IN THE MATTER OF	*	**BEFORE THE**
JOHNS HOPKINS	*	**MARYLAND**
HOWARD COUNTY	*	**HEALTH CARE**
MEDICAL CENTER	*	**COMMISSION**
Docket No.: 24-13-CP050	*	

* *

STAFF REPORT AND RECOMMENDATION

CERTIFICATE OF ONGOING PERFORMANCE
FOR PRIMARY & ELECTIVE PERCUTANEOUS CORONARY INTERVENTION SERVICES

May 21, 2026

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 these hospitals 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 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 in November 2015 and again in January 2019.

The Cardiac Services 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 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 may be conducted. The regulations authorize Commission staff to conduct a focused review based on reported patient safety concerns, aberrations in data, 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 from Commission staff and submit a plan of correction within 30 days of receipt of the list of deficiencies.[2] If a hospital does not submit a plan of correction that addresses the 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 Howard County Medical Center

Johns Hopkins Howard County Medical Center (JH HCMC), formerly Howard County General Hospital[4], is a 253-bed acute care general hospital located in Columbia, Maryland (Howard County). It is part of the Johns Hopkins Health System. The hospital does not have a cardiac surgery program on-site.

JH HCMC initiated primary PCI services in May 2006 and has continued performing primary PCI without cardiac surgery on-site through waivers issued in 2009, 2011, and 2013. The hospital filed its initial application for a Certificate of Ongoing Performance for primary PCI services in March 2019. Approval for the Certificate of Ongoing Performance to continue providing primary PCI services was granted by the Commission on June 18, 2020, for four years. The hospital later applied for a Certificate of Conformance to provide elective PCI services, which was approved on April 16, 2020. This is JH HCMC's first renewal of its Certificate of Ongoing Performance for primary PCI services and its first request for a Certificate of Ongoing Performance for elective PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in the Cardiac Services Chapter. The regions are defined by geographic areas. JH HCMC is in the Baltimore/Upper Shore health planning region. This region includes Baltimore City and Anne Arundel, Baltimore, Caroline, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties. Fourteen hospitals in this health planning region provide primary and elective PCI services. Six of the fourteen hospitals also provide cardiac surgery 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).
[4] The hospital changed its name from Howard County General Hospital to Johns Hopkins Howard County Medical Center on June 12, 2023.

C. Staff Recommendation

MHCC staff recommends that the Commission approve JH HCMC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services for the next four years. A description of JH HCMC's documentation of its performance and MHCC staff's analysis of this information follows.

II. PRODEDURAL HISTORY

JH HCMC applied for its Certificate of Ongoing Performance for primary and elective PCI services on January 12, 2024. MHCC staff extended the hospital's Certificate of Ongoing Performance for PCI services for six-month periods on June 14, 2024, December 17, 2024, May 14, 2025, and October 20, 2025, because a focused review required additional time to be completed. MHCC staff needed updated information for the hospital's application because of the length of time that had passed since the hospital first applied. MHCC staff requested additional information from the hospital on May 14, 2024, July 22, 2024, August 28, 2024, December 15, 2025, April 6, 2026, April 24, 2026, and May 1, 2026. Additional information was provided by JH HCMC on June 18, 2024, August 2, 2024, September 9, 2024, January 13, 2026, April 17, 2026, and May 5, 2026. The gaps between requests for additional information is attributable to the time for completing a focused review.

On December 17, 2024, MHCC initiated a focused review of JH HCMC's primary PCI program based on the hospital's risk adjusted mortality rates for ST-elevation myocardial infarction (STEMI) [5] PCI cases in the three 12-month reporting periods ending in Q4 2023, Q1 2024, and Q2 2024 (Table 6a). The preliminary report was provided to the hospital on October 22, 2024. The hospital responded on October 30, 2024, and the focused review report was finalized on November 13, 2025. Based on the findings of the focused review and the hospital's improved performance with respect to mortality, MHCC staff concluded that a formal plan of correction was not required.

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.

JH HCMC stated in its application that there were no deficiencies in data collection or reporting identified by MHCC staff.

[5] An ST-segment elevation myocardial infarction or STEMI is a type of heart attack that, in most cases, is best treated through performance of a primary PCI procedure.

Staff Analysis and Conclusion

JH HCMC has complied with the submission of data to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI with duplicate data submitted to MHCC in accordance with the established schedule. There are no reporting periods when the hospital's performance on adjusted mortality rates or other key quality metrics cannot be determined. MHCC staff concludes that JH HCMC 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.

JH HCMC reported that the hospital had zero days where primary PCI was not available due to required equipment maintenance or unforeseen circumstances for the period from CY 2020 through CY 2025. The hospital stated that it maintains two cardiac catheterization laboratories (CCLs) to ensure one lab is always available and preventable maintenance is completed outside of normal operating hours. JH HCMC also reported that no patients requiring emergency PCI services were delayed, diverted to another hospital, or provided suboptimal treatment because of CCL downtime. A log of downtimes for each CCL was submitted by JH HCMC, as shown in Table 1.

Table 1. JH HCMC's CCL Downtime by Room, Date, and Duration, January 2020 – December 2025

Room	Date/Start Time	Duration	Description
Lab 1	4/15/2020 1:26pm	4.0 hours	Preventive maintenance
Lab 1	6/15/2020 12:35pm	5.0 hours	Preventive maintenance
Lab 1	10/19/2020 7:27am	4.0 hours	Preventive maintenance
Lab 1	7/6/2021 5:10pm	1.9 hours	Sensor replaced
Mobile Lab	10/4/2021	NR	Leak in procedure room
Lab 1	10/20/2021 5:00pm	3.3 hours	Install FlexVision software
Mobile Lab	10/26/2021	NR	Leak in roof repair
Mobile Lab	11/3/2021	NR	Gap – driver side pull out
Mobile Lab	12/1/2021	NR	Heater not working
Mobile Lab	12/10/2021	NR	Footswitch fluoro button intermittently working
Mobile Lab	1/10/2022	NR	X-ray tube chiller error
Lab 1	2/2/2022 4:16pm	2.7 hours	Sensor replaced
Lab 2	8/2021 through 2/2022	6 months	Installation of new Cath lab with Azurion 5 Cath Lab. A mobile lab was available during construction.
Lab 2	4/5/2022 5:00pm	2.5 hours	Install coronary software onto workstation
Lab 2	5/3/2022 4:30pm	5.0 hours	Install upgrade coronary software onto workstation
Lab 2	9/29/2022 8:00pm	2.0 hours	Preventive maintenance
Lab 1	5/24/2023 5:00pm	4.0 hours	Preventive maintenance
Lab 1	8/16/2023 4:00pm	1.0 hours	Pan knob disconnected
Lab 1	8/18/2023 11:00am	2.0 hours	Geometry module malfunction
Lab 2	9/7/2023 1:00pm	4.0 hours	Broken cable

Room	Date/Start Time	Duration	Description
Lab 2	9/12/2023 2:30pm	4.0 hours	Re-install software
Lab 2	9/13/2023 10:00pm	5.0 hours	Preventive maintenance
Lab 1	12/5/2023 9:00pm	5.5 hours	Preventive maintenance
Lab 2	12/20/2023 4:00pm	1.0 hours	Clean-up log files
Lab 2	1/9/2024 2:00pm	2.0 hours	Monitor repair
Lab 2	3/16/2024 9:00am	8.0 hours	Preventive maintenance
Lab 1	8/22/2024 3:30pm	5.0 hours	Preventive maintenance
Lab 2	9/19/2024 5:00pm	5.0 hours	Preventive maintenance
Lab 1	11/14/2024 3:00pm	5.0 hours	Preventive maintenance
Lab 2	2/27/2025 5:00pm	5.0 hours	Preventive maintenance
Lab 1	3/13/2025 4:00pm	6.0 hours	PC repair
Lab 2	4/10/2025 4:00pm	2.0 hours	Preventive maintenance
Lab 1	5/8/2025 4:00pm	6.0 hours	Preventive maintenance
Lab 1	5/22/2025 3:00pm	6.0 hours	Preventive maintenance
Lab 2	9/22/2025 10:15am	5.75 hours	Preventive maintenance
Lab 1	12/11/2025 10:00am	6.0 hours	Preventive maintenance

Source: JH HCMC's application for a Certificate of Ongoing Performance 2024, p. 3-4, and supplemental information received on June 18, 2024, September 9, 2024, and April 17, 2026.

Notes: Staff rounded the duration of downtime to the nearest 10th of an hour in a few cases.
Downtimes for the mobile lab include dates but times are NR, meaning not reported.

Staff Analysis and Conclusion

MHCC staff reviewed the information on CCL room closures submitted by JH HCMC and determined that there was no overlapping downtime reported. Even with the 6-month closure of Lab 2 for installation of a new CCL, the hospital had a mobile CCL available for PCI patients to utilize during construction. JH HCMC provided dates of downtimes for the mobile CCL, and none of these overlapped with dates of downtime for the other CCL. The hospital's use of two CCLs and a mobile laboratory ensured that a CCL was available for primary PCI services 24 hours per day, seven days per week, during the review period. MHCC staff concludes that JH HCMC 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 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

JH HCMC provided a letter signed by hospital President, M. Shafeeq Ahmed, M.D., MBA, FACOG, dated December 22, 2023, which states that the hospital strives to provide primary PCI services as soon as possible, not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The President also committed to track door-to-balloon (DTB) times for transfer cases and evaluate areas for improvement. The hospital stated that it does not receive transfer patients.

Additionally, JH HCMC provided the number and percentage of non-transfer primary PCI patients, by quarter, with a DTB time of less than 90 minutes, for the period between July 2019

through September 2025 (Table 2). During this period, the hospital data showed that between 38.5 and 95.2 percent of cases met the DTB standard in each quarter. The hospital's information on DTB times indicates there were nine quarters where the DTB standard was not met for at least 75 percent of primary PCI patients.

Table 2. JH HCMC's Reported Door-to-Balloon (DTB) Times for Non-Transfer Primary PCI Cases by Quarter, July 2019 – September 2025

Quarter	Non-transfer Primary PCI Volume	Cases with DTB ≤ 90 Minutes	Percent of Cases with DTB ≤ 90 Minutes
CY 2019 Q3	26	20	77.0%
CY 2019 Q4	24	19	79.2%
CY 2020 Q1	23	19	82.6%
CY 2020 Q2	19	15	79.0%
CY 2020 Q3	14	11	78.6%
CY 2020 Q4	30	22	**73.3%**
CY 2021 Q1	31	23	**74.2%**
CY 2021 Q2	18	15	83.3%
CY 2021 Q3	21	20	95.2%
CY 2021 Q4	19	15	79.0%
CY 2022 Q1	21	16	76.2%
CY 2022 Q2	25	18	**72.0%**
CY 2022 Q3	13	5	**38.5%**
CY 2022 Q4	16	14	87.5%
CY 2023 Q1	18	12	**66.7%**
CY 2023 Q2	21	17	81.0%
CY 2023 Q3	17	12	**70.1%**
CY 2023 Q4	16	12	75.0%
CY 2024 Q1	20	17	85.0%
CY 2024 Q2	31	27	87.1%
CY 2024 Q3	22	18	81.2%
CY 2024 Q4	23	21	91.3%
CY 2025 Q1	17	12	**70.1%**
CY 2025 Q2	15	11	**73.3%**
CY 2025 Q3	26	18	**69.2%**

Source: JH HCMC's application for a Certificate of Ongoing Performance 2024, p. 5, and supplemental information received September 9, 2024, and January 13, 2026.

As a way to improve DTB times, JH HCMC reported that the hospital implemented a Direct-to-the-Lab initiative on May 3, 2022. This initiative allows stable STEMI patients being brought in by emergency medical services (EMS) to be taken directly to the CCL with just a brief pause in the emergency department (ED), during regular CCL business hours. The ED physician performs a brief assessment during registration and is ultimately responsible for ensuring that the patient is stable enough to proceed.

Another way the hospital has taken steps to improve care for STEMI patients is through the installation of a doorbell at the triage and EMS entrances to the ED to alert that an electrocardiogram (EKG) is needed. The hospital has assigned additional staff to the EKG task and changed the diagnoses that trigger the decision to do an EKG on a patient. These process improvements are intended to facilitate achieving door-to-EKG times under 10 minutes; therefore, improving DTB times. JH HCMC provided documentation showing that the percentage of patients who received EKGs within 10 minutes has increased from approximately 30 to 60 percent from

2022 to 2024, respectively.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases for the period from July 2019 to September 2025, as shown in Table 3a. According to this data, between 45.5 and 95.2 percent of primary PCI patients met the DTB standard in each quarter during the review period, with an average of 75.3 percent of STEMI cases meeting the DTB time of 90 minutes or less each quarter. Staff found that JH HCMC did not meet the DTB standard in nine quarters during the period reviewed. For the four quarters where the PCI volume numbers provided by JH HCMC differed substantially from PCI volume numbers obtained from the ACC-NCDR data, the hospital identified the cases that were missing due to an oversight during transcription of the data. JH HCMC reported that a single spreadsheet has been developed to ensure that all cases are accounted for in the future.

Table 3a. Per ACC-NCDR, JH HCMC's Compliance with DTB Benchmark for Non-Transfer Primary PCI Cases by Quarter, July 2019 – September 2025

Quarter	Non-transfer Primary PCI Volume	Cases with DTB ≤ 90 Minutes	Percent of Cases with DTB ≤ 90 Minutes
CY 2019 Q3	23	17	**73.9%**
CY 2019 Q4	24	19	79.2%
CY 2020 Q1	22	19	86.4%
CY 2020 Q2	19	15	78.9%
CY 2020 Q3	14	11	78.6%
CY 2020 Q4	24	18	75.0%
CY 2021 Q1	30	20	**66.7%**
CY 2021 Q2	18	15	83.3%
CY 2021 Q3	21	20	95.2%
CY 2021 Q4	20	16	80.0%
CY 2022 Q1	18	14	77.8%
CY 2022 Q2	14	11	78.6%
CY 2022 Q3	11	5	**45.5%**
CY 2022 Q4	13	10	76.9%
CY 2023 Q1	13	8	**61.5%**
CY 2023 Q2	18	13	**72.2%**
CY 2023 Q3	17	12	**70.6%**
CY 2023 Q4	17	10	**58.8%**
CY 2024 Q1	17	14	82.4%
CY 2024 Q2	25	21	84.0%
CY 2024 Q3	17	15	88.2%
CY 2024 Q4	16	14	87.5%
CY 2025 Q1	17	9	**53.0%**
CY 2025 Q2	17	13	76.5%
CY 2025 Q3	25	15	**60.0%**
2019 Q3 - 2025 Q3	470	354	75.3%

Source: MHCC staff's analysis of ACC-NCDR CathPCI data for July 2019 – September 2025.

For each PCI case with a DTB time greater than 90 minutes in the nine quarters where the hospital did not meet the DTB standard, JH HCMC provided the date of the PCI procedure, DTB time, and reason for the delay, if known. JH HCMC reported four cases were delayed for an issue obtaining the patient's consent and 24 delays were related to a patient's medical condition and the

need for additional testing. There were 19 cases in which there was difficulty with the PCI procedure itself. In eight cases, no reason for delay was identified by the hospital.

MHCC staff compared the information provided with the information available in the ACC-NCDR CathPCI registry on PCI cases with delays and confirmed that many of the PCI cases that did not meet the time standard had a non-system reason for delay.

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 the delay, and MHCC includes all cases in reviewing compliance with this standard. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers the hospital's performance over rolling eight-quarter periods, as shown in Table 3b.

Table 3b. Per ACC-NCDR, JH HCMC's Non-Transfer Primary PCI Voume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Rolling Eight-Quarters, October 2017 – September 2025

Time Period	Total Primary PCI Volume	Cases with DTB ≤ 90 Minutes	Percent of Cases with DTB ≤ 90 Minutes
CY 2017 Q4 - CY 2019 Q3	194	163	84.0%
CY 2018 Q1 - CY 2019 Q4	201	166	82.6%
CY 2018 Q2 - CY 2020 Q1	192	159	82.8%
CY 2018 Q3 - CY 2020 Q2	187	154	82.4%
CY 2018 Q4 - CY 2020 Q3	176	142	80.7%
CY 2019 Q1 - CY 2020 Q4	171	133	77.8%
CY 2019 Q2 - CY 2021 Q1	179	138	77.1%
CY 2019 Q3 - CY 2021 Q2	174	134	77.0%
CY 2019 Q4 - CY 2021 Q3	172	137	79.7%
CY 2020 Q1 - CY 2021 Q4	168	134	79.8%
CY 2020 Q2 - CY 2022 Q1	164	129	78.7%
CY 2020 Q3 - CY 2022 Q2	159	125	78.6%
CY 2020 Q4 - CY 2022 Q3	156	119	76.3%
CY 2021 Q1 - CY 2022 Q4	145	111	76.6%
CY 2021 Q2 - CY 2023 Q1	128	99	77.3%
CY 2021 Q3 - CY 2023 Q2	128	97	75.8%
CY 2021 Q4 - CY 2023 Q3	124	89	**71.8%**
CY 2022 Q1 - CY 2023 Q4	121	83	**68.6%**
CY 2022 Q2 - CY 2024 Q1	120	83	**69.2%**
CY 2022 Q3 - CY 2024 Q2	131	93	**71.0%**
CY 2022 Q4 - CY 2024 Q3	137	103	75.2%
CY 2023 Q1 - CY 2024 Q4	140	107	76.4%
CY 2023 Q2 – CY 2025 Q1	144	108	75.0%
CY 2023 Q3 – CY 2025 Q2	143	108	75.5%
CY 2023 Q4 – CY 2025 Q3	151	111	**73.5%**

Source: MHCC staff's analysis of ACC-NCDR CathPCI data for July 2017 – September 2025.

As shown in Table 3b, over rolling eight-quarter periods, between 68.6 and 84 percent of the hospital's non-transfer primary PCI cases met the DTB time standard. The average percent of cases that met the DTB time standard in each rolling eight-quarter period is 76.9. Additionally, JH HCMC reported implementation of two initiatives aimed at decreasing DTB times. One, the

Direct-to-the-Lab initiative, allows patients to go straight to the CCL with just a brief stop in the ED, and the other aims for door-to-EKG times less than 10 minutes. Based on this analysis and the information provided by JH HCMC regarding process improvement initiatives focusing on DTB times and the door-to-EKG metric, MHCC staff recommends that the Commission find that the hospital is in compliance with 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.

As shown in Table 4a below, JH HCMC reported the number of physicians, nurses, and technicians who are available to provide cardiac catheterization services to acute myocardial infarction patients as of January 2026. JH HCMC explained that it budgets for a higher number of technician and nurse FTEs, six (6) and 10.8, respectively.

Table 4a. Total Number of CCL Physician, Nursing, and Technical Staff

Staff Category	Number/FTEs	Cross Training (S/C/M*)
Physician	9	
Nurse	10.8	C
Technician	5	S/C/M
Agency	2	S/C/M

Source: JH HCMC's application for a Certificate of Ongoing Performance 2024, p. 6 and supplemental information received January 13, 2026.
*Scrub (S), Circulate (C), Monitor (M)

JH HCMC stated that during regular business hours both CCLs are operational with appropriate staffing. The hospital also provides multiple staff who are available to work in the CCL 24/7 including one physician, two STEMI nurses, and two CCL technicians. The hospital reported that it has minimized overtime for both nurses and technicians by providing contracted clinical support as needed.

Staff Analysis and Conclusion

MHCC staff compared the staffing levels described by JH HCMC to information reported by three other existing PCI programs with similar case volumes. A comparison of volume and staffing levels for JH HCMC, Carroll Hospital Center (CHC), University of Maryland Shore Regional Medical Center at Easton (UM Shore) and University of Maryland Baltimore Washington Medical Center (UM BWMC) is shown in Table 4b. Staff observed that several more interventionalists provide PCI services at JH HCMC compared to the other three hospitals, possibly due to the hospital using interventional cardiologists who are faculty and members of the Johns Hopkins School of Medicine. More nurses are devoted to working in the CCL at JH HCMC than at the other hospitals, even though UM Shore and UM BWMC both provide more PCI cases annually. JH HCMC has two more technicians than does CHC and UM Shore, but one fewer than UM BWMC.

Table 4b. CCL Staffing for JH HCMC and Other Select PCI Programs

Program	Total PCI Volume	Number of Interventionalists or FTEs	Nurse FTEs	Technicians FTEs
JH HCMC	194	9	10.8	6
CHC	173	4	9.8	4
UM Shore	206	3	6	4
UM BWMC	231	3	7.5	7

Sources: JH HCMC's application for a Certificate of Ongoing Performance 2024, p.6 and supplemental information received January 13, 2026; CHC's application for a Certificate of Ongoing Performance 2024; UM Shore's application for a Certificate of Ongoing Performance 2025 and supplemental data submission in September 2025; UM BWMC's application for a Certificate of Ongoing Performance 2024; and PCI volume from the ACC-NCDR CathPCI registry report for the period ending September 30, 2025.

Note: Total PCI case volume includes both primary and elective PCIs performed for the 4-quarter period ending in Q3 2025.

Based on the above analysis of the number of staff reported at other hospitals with comparable volumes to JH HCMC, MHCC staff determined that the hospital has adequate physician, nursing, and technical staff available to provide PCI services. Staff concludes that JH HCMC complies with 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.

JH HCMC provided a written commitment, signed by President of JH HCMC, M. Shafeeq Ahmed, M.D., MBA, FACOG, stating that the hospital is dedicated to complying with the MHCC regulations in the Cardiac Services Chapter.

Staff Analysis and Conclusion

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

JH HCMC reported that the hospital has allocated 0.8 FTEs to a Clinical Data Coordinator position. This role is a nursing position and is responsible for PCI, STEMI, and non-STEMI data collection and analysis.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and confirmed that the hospital has been submitting complete and timely information to the ACC-NCDR. MHCC staff concludes that JH HCMC complies 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.

JH HCMC reported that two physicians function as Co-Medical Directors of Invasive Cardiology. Dr. Peter V. Johnston was appointed Medical Director on July 1, 2010. He performs both primary and elective PCIs and takes calls at JH HCMC. Dr. Johnston is assisted by Dr. Eric Schwartz, an electrophysiologist who is also an in-house cardiologist several days a week. JH HCMC described responsibilities to include professional staff services, policies and procedures, regulatory requirements, capital equipment and space, cardiovascular supporting staff, and quality insurance and improvement.

Staff Analysis and Conclusion

MHCC staff reviewed the description of job duties for both Medical Directors provided by the hospital and concludes that JH HCMC complies 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.

JH HCMC provided a list of the educational programs and activities in which Intensive Care Unit (ICU), Special Care Unit, and CCL staff participated from CY 2019 to CY 2025. The hospital stated that all continuing education is tracked through the MyLearning and Healthstream platforms and by Human Resources (HR). It is the responsibility of each Manager to ensure that MyLearning and Healthstream trainings are complete. HR also tracks licensure renewal.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that JH HCMC complies 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 unconditional transfer of the hospital's patients for any required additional care, including emergent or elective cardiac surgery or PCI.

JH HCMC provided transfer agreements between the hospital and both Johns Hopkins Bayview Medical Center (JHBMC) and the Johns Hopkins Hospital (JHH), which were signed and dated by the previous President, Vic Broccolino, in 2006 and 2009, respectively. JHBMC and JHH agree to unconditionally receive transfer of patients from JH HCMC for any required additional care, including emergent or elective cardiac surgery or PCI.

Staff Analysis and Conclusion

MHCC staff reviewed the transfer agreements provided by JH HCMC and noted that the agreements provide for the unconditional transfer of patients, as required. MHCC staff concludes that JH HCMC complies with 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.

JH HCMC provided an agreement signed and dated in 2020 by the hospital's Sr. Vice President of Finance and Chief Financial Officer, Michael Larson, that covers transportation to JH HCMC. The agreement provides that, for time-sensitive emergent calls, Lifestar Response of Maryland, Inc. will provide transportation within 30 minutes of receiving the call, 90 percent of the time. On June 4, 2024, an amendment to this agreement was signed by Lisa Ishii, M.D., M.H.S., Sr. Vice President of Operations for the Johns Hopkins Health System Corporation, clarifying that transportation will be provided within 30 minutes for all time-sensitive emergent calls, which includes transport for PCI patients.

Staff Analysis and Conclusion

MHCC staff reviewed the transport agreement and amendment provided by JH HCMC, noting that for time-critical transport, Lifestar Response of Maryland, Inc. will arrive within thirty (30) minutes of receiving the request for patient transport. MHCC staff concludes that the hospital complies with 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.

JH HCMC provided STEMI Care Committee meeting minutes for CY 2019 through CY 2025, which included dates and a list of attendees and their roles. Participants include Howard County Department of Fire and Rescue (HCDFR) personnel, ED and ICU nursing and physician leadership, CCL nurses and one technician, CCL nursing and physician leadership, cardiac rehabilitation, and nursing education. JH HCMC noted the information discussed in the meetings is reviewed at team huddles and disseminated to other CCL staff members, including those not in attendance. Additionally, when interventionalists are unable to attend the monthly STEMI Care Committee meetings, the Medical Director disseminates pertinent information, such as DTB times, to interventionalists who are unable to attend.

JH HCMC reported that interventional case review takes place at these meetings. Physicians performing primary PCI at the hospital are members of the JHH faculty, and they

participate in both weekly Morbidity and Mortality review that includes cases from JHH, JH HCMC, and JHBMC, as well as case review through the Johns Hopkins Heart and Vascular Institute.

Staff Analysis and Conclusion

The documentation submitted by JH HCMC includes attendance records, meeting dates, and minutes for 12 meetings in CY 2019, six in CYs 2020 and 2021, 11 in CYs 2022, 2023, and 2024, and 12 meetings in CY 2025. Meeting minutes were not provided for the period from July 2020 through June 2021. The hospital explained that the requested minutes were unable to be located, due to administrative turnover in two positions. However, detailed agendas for 12 meetings were provided for this period.

MHCC staff reviewed the roles of attendees for the period from CY 2019 to CY 2025 and confirmed with JH HCMC that while all interventionalists, nurses, and technicians who work in the CCL are encouraged to attend STEMI Care Committee meetings, only one staff member in each position consistently attends these meetings. Based on staff review of the information provided, and the hospital's explanation that information discussed at STEMI Care Committee meetings is distributed to CCL staff, MHCC staff recommends that the Commission find JH HCMC in compliance 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.

JH HCMC provided meeting minutes for the STEMI Care Committee, which meets monthly to review all matters related to the primary PCI system, including identifying issues and process improvements. The hospital provided dates and attendees for most meetings held between CY 2019 and CY 2025. Participants in these meetings include HCDFR personnel, ED and ICU nursing and physician leadership, CCL nurses and technicians, as well as both CCL nursing and physician leadership, cardiac rehabilitation, and nursing education.

Staff Analysis and Conclusion

The documentation submitted by JH HCMC included dates, meeting minutes, and attendance records for 12 meetings in CY 2019, six in CYs 2020 and 2021, 11 in CYs 2022, 2023, and CY 2024, and 12 meetings in CY 2025. Meeting minutes were not available for the period from July 2020 through June 2021. The hospital explained that the requested minutes were unable to be located, due to administrative turnover in two positions. However, the hospital provided detailed agendas for the 12 meetings reportedly held from July 2020 through June 2021. The meeting minutes available for review indicate that appropriate topics were discussed, giving rise to quality improvement initiatives in response to issues identified. MHCC recommends the Commission find that JH HCMC 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.

JH HCMC submitted copies of the external review reports completed so far, which includes elective PCI cases performed between January 2020 and June 2023. JH HCMC uses an MHCC approved review organization, the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ), to complete these external reviews according to standards established by the Commission. These reviews include the evaluation of angiographic images, medical test results, and the patient's medical record and take place on a semi-annual basis.

Staff Analysis and Conclusion

MHCC staff reviewed the seven external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 5. Although only five percent of cases are required to be reviewed externally, between 36.4 and 56.1 percent of cases were reviewed each year.

Table 5. JH HCMC's External Review, January 2020 – June 2023

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2020	66	37	56.1%	Semi-annually	Yes
CY 2021	129	47	36.4%	Semi-annually	Yes
CY 2022	113	50	44.2%	Semi-annually	Yes
Jan-June 2023	41	19	46.3%	Semi-annually	Yes

Source: MHCC staff analysis of ACC-NCDR CathPCI data (CY 2020 – June 2023) and MACPAQ external review reports (January 2020 – June 2023).

For the period between January 2020 and June 2023, MHCC staff assessed whether at least three cases were reviewed for each interventionalist, and, if fewer than three cases had been performed by an interventionalist, then all those interventionalist's cases were reviewed by MACPAQ. During the period from January to June 2023, the appropriate number of cases were reviewed by MACPAQ for all interventionalists except one. The hospital explained that an additional case for this interventionalist was submitted, but it was excluded from the review due to a technical error. JH HCMC reports that an internal auditing process has been put into place to verify that an appropriate number of cases have been reviewed and returned, to ensure that cases are not excluded. This process will be completed twice a year.

MHCC staff concludes that JH HCMC 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 three cases at the hospital 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 review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraphs .07C(4)(d)(i).

10.24.17.07D(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).

10.24.17.07C(4)(e) and .07D(5)(d) 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.

JH HCMC indicated that, in addition to the external reviews described above, JH HCMC stated that the internal review of select PCI cases takes place monthly during the STEMI Care Committee meetings and annually during peer review sessions. The hospital provided the number of cases that were reviewed for each interventionalist, both internally and externally, per calendar year.

Staff Analysis and Conclusion

MACPAQ has been approved by MHCC as a reviewer and their external reviews meet the requirements for these reviews in the Cardiac Services Chapter, MACPAQ's review of cases includes angiographic images, medical test results, and patients' medical records.

MHCC staff reviewed the information provided by JH HCMC and analyzed the ACC-NCDR CathPCI Registry data to determine the number of PCI cases performed by each interventionalist. Staff calculated the number of cases required to be reviewed for each interventionalist, per calendar year and compared the results of the analysis to the number of PCI cases reviewed internally and externally, per physician according to the hospital. MHCC staff observed that very few physicians met the standard of ten percent, or ten cases reviewed, whichever was greater, from CY 2020 through CY 2024. According to the information provided by JH HCMC, this standard was met for only two of 10 interventionalists in 2020, five of 10 in 2021, zero of nine in 2022, three of 11 in 2023, and one of nine in 2024.

MHCC staff determined that JH HCMC has not met this standard as intended in the Cardiac Services Chapter and recommends that the Commission require JH HCMC to show routine compliance with the standard under the following condition:

> JH HCMC shall evaluate the performance of each interventionalist through an internal or external review, by completing an annual review of at least 10 cases, or 10 percent of randomly selected PCI cases, whichever is greater, and all cases if the interventionalist performed fewer than 10 cases at the hospital, as required in COMAR 10.24.17.07C(4)(d). The hospital shall submit to Commission staff the number of PCI cases completed by each interventionalist, along with a list of cases reviewed for each interventionalist, for each six-month period, by February 1 and August 1 of each year, beginning with the list of cases reviewed for each interventionalists from January through June 2026, which is due on August 1, 2026. This condition is in effect until at least August 2028, to document compliance with this condition. After this date, the Executive Director may release JH HCMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

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.

JH HCMC submitted an affidavit from M. Shafeeq Ahmed, M.D., President of JH HCMC, dated December 22, 2023, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for internal case review, multiple area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist review consistent with the Cardiac Services Chapter.

Staff Analysis and Conclusion

MHCC staff reviewed the affidavit and concludes that JH HCMC complies with this standard.

10.24.17.07C(4)(g) and .07D(5)(f) A 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.

JH HCMC reported that quality assurance activities focus on patient safety and process improvement from first medical contact to device deployment in the CCL. Several principal activities are conducted regularly and detailed below.

First, JH HCMC indicated that case review discussions are completed monthly in the STEMI Care Committee, which is a multidisciplinary group that reviews cases and works on quality and process improvement activities. Committee representatives attend from the CCL, ED, ICU, HCDFR, and cardiac rehabilitation. One example of a quality improvement activity initiated by this Committee is taking stable STEMI patients brought in by EMS during normal business hours directly to the CCL with only a brief pause in the ED to ensure that the patient is stable enough to proceed. This initiative was implemented to improve DTB times for STEMI patients. Another initiative that has been implemented is for EKGs to be performed within 10 minutes of a patient presenting with chest pain. This was accomplished through installation of a doorbell at the triage and EMS entrances to the ED and assigning additional staff to the EKG task. The hospital also reported changing the diagnoses that trigger an EKG.

The hospital also reported holding DTB calls every Friday to review all Heart Attack Team activations that took place during the week. The Medical Director, manager and data coordinator for interventional radiology cardiovascular services, physician and nurse leaders from the ED, and Howard County EMS participate in these discussions. These calls were specifically instituted to identify any issues that contribute to delays in DTB times or affect the quality of patient care.

JH HCMC stated that one of the hallmarks of the hospital's primary PCI program is the hospital's robust relationship with HCDFR. A data coordinator provides case feedback to the Howard County EMS for each STEMI case transported to the hospital that was activated in the field. This includes cases that were aborted, as well as all cases that proceed to the CCL for intervention. This data is used by the HCDFR for quality improvement efforts and contributes to ensuring appropriate pre-hospital care for PCI patients. The Medical Director also teaches EKG interpretation annually at the HCDFR, as accurate recognition of STEMI cases is critical to achieving DTB times of less than 90 minutes.

Additionally, JH HCMC created a Heart and Vascular Institute Committee that meets quarterly to review the CCL results from the ACC-NCDR CathPCI data registry and cases with complications. The hospital provided a quality presentation from September 12, 2023, as an example of what is discussed in these meetings. Annual internal peer review sessions are also conducted to review cases performed in the CCL. At least one case from each operator is reviewed at these sessions.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by JH HCMC. Based on the description and documentation of quality assurance activities provided, staff concludes that the hospital complies with this standard.

Patient Outcome Measures

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.

(i) The primary benchmark is the national median risk-adjusted in-hospital mortality rate for STEMI PCI cases; and

(ii) If the statewide median risk-adjusted in-hospital mortality rate for primary PCI cases is obtained by the Commission within twelve months of the end of a reporting period, then the statewide median risk-adjusted in-hospital mortality rate for primary PCI cases will be used as a second benchmark.

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.

(i) The primary benchmark is the national median in-hospital risk-adjusted mortality rate for non-STEMI PCI cases, calculated from the CathPCI Registry data; and

(ii) If the statewide median risk-adjusted mortality rate for elective PCI cases is obtained by the Commission within twelve months of the end of the reporting period, then the statewide median in-hospital risk-adjusted mortality rate for elective PCI cases will be used as a second benchmark.

Staff Analysis and Conclusion

MHCC staff compiled the results from JH HCMC's quarterly reports from the ACC-NCDR CathPCI registry for STEMI PCI cases performed between October 2018 and September 2025. Table 6a shows the risk-adjusted mortality rates (AMR), by rolling 12-month reporting period, for the rolling 12-month periods ending between Q3 2019 through Q3 2025.

Table 6a. JH HCMC's Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for Primary PCI Programs

Reporting Period	Hospital AMR for STEMI Cases	95% Confidence Interval	National AMR for STEMI Cases	Meets MHCC Standard
2018q4-2019q3	8.42	[2.78, 18.81]	6.06	Yes
2019q1-2019q4	7.57	[2.09, 18.57]	6.01	Yes
2019q2-2020q1	10.36	[3.42, 23.08]	5.99	Yes
2019q3-2020q2	5.29	[0.64, 18.40]	6.06	Yes
2019q4-2020q3	4.04	[0.10, 21.71]	6.37	Yes
2020q1-2020q4	7.96	[0.97, 27.58]	6.89	Yes
2020q2-2021q1	8.32	[1.73, 23.37]	7.55	Yes
2020q3-2021q2	13.26	[4.38, 29.55]	7.51	Yes
2020q4-2021q3	2.69	[0.33, 9.35]	2.18	Yes
2021q1-2021q4	1.56	[0.04, 8.40]	2.17	Yes
2021q2-2022q1	1.80	[0.05, 9.65]	2.19	Yes
2021q3-2022q2	0.00	[0.00, 7.83]	2.18	Yes
2021q4-2022q3	0.00	[0.00, 9.61]	2.11	Yes
2022q1-2022q4	0.00	[0.00, 9.29]	2.00	Yes
2022q2-2023q1	3.26	[0.08, 17.42]	1.89	Yes
2022q3-2023q2	3.64	[0.09, 19.28]	1.89	Yes
2022q4-2023q3	8.49	[1.78, 23.29]	1.91	Yes
2023q1-2023q4	8.01	[2.23, 19.14]	1.88	**No**

2023q2-2024q1	6.08	[1.27, 16.78]	0.79	**No**
2023q3-2024q2	5.60	[1.17, 15.66]	0.78	**No**
2023q4-2024q3	1.78	[0.05, 9.58]	0.75	Yes
2024q1-2024q4	1.96	[0.05, 10.58]	0.74	Yes
2024q2-2025q1	1.78	[0.05, 9.61]	0.73	Yes
2024q3-2025q2	1.93	[0.05, 10.33]	0.80	Yes
2024q4-2025q3	2.07	[0.05, 11.13]	0.81	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 October 2018 and September 2025.

Note 1: A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark for ST-elevated myocardial infarction (STEMI), as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the national benchmark for STEMI cases for each reporting period.

Note 2: Reporting of STEMI cases in the ACC-NCDR CathPCI reports changed beginning in the period ending 2021q3; for this period and later, the performance metric excludes cases with cardiogenic shock.

MHCC staff reviewed the AMR data by rolling 12-month periods for STEMI PCI patients and determined that JH HCMC's AMR was not statistically significantly different than the national benchmark in all reporting periods with the exception of the three rolling 12-month periods ending in 2023q4, 2024q1, and 2024q2. The national benchmark fell within the 95 percent confidence interval for JH HCMC for all other 12-month reporting periods between July 2019 and September 2025.

The hospital's statistically significantly worse performance on the mortality metric for STEMI cases triggered a focused review of all STEMI patient deaths in the three 12-month periods ending in 2023q4, 2024q1, and 2024q2. The focused review evaluated the quality of care provided and whether the hospital responded appropriately to issues identified. MHCC contracted with an external organization to provide an independent review by a board-certified interventionalist. A total of four cases were reviewed. The review provided conclusions about the cases and recommendations. Commissioners should refer to Appendix 1. This information is confidential and protected by MHCC's status as a medical review committee.

MHCC staff compiled the results from JH HCMC's quarterly reports from the ACC-NCDR CathPCI registry for non-STEMI PCI cases performed between July 2019 and September 2025. Table 6b shows the AMR, by rolling 12-month reporting period, for the periods ending in Q2 2020 through Q3 2025.

Table 6b. JH HCMC's Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for Elective PCI Programs

Reporting Period	Hospital AMR for Non-STEMI Cases	95% Confidence Interval	National AMR for Non-STEMI Cases	Meets MHCC Standard
2019q3-2020q2	0.00	[0.00, 100.00]	1.00	Yes
2019q4-2020q3	0.00	[0.00, 22.69]	1.06	Yes
2020q1-2020q4	0.00	[0.12, 85.00]	1.13	Yes
2020q2-2021q1	0.00	[0.00, 11.51]	1.21	Yes
2020q3-2021q2	2.31	[0.06, 12.63]	1.18	Yes
2020q4-2021q3	3.96	[0.48, 13.99]	2.23	Yes
2021q1-2021q4	4.48	[0.54, 15.84]	2.23	Yes
2021q2-2022q1	3.87	[0.47, 13.70]	2.25	Yes

2021q3-2022q2	2.64	[0.07, 14.40]	2.26	Yes
2021q4-2022q3	0.00	[0.00, 11.26]	2.20	Yes
2022q1-2022q4	0.00	[0.00, 11.99]	2.14	Yes
2022q2-2023q1	0.00	[0.00, 14.29]	2.05	Yes
2022q3-2023q2	0.00	[0.00, 9.42]	2.02	Yes
2022q4-2023q3	0.00	[0.00, 7.57]	2.02	Yes
2023q1-2023q4	1.00	[0.03, 5.43]	1.99	Yes
2023q2-2024q1	1.00	[0.03, 5.42]	2.00	Yes
2023q3-2024q2	1.13	[0.03, 6.17]	1.99	Yes
2023q4-2024q3	2.12	[0.26, 7.45]	1.97	Yes
2024q1-2024q4	2.64	[0.07, 14.36]	1.95	Yes
2024q2-2025q1	1.42	[0.04, 7.74]	1.94	Yes
2024q3-2025q2	1.92	[0.23, 6.77]	1.92	Yes
2024q4-2025q3	1.09	[0.03, 5.95]	1.90	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 July 2019 and September 2025.

Note: A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark for non-STEMI, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the national benchmark for non-STEMI cases for each reporting period.

MHCC staff determined that the hospital's AMR for non-STEMI PCI patients was not statistically significantly different than the national benchmark in any reporting period because the national benchmark fell within the 95 percent confidence interval for JH HCMC in all 12-month reporting periods between April 2019 and September 2025.

As JH HCMC's AMR has improved since the focused review was conducted and they currently maintain an AMR with a 95 percent confidence interval that contains the national benchmark for both STEMI and non-STEMI cases, MHCC staff recommends that the Commission find that JH HCMC complies with 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.

JH HCMC submitted information on the volume of primary PCI cases at JH HCMC and other hospitals, by physician and quarter, for the period between CY 2019 and September 2025 for Drs. Johnston, Hwang, Hasan, Kalathiya, Trost, Rahman, Maniu, Miller, Resar, Theimann, and Czarny. Each interventionalist signed and dated an affidavit affirming under penalty of perjury that the information provided is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed the physician volumes reported for each interventionalist who performed primary PCI services at JH HCMC from CY 2019 through September 2025 and analyzed data from the ACC-NCDR CathPCI for the same time period.

Staff confirmed that each interventionalist who performed primary PCI services at JH HCMC from CY 2019 through September 2025 performed a minimum of 50 PCI procedures at all hospitals annually, averaged over a 24-month period. Therefore, MHCC staff concludes that JH HCMC complies with this standard.

10.24.17.07D(7)(b) For each physician who performs primary PCI at a hospital without on-site cardiac surgery who 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 physicians 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's analysis determined that this standard does not apply to JH HCMC. While JH HCMC does not have on-site cardiac surgery, MHCC staff analyzed the ACC-NCDR data and verified that each physician performing primary PCI performed at least 50 PCI procedures, on average, over a 24-month period.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital 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.

On February 26, 2024, hospital staff notified MHCC staff that Dr. Resar would take a leave of absence effective immediately, which was scheduled to last 6 to 9 months. JH HCMC stated that Dr. Resar retired from clinical practice in March 2026.

Staff Analysis and Conclusion

While one interventionalist took a leave of absence during the review period, because he did not return to clinical practice at JH HCMC, MHCC staff determined that this standard does not apply.

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 in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

JH HCMC submitted a signed statement from Dr. Peter V. Johnston, Medical Director of the Cardiac Interventional Program at JH HCMC, dated December 30, 2023, acknowledging that all physicians performing primary PCI services at the hospital are board-certified in interventional cardiology or exempt from this requirement. Furthermore, Dr. Johnston attested that each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the attestation provided and concludes that JH HCMC 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.

JH HCMC submitted signed and dated attestations from Drs. Johnston, Hwang, Hasan, Kalathiya, Trost, Rahman, Miller, Maniu, Thiemann, and Czarny 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 attestations provided and determined that JH HCMC complies with this standard.

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

JH HCMC submitted a signed statement from Dr. Peter V. Johnston, Medical Director of the hospital's Cardiac Interventional Program, dated December 30, 2023, acknowledging that each physician who performed primary PCI services during the review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the current on-call schedule. JH HCMC provided on-call schedules for October and December 2023, as well as for October through December 2025. The hospital also stated that interventionalists are on-call for specific shifts and are only on-call for one hospital at a time.

JH HCMC further explained that the PCI on-call schedule is supported by a rotating pool of interventional cardiologists who are members of Johns Hopkins School of Medicine faculty. Physician coverage varies month to month based on availability within this group. The core group

of physicians regularly providing PCI call coverage at JH HCMC includes Drs. Trost, Miller, Maniu, Rahman, and Johnston. During periods of absence, additional coverage is provided by Drs. Czarny, Kalathiya, and Hasan. Dr. Hwang maintains clinical privileges at JH HCMC; however, he no longer participates in the PCI call schedule at this location, as he now provides PCI call coverage exclusively at Frederick Health Hospital.

Staff Analysis and Conclusion

MHCC staff examined the on-call schedules provided by the hospital and observed that all practicing physicians, with the exception of Dr. Hwang, were included in the on-call schedules at different times during those months. However, JH HCMC provided an explanation as to how on-call coverage is scheduled, and that Dr. Hwang is no longer included in the on-call schedule as the physician only provides on-call coverage at Frederick Health Hospital.

Based on the signed statement, the on-call schedules provided, and the hospital's explanation of how call schedules work at JH HCMC, MHCC staff recommends that the Commission find the hospital to be in compliance with this standard.

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.

JH HCMC provided the total annual PCI case volume for CY 2020 and through November 2025, which shows that JH HCMC performed between 151 and 239 total PCI cases annually for the period from CY 2020 through November 2025.

Staff Analysis and Conclusion

The establishment of JH HCMC's elective PCI program was approved in April 2020. MHCC staff reviewed the PCI volumes submitted by JH HCMC as well as analyzing data from the ACC-NCDR CathPCI registry (Table 7) and determined that in three out of the five full years that the hospital provided both primary and elective PCI, the hospital did not meet the annual target volume of 200 PCI cases. While only 177 PCI cases were completed in CY 2022, 178 PCI cases in CY 2023, and 183 PCI cases in 2025, more than 200 PCI cases were completed in both CYs 2021 and 2024.

Table 7. JH HCMC's
Total PCI Volume, CY 2020 – CY 2025

Year	Number of PCI Cases
CY 2020	145
CY 2021	233
CY 2022	177
CY 2023	178

CY 2024	200
CY 2025	183

Source: MHCC staff's analysis of ACC-NCDR CathPCI data registry (CY 2020 – CY 2025).

Because the hospital maintains an average annual PCI volume of approximately 195, and because the volume of 200 cases is a target, not a strict requirement, MHCC staff recommends that the Commission find the hospital to be in compliance with this standard.

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.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI registry data and calculated the volume of primary PCI cases performed at JH HCMC from CY 2019 through CY 2025. As shown in Table 8, the primary PCI volume ranged from 62 to 100 cases each year.

Table 8. Primary PCI Volume at JH HCMC, CY 2019 – CY 2025

Year	Number of Primary PCI Cases
CY 2019	99
CY 2020	85
CY 2021	100
CY 2022	62
CY 2023	74
CY 2024	97
CY 2025	75

Source: MHCC staff's analysis of the ACC-NCDR CathPCI registry data, CY 2019 – CY 2025.

MHCC staff determined that this standard does not apply to JH HCMC, as the hospital exceeded the threshold of 49 primary PCI cases annually during the review period; therefore, no focused review is required.

10.24.17.07D(8)(b) The target volume for each physician who performs primary PCI is 11 or more primary cases annually.

JH HCMC provided the number of primary PCI cases completed, by location and interventionist, for each quarter, from CY 2019 through October 2025.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by JH HCMC and analyzed the ACC-NCDR CathPCI registry data for the period between CY 2019 and CY 2024. This analysis shows that each interventionalist completed at least 11 primary PCI procedures annually, with one exception (Dr. Hasan in 2023), and the physician resumed operating at the target volume the following year. Additionally, the case volume is a target, and not a mandate

according to the Cardiac Services Chapter. MHCC staff recommends the Commission find that JH HCMC is in compliance with 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.

JH HCMC stated in its application that the hospital is not aware of any patients who received elective PCI services inappropriately during the review period.

Staff Analysis and Conclusion

MHCC staff reviewed the MACPAQ external review reports from January 2020 through June 2023 and noted that the external reviews identified two cases to be "rarely appropriate" on more than one of the criteria used to evaluate the appropriateness of PCI procedures with respect to clinical, angiographic, and ACC/AHA appropriate use criteria. The hospital reported that the Medical Director discussed each of the cases with the performing interventionalist and found their explanations to be acceptable. Additionally, it should be noted that a case labeled "rarely appropriate" does not indicate that the PCI case was completed inappropriately. Simply, the determination indicates that the situation would not be expected to happen regularly, but in rare instances.

Based on the external review reports submitted and the reported follow-up by the hospital on cases deemed "rarely appropriate" on multiple criteria, MHCC staff concludes that JH HCMC 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 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.

JH HCMC stated that the hospital is not aware of any patients who received primary PCI services inappropriately during the review period. The hospital initially reported that there were no patients who received PCI following failed thrombolytic therapy; however, HCMC has since stated that one PCI case took place after failed thrombolytics in CY 2024. The hospital reported that the case was overlooked due to a manual data transfer error, but JH HCMC stated that it took steps to ensure this type of data error is not replicated.

Staff Analysis and Conclusion

MHCC staff's analysis of the ACC-NCDR Cath PCI registry data for CY 2019 through CY 2025 is consistent with the information reported by the applicant regarding the use of thrombolytic therapy. Staff also notes that the ACC-NCDR reports for the period from CY 2019 through CY 2025 indicate no PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate.

MHCC staff determines that JH HCMC complies with this standard.

RECOMMENDATION

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

> JH HCMC shall evaluate the performance of each interventionalist through an internal or external review, by completing an annual review of at least 10 cases, or 10 percent of randomly selected PCI cases, whichever is greater, and all cases if the interventionalist performed fewer than 10 cases at the hospital, as required in COMAR 10.24.17.07C(4)(d). The hospital shall submit to Commission staff the number of PCI cases completed by each interventionalist, along with a list of cases reviewed for each interventionalist, for each six-month period, by February 1 and August 1 of each year, beginning with the list of cases reviewed for each interventionalists from January through June 2026, which is due on August 1, 2026. This condition is in effect until at least August 2028, to document compliance with this condition. After this date, the Executive Director may release JH HCMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.