

**IN THE MATTER OF
UNIVERSITY OF MARYLAND
BALTIMORE WASHINGTON
MEDICAL CENTER**

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

Docket No.: 24-02-CP049

*** * * * ***

STAFF REPORT AND RECOMMENDATION

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

September 19, 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 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 affects 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 given number of years 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 Surgery 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

University of Maryland Baltimore Washington Medical Center

University of Maryland Baltimore Washington Medical Center (BWMC) is a 307-bed general hospital located in Glen Burnie, Anne Arundel County, Maryland that does not have an on-site cardiac surgery program. BWMC received approval to provide primary PCI services under a waiver on May 18, 2006, and subsequently received renewals of its waiver to provide primary PCI services in June 2007 and May 2009. The applicant received approval to provide elective PCI services in June 2009 and subsequently received additional renewals of its waiver to provide elective PCI services. BWMC received its first Certificate of Ongoing Performance for both elective and primary PCI services on July 16, 2020, for four years. This is BWMC'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 Surgery Chapter. The regions are defined by geographic areas. BWMC is located in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot counties and Baltimore City. 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 BWMC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services. A description of BWMC's documentation and MHCC staff's analysis of this information follows.

II. PRODEDURAL HISTORY

BWMC applied for renewal of its Certificate of Ongoing Performance for PCI services on January 12, 2024. MHCC staff extended the hospital's Certificate of Ongoing Performance for PCI services for six months on June 14, 2024, because staff required additional time to review the hospital's application. MHCC staff reviewed the application and requested additional information on June 26, 2024, July 16, 2024, and August 15, 2024. MHCC received additional information on July 2, 2024, July 23, 2024, and August 30, 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.

BWMC stated that the hospital participates in uniform data collection and reporting through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI and other registries. The hospital stated that there were no deficiencies in data collection or reporting and that all applicable deadlines were met.

Staff Analysis and Conclusion

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

BWMC provided the dates and duration of downtimes between January 1, 2019, and December 31, 2023, when one or both of its cardiac catheterization laboratory (CCL) rooms were not available, or PCI services were not available for another reason. The occurrences when the CCLs were not available are summarized in Table 1 below. BWMC reported that the hospital went on bypass when PCI services were not available. BWMC also noted that on July 13, 2019, and

October 5, 2020, the hospital had simultaneous STEMI patients. In both cases, BWMC reported that the first STEMI was activated in the field (before patient arrival at the hospital) and the second STEMI patient was diverted to UMMC without delay.

Table 1: BWMC Reported CCL Downtimes, CY 2019 – CY 2023

Date	Duration	Reason
5/20/2019	2.00	Reduced air flow due to AHU 28 maintenance
6/7/2019	2.75	Toshiba collimator failure
6/8/2019	2.50	Toshiba repair of collimator
5/18/2020	1.00	Reduced air flow due to AHU 28 maintenance
8/1/2020	4.00	Emergency Power Outage for ATS D2 & D3 Replacement
5/24/2021	2.00	Reduced air flow due to AHU 28 maintenance
6/7/2021	1.50	Air handler down effecting temperature in both rooms
5/16/2022	2.00	Reduced air flow due to AHU 28 maintenance
12/28/2022	2.50	Interventionalist tested positive for COVID-19 and went home sick. Covering Interventionalist temporarily out of area.
5/8/2023	2.00	Reduced air flow due to AHU 28 maintenance

Source: BWMC application, response to Question 2

Staff Analysis and Conclusion

MHCC staff reviewed the incident descriptions and information on CCL downtimes provided in BWMC’s application and noted that patient care was reported to have not been affected by downtime due to maintenance. BWMC stated that there was no impact to patient care when the cardiac catheterization lab was closed for any maintenance, whether planned or unplanned, as no STEMI was activated during any of the maintenance time periods in question. Although there were times when the CCL was not available, these were a limited number and patient care was not adversely affected. For these reasons, staff recommends the Commission finds that BWMC complies with this standard.

10.24.17.07D(4)(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

BWMC provided a signed statement from its president and CEO, Kathy McCollum, dated January 5, 2024, affirming that BWMC commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital for at least 75% of cases. Additionally, BWMC provided quarterly information on its door-to-balloon (DTB) times for the period January 2019 through September 2023. Table 2 shows information reported through December 2022.⁴ BWMC reported that it does not receive transfer cases from other facilities.

⁴ Staff is not including the information reported for 2023 because staff cannot validate information later than December 2022.

Table 2: BWMC Reported Compliance with DTB Benchmark for Non-Transfer Primary PCI Cases by Quarter, January 2019 – June 2023

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases with DTB <=90 Minutes
CY 2019 Q1	31	29	93.6%
CY 2019 Q2	26	23	88.5%
CY 2019 Q3	25	25	100.0%
CY 2019 Q4	8	7	87.5%
CY 2020 Q1	18	16	88.9%
CY 2020 Q2	20	18	90.0%
CY 2020 Q3	25	23	92.0%
CY 2020 Q4	30	28	93.3%
CY 2021 Q1	21	20	95.2%
CY 2021 Q2	23	23	100.0%
CY 2021 Q3	23	22	95.7%
CY 2021 Q4	23	23	100.0%
CY 2022 Q1	27	26	96.3%
CY 2022 Q2	19	19	100.0%
CY 2022 Q3	28	27	96.4%
CY 2022 Q4	33	27	81.8%

Source: BWMC application, Question 3b

Note: MHCC staff rounded the percentage of cases with a DTB less than 90 minutes.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer PCI cases and found that BWMC met the DTB standard in all but one quarter, Q2 of 2020. 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 the DTB metric used by MHCC includes all cases. MHCC staff asked BWMC to explain the DTB delays in the second quarter of 2020. BWMC responded with information that indicates in four of the six cases in which the DTB standard was not met, the root cause was attributable to the patient’s condition, which is outside the control of the hospital. These reasons included cardiac arrest for two patients and the need for additional testing in two patients based on their symptoms.

MHCC staff also considers a hospital’s performance on the DTB standard over longer periods that include multiple quarters. Over rolling eight quarter periods BWMC complied with this standard, with between 85.2% and 90.82% of PCI cases meeting the door-to-balloon time standard over rolling eight-quarter periods, as shown below in Table 3.

Table 3: BWMC Non-Transfer Primary PCI Case Volume and Percentage of Cases With DTB Less Than or Equal to 90 Minutes, by Time Period

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
2019q1	25	20	80.00%			
2019q2	23	21	91.30%			
2019q3	29	26	89.66%			
2019q4	19	17	89.47%			
2020q1	21	18	85.71%			
2020q2	22	16	72.73%			
2020q3	28	23	82.14%			
2020q4	29	26	89.66%	196	167	85.20%
2021q1	26	22	84.62%	197	169	85.79%
2021q2	25	24	96.00%	199	172	86.43%
2021q3	25	23	92.00%	195	169	86.67%
2021q4	23	21	91.30%	199	173	86.93%
2022q1	30	27	90.00%	208	182	87.50%
2022q2	20	19	95.00%	206	185	89.81%
2022q3	29	26	89.66%	207	188	90.82%
2022q4	31	26	83.87%	209	188	89.95%

Source: MHCC analysis of ACC-NCDR CathPCI data, January 1, 2019 – Dec. 31, 2022.

Based on the letter of commitment provided and MHCC staff’s analysis of the ACC NCDR CathPCI data, and MHCC staff’s review of information submitted by BWMC, MHCC staff concludes that BWMC 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 patients with acute myocardial infarction 24 hours per day, seven days per week.

BWMC provided the number of physicians, nurses, and technicians who provide cardiac catheterization services to acute myocardial infarction patients as January 5, 2024, as shown below in Table 4.

Table 4: BWMC Reported CCL Physician, Nursing, and Technician Staff

Role	Number / FTEs	Cross Training (S/C/M)*
Physician	3	
Nurse (FTE)	7.4	C, M
Technician (FTE)	7.0	S, M

Source: BWMC January 2024 PCI Certificate of Ongoing Performance renewal application, page 10

* (S) scrub, (C) circulate, (M) monitor

Staff Analysis and Conclusion

MHCC staff compared the reported staffing levels at BWMC to the staffing levels for programs at three other hospitals with similar PCI case volume. A comparison of volume and staffing levels for BWMC, Medstar Southern Maryland (MSMHC), Carroll Hospital Center (CHC), and University of Maryland Shore Regional Medical Center (UM SRH) is shown in Table 5. The four facilities employ approximately the same number of interventionalists. BWMC handles a larger volume of PCI cases than CHC and UM SRH and correspondingly employs a larger combination of nurses and technicians than those facilities. MSMHC utilizes a larger combination of nurses and technicians than BWMC, 16 compared to 14.5 for BWMC, but MSMHC also has a PCI case volume that is about 20% larger than BWMC’s.

Table 5: CCL Staffing for BWMC and Other Select PCI Programs

Facility	Total PCI Volume in 2023	Physicians	Nurse FTEs	Technician FTEs
BWMC	248	3	7.4	7
MSMHC	297	2 FT, 3 PT, 1 after hours PRN call	11	5
UM SRH	224	3	7.25	3
CHC	221	4	10	4

Sources: BWMC’s application and BWMC’s PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2023; September 2023 letter from MSMHC to MHCC and MSMHC’s PCI volume from its ACC-NCDR CathPCI registry report for period ending December 31, 2023; UM SRH’s January 6, 2023 application for a Certificate of Conformance for Primary and Elective PCI Services and UM SRH’s PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2023; CHC’s April 4, 2024 application for renewal of its Certificate of Ongoing Performance for Primary and Elective PCI Services and CHC’s PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2023.

The staffing of the CCL at BWMC is comparable to other PCI programs with similar volume, and there will likely be adequate nursing and technical staff to provide services. MHCC staff concludes that BWMC complies with this standard.

10.24.17.07D(4)(d) The hospital president or Chief Executive Officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.

BWMC provided a signed letter of commitment from its president and CEO, Kathy McCollum, dated January 5, 2024, stating that BWMC will continue to provide PCI services in accordance with the requirements established by the Commission.

Staff Analysis and Conclusion

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

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.

BWMC stated that the hospital’s quality department maintains two FTE positions responsible for the necessary data management, reporting, and coordination with institutional

quality improvement efforts. These staff are a registered nurse and a data analyst. The patient and registry data managed by these two individuals is reviewed monthly at BWMC's Cardiac Collaborative meetings and is also reviewed by the CCL's nurse manager and medical director.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that BWMC 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 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.

BWMC stated that Dr. Ratnakar Mukherjee, an interventional cardiologist, was appointed as the medical director of the CCL on December 31, 2017. BWMC's Dr. Mukherjee is responsible for oversight of the CCL services, quality of care, and operations. He reviews all PCI cases at least monthly during case review meetings. He also reviews and presents external peer review summaries, oversees equipment improvements, collaborates with multidisciplinary and corporate quality improvement committees, and participates in quality improvement projects.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that BWMC complies with this standard.

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

BWMC submitted documents identifying the continuing education programs and activities in which staff in the CCL and the Coronary Care Units participated from January 2019 through December 2023. Some of the topics regularly covered included radiation safety, reviews on proper usage of an intra-aortic balloon pump (IABP), sedation administration and monitoring, and effective performance of bubble echocardiograms. The curriculum also included a variety of other topics covered on a one-time basis or with less frequency, and BWMC's documentation specified which educational sessions included only technicians, only registered nurses, and both nurses and technicians.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation submitted and notes that the continuing medical education programming for BWMC cardiac staff includes appropriate topics. MHCC staff concludes that BWMC is compliant with this standard.

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

BWMC stated that it has a current, signed and dated agreement with University of Maryland Medical Center (UMMC), a tertiary care center that provides for the unconditional transfer of primary PCI patients from BWMC to UMMC and provided a copy of this agreement. This agreement also covers the transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI.

Staff Analysis and Conclusion

MHCC staff reviewed the transfer agreement between UMMC and BWMC and concludes that BWMC is compliant with this standard.

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

BWMC provided a copy of its current, signed and dated agreement with ExpressCare, a licensed advanced cardiac support emergency medical service provider, which guarantees the arrival of an air or ground ambulance at BWMC within thirty minutes of a request for the transport of a primary PCI patient to a tertiary care center.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement between ExpressCare and BWMC and concludes that BWMC is compliant with this standard.

Quality

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

BWMC provided the dates of its interventional case review meetings as well as lists with the staff in attendance, for the period January 2019 through December 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and lists of attendees for the monthly case review meetings. The meeting records indicate that appropriate staff were regularly in attendance, including interventional cardiologists, nurses, technicians and CCL leadership. The hospital held 30 case review meetings in 2019, 25 meetings in 2020, 20 meetings in 2021, 26 meetings in 2022, and 23 meetings in 2023. MHCC staff concludes that BWMC complies with this standard.

10.24.17.07C(4)(b) and .07D(5)(b) A hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

BWMC provided the dates of its multiple care area group meetings, known as the Cardiac Collaborative, as well as a list of those who have attended the meetings, for the period January 2019 through December 2023. BWMC also stated that representation at all Cardiac Collaborative meetings includes staff from the CCL, the medical director, and the manager of the CCL.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for the Cardiac Collaborative meetings. There were ten meetings in CY 2019, nine meetings in CY 2020, ten meetings in CY 2021, eleven meetings in CY 2022, eight meetings in CY 2023, and seven meetings in the first eight months (January through August) of 2024. The attendance records for these meetings indicate that physician and nurse leadership for the emergency department, CCL, and CCU regularly attended these meetings. Although BWMC fell well below the standard of holding 12 meeting each year in CY 2020 and CY 2023, the pandemic in CY 2020 affected the ability of many hospitals to hold the requisite number of meetings, and the hospital appears to be back on track to hold a sufficient number of meetings in 2024. MHCC staff recommends the Commission find that BWMC 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.

BWMC provided MHCC with external review reports for the periods from January 2019 through December 2022. Reports for 2023 are not available from MACPAQ yet. The external reviews were completed by the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ).

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted by BWMC. The volume of elective PCI cases for each year, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 6. Although only 5% of cases are required to be reviewed externally, between 5.8% and 23.2% of cases were reviewed each year between CY 2019 and CY 2022. Staff analyzed the ACC-NCDR CathPCI data and verified that in each six-month review period at least five percent of cases underwent the external review and that at least three cases per physician were reviewed, or all cases were reviewed, if the interventionalist performed fewer than three cases. MHCC staff concludes that BWMC complies with this standard.

Table 6: BWMC External Review Numbers by Year

Calendar Year	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Meets Standard?
CY 2019 (Jan – Jun)	191	11	5.8%	Yes
CY 2019 (Jul – Dec)	109	17	15.6%	Yes
CY 2020 (Jan – Jun)	108	18	16.7%	Yes
CY 2020 (Jul – Dec)	82	19	23.2%	Yes
CY 2021 (Jan – Jun)	106	18	17.0%	Yes
CY 2021 (Jul – Dec)	104	18	17.3%	Yes
CY 2022 (Jan – Jun)	99	17	17.2%	Yes
CY 2022 (Jul – Dec)	99	18	18.2%	Yes

Source: MHCC staff analysis of MACPAQ reports

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.*

BWMC stated that MACPAQ is the review organization providing external BWMC PCI performance reviews and that an internal peer review is performed on all PCI cases and all patients who are transferred for CABG. The medical director of the CCL and other interventionalists participate in internal peer reviews.

Staff Analysis and Conclusion

The external reviews conducted by MACPAQ meet the requirements of 10.24.17.07C(4)(e) and .07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization. The review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records.

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number of cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of cases to be reviewed to satisfy the requirements for review of individual interventionalists. The bulletin states that a semi-annual review of at least three cases or 10% of cases, whichever is

greater, per interventionalist, as part of an external review meets the standard, and the requirements in COMAR 10.24.17.07D(5)(c) are equivalent to those in COMAR 10.24.17.07C(4)(d).⁵

MHCC staff 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. For most physicians the number of cases reviewed by MACPAQ constituted at least ten percent of the elective PCI cases performed by each physician. For one or two physicians, the number of cases reviewed by MACPAQ each year was less than the required ten cases and the standard was met through a combination of internal and external case review. BWMC reported that all PCI cases are reviewed internally. MHCC staff concludes that BWMC complies with the standards for review of individual interventionalists.

10.24.17.07D(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.

BWMC provided a signed statement from its president and CEO, Kathy McCollum, dated January 5, 2024, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in COMAR 10.24.17, including those regarding internal peer review of cases and external review of cases.

Staff Analysis and Conclusion

MHCC staff reviewed the statement provided and concludes that BWMC complies with 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.***

BWMC explained that its Collaborative Interventional Cardiovascular Committee (CICC) meetings are used for quality improvement opportunities. The CICC is part of BWMC's system for upholding care standards for PCI patients in accordance with regulatory guidelines and current evidence-based practices and standardized metrics for quality available to participants in the ACC-NCDR CathPCI registry. BWMC detailed eight distinct actions the hospital took in response to

⁵https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_esac_bulletin_pci_cases_20151020.pdf

concerns identified through its internal quality assurance processes and stated that the hospital has already seen measurable enhancements in patient outcomes through the quality improvement initiatives developed.

Staff Analysis and Conclusion

MHCC staff reviewed the hospital's ACC-NCDR CathPCI reports to validate whether there had been improvement on specific metrics relevant to BWMC's quality improvement activities, and this analysis confirmed the hospital's performance has improved. Staff also reviewed BWMC's detailed description of its internal processes for quality assurance. Based on this review MHCC staff concludes that BWMC 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 with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause 30-day risk-adjusted mortality rate for primary PCI cases.

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

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

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

BWMC's adjusted mortality rates, by rolling 12-month reporting period, for 2019 Q1 through 2023 Q4, are shown below in Table 7.

Table 7: BWMC Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI				NON-STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2023q1-2023q4	0.00	[0.00, 9.72]	1.88	Yes	0.00	[0.00, 3.44]	1.99	Yes
2022q4-2023q3	0.00	[0.00, 10.24]	1.91	Yes	0.00	[0.00, 3.74]	2.02	Yes
2022q3-2023q2	0.00	[0.00, 8.89]	1.89	Yes	0.00	[0.00, 2.15]	2.02	Yes
2022q2-2023q1	0.00	[0.00, 8.18]	1.89	Yes	0.58	[0.01, 3.21]	2.05	Yes
2022q1-2022q4	0.00	[0.00, 6.79]	2.00	Yes	0.70	[0.02, 3.87]	2.14	Yes
2021q4-2022q3	0.00	[0.00, 6.17]	2.11	Yes	1.15	[0.14, 4.08]	2.20	Yes
2021q3-2022q2	0.00	[0.00, 4.80]	2.18	Yes	1.92	[0.23, 6.85]	2.26	Yes
2021q2-2022q1	0.00	[0.00, 4.94]	2.82	Yes	0.90	[0.32, 9.24]	2.25	Yes
2021q1-2021q4	0.00	[0.00, 5.41]	2.74	Yes	0.56	[0.01, 3.07]	2.23	Yes
2020q4-2021q3	0.00	[0.00, 6.03]	2.18	Yes	0.00	[0.00, 13.20]	2.23	Yes
2020q3-2021q2	7.89	[2.94, 16.58]	7.51	Yes	0.00	[0.00, 1.72]	1.18	Yes
2020q2-2021q1	7.41	[2.76, 15.57]	7.55	Yes	0.40	[0.01, 2.17]	1.21	Yes
2020q1-2020q4	6.58	[2.45, 13.82]	6.92	Yes	0.51	[0.01, 2.78]	1.16	Yes
2019q4-2020q3	6.95	[2.59, 14.57]	6.37	Yes	0.74	[0.02, 4.05]	1.06	Yes
2019q3-2020q2	2.59	[0.32, 9.12]	6.06	Yes	0.66	[0.02, 3.64]	1.00	Yes
2019q2-2020q1	2.52	[0.31, 8.87]	5.99	Yes	NR	[0.00, 3.85]	0.95	Yes
2019q1-2019q4	3.60	[0.75, 10.22]	6.01	Yes	NR	[0.00, 2.04]	0.95	Yes

Source: MHCC Staff compilation of results from the hospital's quarterly reports from the ACC NCDR CathPCI for PCI cases performed between January 2019 and December 2023.

Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark for STEMI or NSTEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the national benchmark for STEMI or NSTEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEMI and NSTEMI cases for each reporting period. "NR" means not reported. When a hospital has zero mortality, then no adjusted mortality rate is sometimes reported. Reporting on 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

Staff Analysis and Conclusion

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 for BWMC for all 12-month reporting periods between January 2019 and December 2023.

Based on the hospital's acceptable performance on the mortality metric for STEMI and non-STEMI cases during the review period, MHCC staff concludes that BWMC 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.

BWMC submitted information on the volume of primary and elective PCI cases performed by physicians at BWMC and other hospitals, by quarter, for the period from January 2019 through July 2023. The hospital reported primary PCI volume for three physicians.

Staff Analysis and Conclusion

MHCC staff reviewed the reported physician volumes for the three interventionalists who performed primary PCI services at BWMC from 2019 through 2023 and analyzed the ACC-NCDR CathPCI data for the period from January 2019 through December 2022. During the reporting period from 2019 through 2022, each one of these physicians performed at least fifty PCI procedures annually averaged over any 24-month period. MHCC staff concludes that BWMC complies with the standard.

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

BWMC submitted information on the volume of primary and elective PCI cases at BWMC and other hospitals, by physician and quarter, for January 2019 through July 2023.

Staff Analysis and Conclusion

MHCC staff determined that these standards do not apply to BWMC. While BWMC does

not have on-site cardiac surgery, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that each of the three physicians performing primary PCI performed at least fifty PCI procedures, on average, over a 24-month period.

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].

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

BWMC provided a signed statement, dated December 7, 2023, from the hospital's medical director of cardiac interventional services confirming that each physician performing primary PCI services at BWMC is board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that BWMC complies with the 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.

BWMC provided signed attestations from each interventionalist performing primary PCI at BWMC confirming that he or she had completed at least 30 hours of continuing medical education credits in the area of interventional cardiology during the two years prior to signing the attestation.

Staff Analysis and Conclusion

Based on the signed attestations provided, MHCC staff concludes that BWMC complies with the standard.

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

BWMC provided a signed and dated statement from BWMC's medical director of cardiac interventional services stating that each of the three physicians who performed primary PCI during the review period participated in the on-call schedule and that all physicians performing primary PCI as of the date of the PCI Certificate of Ongoing Performance renewal application were participating in the on-call schedule. In addition to the signed statement, BWMC provided on-call schedules.

Staff Analysis and Conclusion

Based on the signed and dated statement and review of the on-call schedules, each physician who performs primary PCI at BWMC is participating in on-call coverage. MHCC staff concludes that BWMC is compliant with the 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.

BWMC submitted volume information by calendar year, as shown in Table 8.

Table 8: BWMC PCI Volume

Calendar Year	Total PCI Volume
2019	394
2020	315
2021	323
2022	325
2023	258

Source: BWMC Application, Question 25

Staff Analysis and Conclusion

MHCC staff reviewed the volume information included in the hospital's quarterly ACC-NCDR CathPCI report for CY 2023 and staff analyzed the ACC-NCDR CathPCI registry data from CY 2019 through CY 2022. Staff's analysis of this data and the information in the 2023 ACC-NCDR CathPCI report indicates that BWMC exceeded the target volume of 200 PCI procedures annually, during each year of the review period. MHCC staff concludes that BWMC complies 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 data to calculate the primary PCI volume for CY 2019 through CY 2022. This analysis shows primary PCI volume ranged from 106 to 114 cases each calendar year (Table 9). Because BWMC performed over 49 cases annually no focused review is required.

Table 9: BWMC Primary PCI Volume

Calendar Year	Primary PCI Volume
2019	111
2020	113
2021	106
2022	114

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2019 – CY 2022.

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

Only three physicians at BWMC performed primary PCI during the reporting period. BWMC submitted primary PCI volume for each interventionalist by calendar year from 2019 through 2023.

Staff Analysis and Conclusion

MHCC staff analyzed the data in the ACC-NCDR CathPCI registry for the period 2019 through 2022 and observed that all BWMC interventionalists who performed primary PCI at BWMC completed at least 11 primary PCI procedures per year. Staff did not have data from the ACC-NCDR CathPCI registry available for analysis. The information provided by the applicant for 2023 indicates each physician performed at least 11 primary PCI procedures in 2023. MHCC staff concludes that BWMC complies 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.

BWMC stated that internal and external review did not identify any inappropriate PCI cases.

Staff Analysis and Conclusion

MHCC staff reviewed the MACPAQ reports submitted by BWMC for the period from January 2019 through December 2022 and noted that there were no cases determined to be inappropriate by two or more of the three criteria used to evaluate appropriateness. MHCC staff determines that BWMC complies with the standard.

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

- (a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF / AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association / Society for***

Cardiovascular Angiography and Interventions (ACCF / AHA / SCAI) for Percutaneous Coronary Intervention.

- (b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician (s) believes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.***
- (c) Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.***
- (d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believes that transfer to a tertiary institution may be harmful to the patient.***

BWMC reported that during the review period, there were no cases in which a patient received primary PCI inappropriately based on internal review. BWMC also indicated that during the review period no STEMI patients received thrombolytic therapy because PCI services were unavailable and had thrombolytic therapy fail.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for the period 2019 through 2022 and observed that during that time period, only one patient received thrombolytic therapy at BWMC that subsequently failed, which was in 2022. Based on MHCC staff's review of information available in the ACC-NCDR CathPCI data and provided by BWMC, the decision to give thrombolytic therapy to this patient was not due to a lack of available PCI services. Staff also notes that the ACC-NCDR CathPCI reports for the period from CY 2019 through CY 2023, indicate no PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate. Based on MHCC's analysis of the ACC-NCDR CathPCI data and review of the ACC-NCDR CathPCI reports, MHCC staff determines that BWMC complies with the standard.

RECOMMENDATION

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