 13:30 PM	Phillips PM	Yes	5.50
12/11/2023 8:00am	12/14/2023 7:30 AM	Equipment malfunction, computer fried and had to order part replacement	Yes	71.50

Source: JHBMC's application for Certificate of Ongoing Performance, January 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and notes that the amount of downtime for this CCL is much greater than for most other Maryland hospitals with PCI services. The number of STEMI patients impacted over the span of four years, four patients total, is greater than the number reported by most other Maryland hospitals, over a similar time period. The reason for downtime, equipment malfunction or maintenance and lack of back-up space for PCI procedures, should be addressed in a way that will minimize downtime in the future. MHCC recommends that the Commission find that JHBMC complies with this standard with the condition:

JHBMC must adhere to its backup plan when the CCL has planned downtime or is unexpectedly down, which includes having an ambulance and team stationed on-

site specifically for transport of STEMI patients. The hospital will also report, at least quarterly, on the amount of CCL downtime, including the date of downtimes with start and end times, any instances in which STEMI patients were transported to another hospital due to CCL downtime, the amount of time taken for patient transport to another hospital, and the time taken for ambulance arrival, if an ambulance is not yet stationed at the hospital for STEMI patients, due to unexpected CCL downtime. This information shall be reported within 30 days of the end of each quarter of the calendar year, beginning with the fourth quarter of 2024 and continuing for at least eight quarters, until JHBMC is released from the condition.

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 door-to-balloon times for transfer cases and evaluate areas for improvement.

JHBMC provided a signed statement from Jennifer Nickoles, M.S., the hospital President, stating that JHBMC will provide primary PCI services and not exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. She also stated that the program will continue to track door-to-balloon (DTB) times for all cases and evaluate areas for improvement through its PCI committee. As shown in Table 2A, JHBMC provided the number and percentage of primary PCI cases with a DTB time of 90 minutes or less for the period between CY 2019 Q1 to and CY 2023 Q3. JHBMC also reported that the hospital has not received any transfer PCI cases over this period.

**Table 2A: JHBMC's Door-to-Balloon Times for
Non-Transfer Primary PCI Cases by Quarter, January 2019 – September 2023**

Quarter Ending	Number of Non- Transfer Primary PCI Patients	Non-Transfer Patients with DTB Time <=90 Minutes		ACC-NCDR CATH/PCI DTB < 90 Minutes
		Number	Percent	Percent
CY 2019 Q1	18	10	56%	92.3%
CY 2019 Q2	16	12	75%	83.3%
CY 2019 Q3	15	8	53%	76.9%
CY 2019 Q4	14	10	71%	83.3%
CY 2020 Q1	9	9	100%	100.0%
CY 2020 Q2	10	8	80%	100.0%
CY 2020 Q3	20	16	80%	88.2%
CY 2020 Q4	14	9	64%	73.0%
CY 2021 Q1	6	5	83%	100.0%
CY 2021 Q2	13	8	62%	82.0%
CY 2021 Q3	14	11	100%	92.0%
CY 2021 Q4	17	11	65%	92.0%
CY 2022 Q1	10	8	80%	100.0%
CY 2022 Q2	17	11	65%	100.0%
CY 2022 Q3	20	15	75%	88.0%
CY 2022 Q4	13	12	92%	100.0%
CY 2023 Q1	8	5	63%	100.0%
CY 2023 Q2	11	9	82%	100.0%
CY 2023 Q3	17	12	71%	100.0%

Source: JHBMC's Certificate of Ongoing Performance application, January 2024.

Notes: MHCC staff rounded the percentage of cases with DTB<=90 minutes, provided by JHBMC. The ACC-NCDR CathPCI calculation of DTB times excludes certain cases, including those with a non-system reason for delay. MHCC staff do not exclude any cases when reviewing compliance with the standard.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer primary PCI cases and found that JHBMC met the door-to-balloon time standard in 12 quarters between CY 2019 and Q3 2023. MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases. MHCC staff also considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, JHBMC achieved the DTB standard in only four of 12 rolling eight-quarter periods, with between 70 and 76 percent of PCI cases meeting the DTB standard, as shown below in Table 2B.

Table 2B: JHBMC's Non-Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period, CY 2019 – CY 2023

Time Period	Quarter			Rolling 8-Quarters		
	Total Primary PCI Volume	Cases With DTB <=90 Minutes	Percent of Cases with DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB <=90 Minutes	Percent of Cases with DTB <=90 Minutes
2019 Q1	18	10	56%			
2019 Q2	16	12	75%			
2019 Q3	15	8	53%			
2019 Q4	14	10	71%			
2020 Q1	9	9	100%			
2020 Q2	10	8	80%			
2020 Q3	20	16	80%			
2020 Q4	14	9	64%	116	82	71%
2021 Q1	6	5	83%	104	77	74%
2021 Q2	13	8	62%	101	73	72%
2021 Q3	14	11	79%	100	76	76%
2021 Q4	17	11	65%	103	77	75%
2022 Q1	10	8	80%	104	76	73%
2022 Q2	17	11	65%	111	79	71%
2022 Q3	20	15	75%	111	78	70%
2022 Q4	13	12	92%	110	81	74%
2023 Q1	7	5	71%	111	81	73%
2023 Q2	12	10	83%	110	83	75%
2023 Q3	17	12	71%	113	84	74%
2023 Q4	12	8	67%	108	81	75%

Source: MHCC staff analysis of ACC-NCDR CathPCI Data (2019-2023).

Note: Calculations for each quarter are based on the procedure date.

MHCC staff requested detailed information on the reasons for DTB delays on each case, in quarters when the DTB standard was not met. Frequently, these reasons were non-system reasons for delays, as reflected in the much higher level of compliance with the DTB metric used by the American College of Cardiology (ACC) for the ACC-NCDR CathPCI data. As shown in Table 2A, the hospital was meeting the ACC's DTB standard for the period from January 2021 through September 2023. In instances where there were delays for reasons other than non-system reasons, the hospital identified opportunities for improvement and followed through with making changes. In one case, the communication protocol for activating the Heart Attack Team was not followed and delayed preparation of the CCL by a newly trained nurse. Those staff involved were provided with feedback and education to facilitate better care. Based on MHCC staff's analysis of the ACC-NCDR CathPCI data and the information submitted by JHBMC, MHCC staff recommends the Commission find that JHBMC meets this standard.

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 acute MI patients 24 hours per day, seven days per week.

JHBMC provided the number of physicians, nurses, and technicians who can provide cardiac catheterization services to acute myocardial infarction patients as of one week before the due date of the application, as shown in Table 3A. At the time of submission of the application, JHBMC reported that one nurse was in orientation and another nurse started December 31, 2023.

Table 3A: JHBMC's CCL Physician, Nursing and Technical Staff

Staff Category	Number/FTEs	Cross Training
Physician	9	
Nurse	5.0 FTE	2 circulate / monitor, 1 monitor, 1 in orientation, 1 new hire
Cardiovascular Technologist	6.0 FTE	All scrub, monitor, and circulate

Source: JHBMC's Certificate of Ongoing Performance application, question 4A.

Staff Analysis and Conclusion

MHCC staff compared the staffing levels described by JHBMC to information reported in the Certificate of Ongoing Performance applications for three other programs that are among the closest to JHBMC in volume, specifically Carroll Hospital Center (CHC), Johns Hopkins Howard County Medical Center (JH HCMC), and University of Maryland Capital Regional Medical Center (UM CRMC). As shown in Table 3B, the number of nurse full-time equivalents (FTEs) for JHBMC, five, is much lower than for CHC, JH HCMC, and UM CRMC, which had approximately eight to 10 nurse FTEs. Although JHBMC has almost half the number of nurse FTEs as CHC, it also has only about 58 percent of the volume of CHC. These programs have significantly higher volume than JHBMC, as shown in Table 3B below.

Table 3B: CCL Staffing for JHBMC and Other Select PCI Programs

Program	Total PCI Case Volume in	Number (N) or FTE Interventionalists	Nurse FTEs	Technician FTEs
JHBMC	129	N = 9	5.0	6.0
CHC 2024	221	N = 4	9.8	4.0
JH HCMC 2024	177	N = 9	8.55	6.0
UM CRMC 2024	175	N = 7	7.9	3.6

Sources: JHBMC's 2024 PCI Certificate of Ongoing Performance application and PCI volume from ACC-NCDR CathPCI report for the period ending December 30, 2023; CHC's 2024 PCI Certificate of Ongoing Performance application and ACC-NCDR CathPCI report for period ending December 30, 2023; JH HCMC's PCI 2024 Certificate of Ongoing Performance application and PCI volume from ACC-NCDR CathPCI report for the period ending December 30, 2023; and UM CRMC's 2024 PCI Certificate of Ongoing Performance application and PCI volume from ACC-NCDR CathPCI report for the period ending December 30, 2023.

Based on the comparative information available, MHCC staff concludes that JHBMC has adequate nursing and cardiovascular technologists' staff to provide services; MHCC staff concludes that JHBMC meets this standard.

10.24.17.07D(4)(d) The hospital president or chief executive officer, as appropriate, shall provide a written commitment stating the hospital administration will support the program.

JHBMC provided a signed letter of commitment from its President, Jennifer Nickoles, M.S., dated January 9, 2024, stating that JHBMC will provide primary PCI services in accordance with the requirements established by the Commission.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of commitment provided and concludes that JHBMC 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.

JHBMC employs a full-time outcomes data coordinator who is responsible for submitting all data to the ACC-NCDR CathPCI and the MHCC Quality Reports website. This coordinator oversees the PCI Committee meetings, reviewing all PCI data, adverse events, and any issues concerning PCI patients or the CCL. Additionally, the coordinator participates in the JHBMC Quality Practice Safety Council meetings and reports data to the Johns Hopkins Heart and Vascular Institute Quality Council.

Staff Analysis and Conclusion

MHCC staff concludes that JHBMC 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 cardiac 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.

JHBMC reported that Dr. Jeffery C. Trost serves as the Director of Invasive and Interventional Cardiology. He was named the Director in 2007. As Director, he is the physician contact for all clinical, research, and administrative issues related to interventional cardiology procedures. JHBMC submitted a form with a list of the Director's responsibilities. These responsibilities include ensuring that there are a comprehensive set of quality standards for the provisions of cardiology services related to the Interventional Cardiology and PCI Program at JHBMC; assisting with capital equipment purchases and software; participating in interviews for hiring staff; ensuring compliance with all state requirements; and ensuring compliance of all members of the Division of Cardiology with Health System, University, and Departmental, and Divisional Policies.

Staff Analysis and Conclusion

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

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

JHBMC provided a list of educational activities for staff in the CCL and cardiac intensive care unit for the period of January 2020 through December 2023. JHBMC also stated that while no specific number of continuing education units are required, JHBMC requires annual competency testing for all staff on equipment such as an oximetry device, glucometer, and intra-aortic balloon pump. The hospital has mandatory annual online training for staff regarding safety and infection control. The hospital also requires staff to be certified in Basic Cardiac Life Support and Advanced Cardiac Life Support. Occasionally, vendors provide in-service training.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that JHBMC has a continuing medical education program for CCL and cardiac intensive care unit staff. MHCC staff concludes that JHBMC is compliant with this standard.

10.24.17.07D(4)(h) A hospital that performs primary PCI without on-site cardiac surgery shall have a formal, written agreement with a tertiary institution that provides for the unconditional transfer of the hospital's patients for any required additional care, including emergent or elective cardiac surgery or PCI.

Richard Bennett, M.D., the president of JHBMC in 2018 and Redonda Miller, M.D., President, Johns Hopkins Hospital (JHH), signed and dated a letter of agreement in which JHH, a tertiary care hospital, commits to fully support the PCI program at JHBMC. The agreement states that JHH will unconditionally accept the transfer of PCI patients from JHBMC for any required additional care, including emergent or elective cardiac surgery or PCI.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of agreement and the patient transfer agreement submitted and concludes that JHBMC meets this standard.

10.24.17.07D(4)(i) The hospital shall maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

JHBMC submitted a signed letter of agreement between Richard Bennett, M.D., the president of JHBMC in 2018, Redonda G. Miller, M.D., President, Johns Hopkins Hospital, and James Scheulen, P.A., M.B.A., President, Johns Hopkins Emergency Medical Services, expressing the full commitment of the Johns Hopkins Lifeline to provide ground and air medical transportation services to the PCI program at JHBMC. The agreement states that patients will be transported by air or ground from JHBMC and arrive at the JHH within 30 minutes of a request from JHBMC.

Staff Analysis and Conclusion

MHCC staff reviewed the transportation agreement with Lifeline and concludes that JHBMC meets this standard.

Quality

10.24.17.07C(4)(a) and .07D(5)(a) The hospital shall develop a formal process for interventional case review that includes regularly scheduled meetings (at least every other month) with required attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

JHBMC reported that its CCL staff routinely attend the weekly Johns Hopkins Mortality and Morbidity (M&M) Conferences, which are led by the Johns Hopkins Medicine interventional cardiology attending group. At this weekly M&M Conference, staff reviews STEMI cases along with other PCI cases. The cases reviewed are from the following hospitals: JHBMC, JHH, JH HCMC, and Frederick Health Hospital. The M&M Conference is also a forum used to teach interventional fellows by sharing techniques and concepts.

JHBMC submitted documentation of meetings with PCI case review. This documentation shows meetings were held approximately monthly in 2019; a total of 12 meetings were held. In CY 2020, a total of 22 meetings were held. There were no meetings in January or December 2020. In other months, the number of meetings held ranged from one to four. In CY 2021, a total of 32 meetings were held, and a similar number of meetings, 38 total, were held in CY 2022. In CY 2023, a total of 43 meetings were held. Interventional cardiologists, nurses, technicians CCL leadership, and data coordinators attended these meetings.

Staff Analysis and Conclusion

MHCC staff reviewed attendance records from CY 2019 through CY 2023 and determined that interventional cardiologists, nurses, technicians, and other physicians attend meetings that include PCI case review. MHCC staff also determined that the frequency of these meetings is greater than required. MHCC staff concludes that JHBMC complies with this standard.

10.24.17.07C(4)(b) and .07D(5)(b) The 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.

JHBMC provided a list of meeting dates and participants for the PCI Committee meetings. The Committee meets monthly to review all issues related to the primary and elective PCI system, identify problem areas, and develop relevant solutions.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation provided for meetings held between January 2019 and December 2023. Staff noted that nine PCI Committee meetings were held in CY 2019.

In April 2019, the PCI Committee meeting was canceled because many people were not available to meet due to being out of the office or having a schedule conflict. The July meeting was canceled due to attendance issues, and the December 2019 meeting was called off due to an emergency. In 2020, 11 meetings were held. The April meeting was canceled due to the COVID-19 pandemic. In 2021, there were 11 meetings held. The August meeting was canceled due to low attendance. In 2022, 11 meetings were held; the July meeting was cancelled. In 2023, 12 meetings were held.

MHCC staff generally regards holding 10 or 11 meeting each year as acceptable because there may be legitimate unavoidable reasons for canceling one or two meetings each year. Holding fewer meetings in one of five years, when sufficient meetings have been held in the most recent four years should also be regarded as acceptable. MHCC staff recommends the Commission find that JHBMC complies with this standard.

10.24.17.07C(4)(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

JHBMC provided copies of external review reports for elective PCI cases performed between January 2019 and December 2021 and information on the number of cases reviewed in CY 2022. The external review organization, the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), has been approved by MHCC as an external review organization that meets the requirements in the Cardiac Services Chapter for conducting external reviews of PCI cases. JHBMC also provided the number of elective PCI cases reviewed by MACPAQ for each physician from CY 2019 through CY 2022.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. As shown in Table 4, between 29 and 49 percent of cases were reviewed each year, consistent with the requirement that at least 5 percent of cases be reviewed.

Table 4: JHBMC's External Reviews, CY 2019 - CY 2022

Time Period	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Review	Meets Standard
CY 2019	130	38	29%	Semiannual	Yes
CY 2020	113	42	37%	Semiannual	Yes
CY 2021	98	42	43%	Semiannual	Yes
CY 2022	78	38	49%	Semiannual	Yes

Source: MHCC staff analysis of MACPAQ reports for January 2019 through June 2022 and response to questions February 26, 2024.

For the period between January 2019 and June 2022, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that, in each six-month review period, at least three cases per physician were reviewed, or all cases were reviewed, if an interventionalist performed fewer than three cases, as required, with one exception. It appears that one more case should have been reviewed for one physician who had five cases reviewed in the span of a year instead of six cases.

MHCC staff regards this as an unintentional oversight by the external review organization that should not negatively affect MHCC staff's assessment of the program's compliance with this standard.

MHCC staff recommends the Commission find that JHBMC complies with this standard.

10.24.17.07C(4)(d) 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 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 in Regulations .08 and .09; or***
- (ii) 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 three 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 3 cases during the relevant period, as provided in Regulation .08; or***
- (iii) 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 Subparagraphs .07C(4)(d)(i).***

10.24.17.07C(4)(e) The external review of PCI cases and the performance review of an interventionalist referenced in Paragraphs .07C(4)(c) and .07C(4)(d) 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.

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.

JHBMC stated that internal review of interventional cardiologists is performed by both the Johns Hopkins Medicine cardiac catheterization section chief and the CCL medical director for JHBMC. This review includes at least 10 percent of cases for each interventional cardiologist. JHBMC noted that the CCL medical director reviews all STEMI cases on an ongoing basis throughout the year. The interventional cardiologists are provided feedback at least annually and for specific cases, if concerns have been identified.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by JHBMC and analyzed the ACC-NCDR CathPCI data to determine the number of elective PCI cases performed by each interventionalist and calculated the number of cases required to be reviewed each year. MHCC staff compared the results of its analysis to the number of elective PCI cases reviewed per physician reported in MACPAQ reports. Staff noted that greater than 10 percent of cases are reviewed annually both internally and externally for all interventionalists.

MHCC staff concludes that JHBMC meets this standard

10.24.17.07C(4)(f) and .07D(5)(e) The chief executive officer of the hospital shall certify upon request by Commission staff 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.

JHBMC submitted a statement from its President, Jennifer Nickoles, M.S., dated November 16, 2023, stating that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in the Cardiac Services Chapter, including those regarding internal peer review of cases and external review of cases.

Staff Analysis and Conclusion

MHCC staff concludes that JHBMC meets this standard.

10.24.17.07C(4)(g) and .07D(5)(f) The hospital's application for a Certificate of Ongoing Performance shall demonstrate that it has taken appropriate action in response to each concern identified through its quality assurance processes.

- (i) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.***
- (ii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.***

JHBMC provided meeting minutes of issues discussed in the PCI committee demonstrating the hospital takes appropriate actions to concerns identified regarding quality assurance processes. These include the proportion of EMS patients who receive field electrocardiograms (EKGs); the proportion of walk-in patients who receive timely EKGs and activation of the Heart Attack Team; and the time for patient transport to the CCL upon Heart Attack Team activation. JHBMC explained that MACPAQ reports are reviewed at the Clinical Practice Committee by Debra Franckowiak. Dr. Trost also reviews MACPAQ reports, and all primary cases performed at JHBMC. All interventional cardiologists who perform procedures at JHBMC or JHH participate in a weekly joint interventional M&M conference to review cases. Quality data from the ACC-NDCR CathPCI registry are presented to cardiology administration and faculty via Program Leadership and Development Conferences.

The CCL nurse manager reports quality measures to the Joint Practice Council and the Intensive Care Joint Practice Council, which meet quarterly to provide input on quality improvement initiatives. The CCL nurse manager also performs a follow-up call or visit for all patients post-procedurally and records patient comfort during the procedure, any complications, and pain level. The feedback is used to improve patient comfort and for patient education. The CCL team also collects data for improvement of charting accuracy and in-room procedure start time; all charts are audited monthly.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and noted that there are objective measures the hospital tracks in some cases, which show improvement in outcomes targeted for improvement in its quality assurance processes. MHCC staff concludes that JHBMC complies with this standard.

Patient Outcome Measures

10.24.17.07C(5)

- (a) An elective 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 shall be subject to a focused review if it has a risk-adjusted mortality rate for non-STEMI PCI cases that exceeds an established benchmark beyond the 95 percent confidence interval calculated for the hospital's all-cause in-hospital risk-adjusted mortality rate for non-STEMI PCI cases.*

10.24.17.07D(6)

- (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 STEMI PCI cases that exceeds the established benchmark 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 in-hospital risk-adjusted mortality rate for STEMI PCI cases.*

JHBMC submitted reports that include adjusted mortality by rolling 12-month reporting periods for October 2018 through December 2023, as shown in Table 5.

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

Reporting Period	STEMI				NONSTEMI			
	Hospital AMR	95% CI	National AMR	Meets MHCC Standard	Hospital AMR	95% CI	National AMR	Meets MHCC Standard
2023q1-2023q4	2.51	[0.06, 13.18]	1.88	Yes	0.60	[0.02, 3.22]	1.99	Yes
2022q4-2023q3	2.94	[0.07, 15.38]	1.91	Yes	0.48	[0.01, 2.58]	2.02	Yes
2022q3-2023q2	2.49	[0.06, 13.20]	1.89	Yes	0.48	[0.01, 2.60]	2.02	Yes
2022q2-2023q1	1.94	[0.05, 10.31]	1.89	Yes	0.61	[0.02, 3.29]	2.05	Yes
2022q1-2022q4	3.43	[0.42, 11.73]	2.00	Yes	0.00	[0.00, 4.41]	2.14	Yes
2021q4-2022q3	5.59	[1.17, 15.35]	2.11	Yes	0.68	[0.02, 3.68]	2.20	Yes
2021q3-2022q2	4.40	[1.23, 10.44]	2.18	Yes	1.32	[0.16, 4.62]	2.26	Yes
2021q2-2022q1	3.59	[0.75, 9.72]	2.82	Yes	0.96	[0.12, 3.45]	2.25	Yes
2021q1-2021q4	2.82	[0.35, 9.43]	2.74	Yes	1.15	[0.24, 3.28]	2.23	Yes
2020q4- 2021q3	3.00	[0.37, 10.01]	2.18	Yes	1.26	[0.28, 3.86]	2.23	Yes
2020q3-2021q2	9.40	[3.92, 17.87]	7.51	Yes	1.29	[0.16, 4.56]	1.18	Yes
2020q2-2021q1	8.87	[4.46, 14.83]	7.55	Yes	1.57	[0.19, 5.53]	1.21	Yes
2020q1-2020q4	8.48	[4.04, 14.78]	6.89	Yes	2.38	[0.29, 8.41]	1.13	Yes
2019q4-2020q3	5.98	[2.25, 12.18]	6.37	Yes	2.52	[0.52, 7.18]	1.06	Yes
2019q3-2020q2	6.37	[2.4, 12.93]	6.06	Yes	2.94	[0.61, 8.37]	1.00	Yes
2019q2-2020q1	7.57	[2.51, 16.64]	5.99	Yes	2.55	[0.53, 7.29]	0.95	Yes
2019q1-2019q4	8.60	[4.06, 15.30]	6.01	Yes	0.98	[0.18, 5.27]	0.95	Yes
2018q4-2019q3	8.62	[3.85, 15.78]	6.06	Yes	1.18	[0.03, 6.45]	0.98	Yes

Source: MHCC Staff compilation of results from the hospital's quarterly reports from the ACC-NCDR for PCI cases performed between CY 2018 Q4 and CY 2023 Q4.

⁴ A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the national AMR or indicates statistically significantly better performance than the national AMR for ST-elevated myocardial infarction (STEMI) or non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the national AMR for STEMI or non-STEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEMI and non-STEMI cases for each reporting period.

Staff Analysis and Conclusion

As shown in Table 5 above, MHCC staff compiled the results from JHBMC's quarterly reports from the ACC-NCDR CathPCI for STEMI and non-STEMI PCI cases performed between January 2019 and December 2023. MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's risk-adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period. The national benchmark fell within the 95 percent confidence interval (CI) for JHBMC for all 12-month reporting periods between January 2019 and December 2023.

MHCC staff concludes that JHBMC met this standard.

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 Commission on a quarterly basis.

JHBMC provided documentation indicating that for each calendar year from January 2019 through December 2023, each of their physicians completed at least 50 PCI procedures per year.

Staff Analysis and Conclusion

MHCC staff analyzed data from the ACC-NCDR CathPCI registry to validate that interventionalists who performed primary PCI between January 2019 and December 2023 performed an average of at least 50 cases annually over 24-month periods. This analysis confirms that all the interventionalists met the standard for this entire period, except for one interventionalist due to lack of available data. One interventionalist primarily performs cases at other hospitals for which 2023 data is not yet available. However, JHBMC provided documentation that the standard was met for this interventionalist standard during the 24-month period ending in December 2023. MHCC staff finds that the JHBMC's documentation stating the volumes were met combined with MHCC's verification that all other interventionalists met the standard, was sufficient to meet this standard.

MHCC staff concludes that JHBMC complies with this standard.

10.24.17.07C(6)(b) and .07D(7)(b) For each physician who performs primary PCI at a hospital without on-site cardiac surgery and does not perform a minimum of 50 PCI procedures annually averaged over a 24-month period, for reasons other than a leave of absence, the hospital shall arrange for an external review of all the physician's cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to the Commission. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to JHBMC. While JHBMC does not have on-site cardiac surgery, each physician performing primary PCI performed over 50 PCI procedures annually on average over 24-month periods between January 2019 and December 2023, based on information reported by JHBMC. MHCC staff was able to independently validate this information for all but one physician.

10.24.17.07C(6)(c) and .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, and 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.***

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to JHBMC. While JHBMC does not have on-site cardiac surgery, each physician performing primary PCI performed over 50 PCI procedures annually averaged over each of two 12-month periods between January 2019 and December 2023.

10.24.17.07C(6)(e) and .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.

10.24.17.07C(6)(f) and .07D(7)(f) Each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

JHBMC submitted a signed and dated statement from Jeffrey C. Trost, M.D., director of the CCL, confirming that all physicians performing primary PCI services at JHBMC are board-certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that JHBMC meets the standards for board certification.

10.24.17.07C(6)(g) and .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.

JHBMC submitted signed and dated attestations from Drs. Trost, Hasan, Thiemann, Hwang, Czarny, Resar, Rahman, Johnston, and Miller stating each physician completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years. JHBMC did not include a statement for Drs. Chacko and Williams because they are no longer employed by the hospital.

Staff Analysis and Conclusion

MHCC staff reviewed the attestations provided and concludes that JHBMC meets this standard.

10.24.17.07C(6)(h) and .07D(7)(h) Each physician who performs primary PCI shall agree to participate in an on-call schedule.

JHBMC submitted a signed statement from the medical director of the CCL, Dr. Trost, attesting that each physician who has performed primary PCI services during the performance period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. The hospital also provided a recent copy of the on-call schedule.

Staff Analysis and Conclusion

MHCC staff concludes that JHBMC meets this standard based on the letter and on-call schedule provided.

Volume

10.24.17.07C(7)(a) The target volume for an existing program with both primary and non-primary PCI services is 200 cases annually.

10.24.17.07C(7)(b) A PCI program that provides both primary and elective PCI that fails to reach the target volume of 200 cases annually may be subject to a focused review.

As shown in Table 6, JHBMC provided the number PCI cases performed each fiscal year between CY 2019 and CY 2023.

Table 6: JHBMC PCI Volume, FY 2019 - FY 2023

Fiscal Year	Total PCI
FY 2019	207
FY 2020	183
FY 2021	177
FY 2022	165
FY 2023	129

Source: JHBMC's Certificate of Ongoing Performance application, January 2024, p18.

MHCC staff requested an explanation for the declining volume of cases and JHBMC explained that several factors have led to declining volume. JHBMC stated that these factors include the demographics and health of the community served by the hospital, which determines the need for PCI; the availability of resources, such as cardiologists, which facilitate referrals for PCI; the capacity of other hospitals that provide PCI services; and changes in PCI care based on contemporary research and evidence-based guidelines.

JHBMC noted that 90 percent of its PCI volume has historically been derived from inpatients with acute coronary syndrome, rather than outpatients with stable coronary disease and the number of those patients at JHBMC has declined over time. JHBMC stated it was unclear to what extent the decline is attributable to changing demographics or competition from newer elective PCI programs. JHBMC also noted that new tools are also available to determine whether lesions have physiologic or anatomic evidence of obstruction, which has led to deferral of PCI in more cases. This practice is evidence-based, guideline-supported and represents appropriate, safe, evidence-based care.

Staff Analysis and Conclusion

MHCC staff reviewed the case volume information submitted by JHBMC. This data shows that JHBMC did not meet the target volume of 200 PCI cases in four of five years. JHBMC met the target volume only in FY 2019, when the hospital reported a volume of 207 PCI cases. MHCC staff also calculated the volume of PCI cases for CY 2019 through CY 2023, by using the ACC-NCDR CathPCI data. This analysis indicates JHBMC performed 197 cases in CY 2019, 168 cases in CY 2020, 142 cases in CY 2021, 141 cases in CY 2022, and 131 cases in CY 2023. JHBMC provided several reasons why volume for the program has been trending lower, and it appears JHBMC has limited ability to reverse this trend.

The reason for having a standard with a target volume of 200 cases is because higher volume is associated with better quality. Staff notes the hospital's performance on the mortality metric for both STEMI and non-STEMI cases has been statistically similar to the national average, as shown in Table 5. Staff also notes that even if the program volume is much lower than the target of 200 cases, all the interventionalists have been performing 50 cases or more on average over rolling 24-month periods, including in 2020 and 2021, when this standard was waived by MHCC due to the COVID-19 pandemic.

Based on the hospital's acceptable performance with respect to mortality for PCI cases and individual interventionalists meeting the volume standard for 24-month rolling periods, MHCC staff recommends that the Commission find that JHBMC's performance on this standard is acceptable.

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.

JHBMC provided the following information.

Table 7: JHBMC's Primary PCI Volume, CY 2019 - CY 2023

Year	Number of Cases
CY 2019	67
CY 2020	55
CY 2021	44
CY 2022	63
CY 2023	53

Source: MHCC staff analysis of ACC-NCDR CathPCI Data, CY2019 - CY 2023.

Staff Analysis and Conclusion

As shown in Table 7, JHBMC also provided the primary PCI volume by calendar year to demonstrate that the primary PCI volume met the threshold in the standard. MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2019 through CY 2023. This analysis is consistent with the volume reported by JHBMC, and it confirms that JHBMC met the threshold of 49 cases annually, except in CY 2021. Because JHBMC met the primary PCI volume standard in all years reviewed except one, CY 2021, when MHCC waived various volume standards for both cardiac surgery and PCI programs, staff has determined that it is appropriate to conclude that JHBMC complies with this standard.

MHCC staff recommends the Commission find that JHBMC meets this standard.

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

JHBMC provided the number of primary PCI cases by interventionalist on a quarterly basis for the period from January 2019 to December 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the information submitted by JHBMC for all interventionalists. While JHBMC did not submit signed affidavits regarding PCI case volume for Drs. Williams and Chacko, because they are no longer employed by JHBMC, MHCC staff analyzed the data in the

ACC-NCDR CathPCI registry and confirmed that each interventionalist met the target of 11 or more primary PCI cases annually.

MHCC staff concludes that JHBMC meets this standard.

Patient Selection

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for appropriate patients, as described in Expert Guidelines for hospitals with and without cardiac surgery on-site.

JHBMC responded that there are no patients who received elective PCI inappropriately based on internal review of cases.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from MACPAQ for January 2019 through June 2022 and noted that only one case from 2019 that was determined to be “rarely appropriate” with respect to multiple criteria. MHCC staff asked the hospital to explain how it followed up on this case. JHBMC reported that the case and findings were reviewed with the provider. The hospital also reported that there have not been concerns based on other case review and subsequent MACPAQ reports.

MHCC staff concludes that JHBMC complies with this standard.

10.24.17.07D(9) A hospital shall commit to only providing primary PCI services for suitable patients. Suitable patients are:

- (a) Patients described as appropriate for primary PCI in the Expert Guidelines.***
- (b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) reasonably concludes 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 primary PCI services were 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) reasonably concludes that transfer to a tertiary institution may be harmful to the patient.***

JHBMC responded that no patients received primary PCI services inappropriately, according to internal review. JHBMC also responded that two PCI patients received thrombolytic therapy that subsequently failed during the review period.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data and noted that between CY 2019 and CY 2023, there was one PCI patient who received thrombolytic therapy during this time. The number of patients who JHBMC reported received thrombolytic therapy between CY 2019 and CY 2023 that subsequently failed is well below the required threshold.

MHCC concludes that JHBMC complies with this standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff recommends that the Commission find that JHBMC meets all the requirements for a Certificate of Ongoing Performance and issue a Certificate of Ongoing Performance that permits JHBMC to continue providing primary and elective percutaneous coronary intervention services for four years with the following condition:

JHBMC must adhere to its backup plan when the CCL has planned downtime or is unexpectedly down, which includes having an ambulance and team stationed on-site specifically for transport of STEMI patients. The hospital shall report, at least quarterly, on the amount of downtime for the CCL, including the date of downtimes with start and end times, any instances in which STEMI patients were transported to another hospital due to downtime of the CCL, the amount of time taken for patient transport to another hospital, and the time taken for ambulance arrival, if an ambulance was not stationed at the hospital for STEMI patients, due to unexpected downtime. This information shall be reported within 30 days of the end of each quarter of the calendar year, beginning with the fourth quarter of 2024 and continuing for at least eight quarters, until staff releases JHBMC from the condition.