IN THE MATTER OF	*	**BEFORE THE**
LUMINIS HEALTH ANNE ARUNDEL	*	**MARYLAND**
MEDICAL CENTER	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 24-02-CP048	*	

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STAFF REPORT AND RECOMMENDATION

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

June 20, 2024

I. INTRODUCTION

A. Background

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

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

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

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter (Cardiac Surgery Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Surgery Chapter was subsequently revised in November 2015 and again in January 2019. The main change in these revisions that 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 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. At the end of the period, the hospital must renew its authorization to provide PCI services by demonstrating that it continues to meet the requirements in COMAR 10.24.17 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

Luminis Health Anne Arundel Medical Center

Luminis Health Anne Arundel Medical Center (AAMC) is a 377-bed general hospital located in Annapolis, Anne Arundel County, Maryland. AAMC has a cardiac surgery program on site that was established in December 2021.

AAMC received approval to provide primary PCI services under a waiver on May 18, 2006. AAMC subsequently received renewals of its waiver to provide primary PCI services in June 2007, May 2009, and May 2011. AAMC received approval to provide elective PCI services in September 2008. AAMC subsequently twice received renewals of its waiver to provide elective PCI services. AAMC received its first Certificate of Ongoing Performance for both elective and primary PCI services on July 16, 2020 for four years. This in AAMC'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 COMAR 10.24.17. The regions are defined by geographic areas. AAMC 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 10.07B(2)(a), .07C(2)(a), and .07D(2)(a).
[2] COMAR 10.07(B)(2)(c), .07C(2)(c) and .07D(2)(c).
[3] COMAR 10.07(B)(2)(e), .07C(2)(e) and .07D(2)(e).

C. Staff Recommendation

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

II. PRODEDURAL HISTORY

AAMC applied for renewal of its Certificate of Ongoing Performance for PCI services on January 12, 2024. MHCC staff requested additional information regarding the on-call schedule on June 10, 2024, and received a response the same day.

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.

AAMC advised 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, with submission of information to MHCC. The hospital stated that it is not aware of any deficiencies in data collection or submission.

Staff Analysis and Conclusion

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

AAMC reported that between January 2019 and December 2023, PCI services were nearly always available. The hospital provided information on downtime for the cardiac catheterization laboratory (CCL) during this period. AAMC reported that in June 2021, the CCL was unavailable due to two separate circumstances, both of which were beyond the hospital's control. For two brief periods, one hour for a minor electrical fire and four hours twenty-three minutes for an equipment malfunction, AAMC was not receiving STEMI patients through emergency medical

system (EMS) transport. In both instances, AAMC followed appropriate protocols and promptly alerted EMS and Baltimore Washington Medical Center (BWMC) for bypass of STEMI patients. Also, during both brief downtimes, there were no inpatient or walk-in STEMI patients.

In addition to providing a narrative of downtimes, AAMC also submitted logs of downtimes by room for January 1, 2019 through October 31, 2023. The logs are summarized below in Table 1.

Table 1: Number of Separate Instances of Downtime Reported by AAMC for the CCL by Room, January 2019 – October 2023

Calendar Year	CCL 4	CCL 5	CCL 6	Simultaneous Downtime*
2019	1	2	5	NO
2020		1	3	NO
2021	3	4	7	YES
2022	1	1	1	NO
2023		1	2	NO

Source: AAMC application, Question 2
* Simultaneous downtime refers to downtime reported that overlaps for all three rooms on the same date

Staff Analysis and Conclusion

MHCC staff reviewed the narrative information and tables with CCL downtimes provided in AAMC's application and concludes that AAMC 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.

AAMC provided a signed statement from its president, Dr. Sherry B. Perkins, dated November 28, 2023, affirming that AAMC 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. The statement also affirms that AAMC commits to tracking and improving door-to-balloon (DTB) times for transfer cases. Additionally, AAMC provided quarterly information on its DTB times for the period from July 2019 through September 2023 (Table 2).

Table 2: AAMC Reported Compliance with DTB Benchmark for Non-Transfer Primary PCI Cases by Quarter, July 2019 – September 2023

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2019 Q3	38	34	89.5%
CY2019 Q4	36	33	91.7%
CY2020 Q1	25	23	92.0%
CY2020 Q2	30	29	96.7%
CY2020 Q3	29	27	93.1%
CY2020 Q4	41	36	87.8%
CY2021 Q1	30	26	86.7%
CY2021 Q2	27	25	92.6%
CY2021 Q3	39	32	82.1%
CY2021 Q4	28	27	96.4%
CY2022 Q1	32	30	93.8%
CY2022 Q2	32	31	96.9%
CY2022 Q3	37	36	97.3%
CY2022 Q4	31	30	96.8%
CY2023 Q1	24	22	91.7%
CY2023 Q2	23	21	91.3%
CY2023 Q3	31	29	93.5%

Source: AAMC application, Question 3.

AAMC also provided DTB information about primary PCI transfer cases. As shown in Table 3, between July 2019 and September 2023, AAMC received twelve primary PCI transfer cases; ten of which had a DTB time of 120 minutes or less.

Table 3: AAMC Reported Compliance with DTB Benchmark for Primary PCI Transfer Cases by Quarter, July 2019 – September 2023

Quarter	Total Primary PCI Transfer Volume	Cases with DTB <= 120 minutes	Percent of Cases With DTB <=120 Minutes
CY2019 Q3	1	1	100%
CY2019 Q4	1	1	100%
CY2020 Q1	1	1	100%
CY2020 Q2	1	1	100%
CY2020 Q3	3	3	100%
CY2020 Q4	2	2	100%
CY2021 Q1	1	0	0%
CY2021 Q2	0	n/a	n/a
CY2021 Q3	0	n/a	n/a
CY2021 Q4	0	n/a	n/a
CY2022 Q1	0	n/a	n/a
CY2022 Q2	0	n/a	n/a
CY2022 Q3	0	n/a	n/a
CY2022 Q4	1	0	0%
CY2023 Q1	0	n/a	n/a
CY2023 Q2	0	n/a	n/a
CY2023 Q3	1	1	100%
TOTALS	**12**	**10**	**83.3%**

Source: AAMC application, Question 3

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer PCI cases and found that AAMC met the door-to-balloon time standard in all quarters. AAMC met the DTB standard in all quarters with between 86.1% and 96.7%of cases meeting the DTB standard. MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases. MHCC staff also considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, AAMC achieved the DTB standard, with between 90.9% and 92.9% of PCI cases meeting the DTB standard, as shown below in Table 4.

Table 4: AAMC Non-Transfer Primary PCI Case Volume and Percentage of Cases With DTB Less Than or Equal to 90 Minutes, by Time Period, July 2019 – December 2022

Quarter				Rolling 8-Quarters		
Time Period	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
2019q3	39	36	92.3%			
2019q4	32	30	93.8%			
2020q1	21	20	95.2%			
2020q2	29	28	96.6%			
2020q3	29	28	96.6%			
2020q4	37	33	89.2%			
2021q1	29	25	86.2%			
2021q2	22	21	95.5%	238	221	92.9%
2021q3	36	31	86.1%	235	216	91.9%
2021q4	27	24	88.9%	230	210	91.3%
2022q1	30	29	96.7%	239	219	91.6%
2022q2	29	28	96.6%	239	219	91.6%
2022q3	37	35	94.6%	247	226	91.5%
2022q4	28	27	96.4%	238	220	92.4%

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

Based on MHCC staff's analysis of the ACC-NCDR CathPCI data and the information submitted by AAMC, MHCC staff concludes that AAMC meets this standard.

10.24.17.07D(4)(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.

AAMC provided the number of physicians, nurses, and technicians who provide cardiac catheterization services to acute myocardial infarction patients as of one week before the due date of the application, as shown below in Table 5. AAMC also stated that the staffing reported is consistent with the typical staffing levels for the AAMC CCL.

Table 5: CCL Physician, Nursing, and Technician Staff

Role	Number / FTEs	Cross Training (S/C/M)*
Physician	5	
Nurse (FTE)	8.5 FTEs	M/C
Technician (FTE)	7.0 FTEs	S/M

Source: AAMC application, Question 4
* (S) scrub, (C) circulate, (M) monitor

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by AAMC to information reported by three other PCI programs with a similar volume of cases, as shown in Table 6 below.

Table 6: CCL Staffing for AAMC and Other Select PCI Programs

Facility	Annual PCI Volume	Physicians	Nurse FTEs	Technician FTEs
AAMC	329	5	8.5	8.0
Adventist Shady Grove	286	5	6.0	7.5
Medstar Southern Maryland	309	2 FT, 3 PT	11	5
Univ. of MD Baltimore Washington Medical Center	284	3	7.4	7

Sources: AAMC application and AAMC's PCI volume from ACC-NCDR CathPCI registry report for period ending June 30, 2023; MHCC's staff report, dated July 15, 2021, regarding Adventist Shady Grove's application for Certificate of Ongoing Performance for primary and elective PCI Services and Adventist Shady Grove's PCI volume from ACC-NCDR CathPCI registry report for the period ending September 30, 2021; Medstar Southern Maryland's September 2023 supplemental PCI application submitted to MHCC and PCI volume from ACC-NCDR CathPCI registry report for period ending June 30, 2023; and BWMC's January 2024 PCI application and PCI volume from ACC-NCDR CathPCI registry report for period ending June 30, 2023.

Based on the similarity in staffing numbers to other duly certified PCI programs, MHCC staff concludes that there will likely be adequate nursing and technical staff to provide services; AAMC 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.

AAMC provided a signed letter of commitment from its president, Dr. Sherry B. Perkins, dated November 28, 2023, stating that AAMC will continue to provide PCI services in accordance with the requirements established by the Commission.

Staff Analysis and Conclusion

MHCC staff concludes that AAMC 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.

AAMC identified two members of its staff responsible for the necessary data management, reporting, and coordination with institutional quality improvement efforts. These staff are the Cardiac Program Coordinator and the Quality and Patient Safety Specialist Registered Nurse.

Staff Analysis and Conclusion

MHCC staff concludes that AAMC 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.

AAMC reported that Scott M. Katzen, M.D. is the physician director of interventional cardiology services and was appointed to that role in 2017. AAMC further explained that some of the responsibilities listed in COMAR 10.24.17.07.D(4)(f) are shared by AAMC's medical director for the CCL, the medical director of cardiovascular services, and the hospital's chairman of Medicine.

Staff Analysis and Conclusion

MHCC staff concludes that AAMC 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.

AAMC submitted documentation of continuing education activities for CCL and coronary care unit (CCU) staff, during the period from January 2019 through October 2023. Some of the topics regularly covered include stroke education, emergency management, radiation safety, advanced cardiovascular life support, and blood administration.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that AAMC is compliant with this standard.

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

Staff Analysis and Conclusion

Because AAMC has an on-site cardiac surgery program, MHCC staff concludes that this standard does not apply to AAMC.

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.

Staff Analysis and Conclusion

Because AAMC has an on-site cardiac surgery program, MHCC staff concludes that this standard does not apply to AAMC.

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.

AAMC reported that its Interventional Cardiology Case Review Mortality and Morbidity Conference is scheduled to meet monthly with limited exceptions for the occasional scheduling conflict or to accommodate holidays. AAMC submitted documentation that shows the Interventional Cardiology Case Review Mortality and Morbidity Conference convened eight times in CY 2020, eight times in CY 2021, ten times in CY 2022 and ten times in CY 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for the Interventional Cardiology Mortality and Morbidity Case Review Conferences. At least six meetings are required to be held, and AAMC held at least eight meetings per year from January 2020 through December 2023. The meeting records indicate that nurses, technicians, and interventionists and other physicians who care for primary PCI patients regularly attended.

MHCC staff concludes that AAMC complies with this standard.

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

AAMC stated that its Cardiac Interventional Work Group meets monthly, with limited exceptions. Allowances are made for the occasional scheduling conflict or to accommodate summer and winter holidays. The work group is responsible for providing executive level oversight over the established goals of the Cardiac Intervention Center and oversight of PCI services. The primary PCI team's process, performance measures, and quality metrics are discussed at Cardiac Interventional Work Group meetings. Also, team members perform root cause analysis of any cases that do not meet door-to-EKG and door-to-balloon goals. Team members discuss and identify appropriate solutions to issues identified through root cause analysis. AAMC submitted documentation of these meetings, including meeting minutes for all meetings and attendance for the period January 2020 through December 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the meeting minutes and attendance records for the Cardiac Interventional Work Group meetings. There were eight meetings in CY 2020, ten meetings in CY 2021, 11 meetings in CY 2022, and 11 meetings in CY 2023. The attendance records for these meetings indicate that physician and nurse leadership for the emergency department, CCL, and CCU regularly attended these meetings. MHCC staff concludes that AAMC 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.

AAMC reported that it uses the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ) to provide external review of AAMC's elective PCI cases. AAMC submitted reports from MACPAQ to MHCC staff for the period from January 2019 through December 2022.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. As shown in Table 7, between 11.1% and 12.1% of cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed.

Table 7: AAMC External Reviews, CY 2019 - CY 2022

Calendar Year	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard?
CY 2019	233	27	11.6%	Semiannual	Yes
CY 2020	198	24	12.1%	Semiannual	Yes
CY 2021	228	26	11.4%	Semiannual	Yes
CY 2022	216	24	11.1%	Semiannual	Yes

Source: MHCC staff analysis of MACPAQ reports.

For the period between January 2019 and December 2022, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that, in each six-month review period, at least three cases per physician were reviewed, or all cases were reviewed, if an interventionalist performed fewer than three cases.

MHCC staff concludes that AAMC complies with this standard.

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

(i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or

all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or

(ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08; or

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

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

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

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

AAMC stated that MACPAQ is the review organization providing external AAMC PCI performance reviews, and its review of cases meets the requirement for review of individual interventionalist's cases.

Staff Analysis and Conclusion

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. Except for one physician in CY 2021, the number of cases reviewed by MACPAQ constituted at least ten percent of the elective PCI cases performed by each physician each year. In CY2021, there was one physician who should have had two additional cases reviewed. Eight cases instead of ten cases were reviewed by MACPAQ. However, AAMC also provided minutes from its monthly Interventional Cardiology Case Review Mortality and Morbidity Conferences which indicate that approximately four cases are reviewed at each meeting. Given the combination of reviews of elective PCI cases by MACPAQ, AAMC's internal case review processes, and AAMC's performance relative to the national benchmarks for mortality, MHCC staff recommends that the Commission find that AAMC is compliant 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.

AAMC submitted an affidavit from its president, Dr. Sherry B. Perkins, dated November 28, 2023, 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 concludes that AAMC 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.

AAMC provided detailed meeting minutes to demonstrate the hospital takes appropriate action in response to concerns identified. AAMC also noted that at the Cardiology Interventionalist meetings, which occur at least quarterly, the results of MACPAQ reports are presented and the team reviews individual cases in detail with their accompanying films. After analysis at the Cardiac Interventionalist meeting, a summary of the results from the external reviews by MACPAQ are provided to the Executive Quality Committee. PCI cases needing further review are referred to the hospital's Quality Review Panel through the Medical Staff Office. Additionally, AAMC provided its standard operating procedures for ensuring the quality of its PCI program.

Staff Analysis and Conclusion

MHCC staff reviewed the detailed meeting minutes provided and noted that AAMC is routinely identifying areas for improvement and taking actions to address concerns. MHCC staff concludes that AAMC complies with this standard.

<u>Patient Outcome Measures</u>

10.24.17.07C(5)

(a) An elective PCI program shall meet all performance standards established in statute or in State regulations.

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

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

10.24.17.07D(6)

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

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

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

AAMC stated that MHCC had provided AAMC's risk adjusted mortality rate for both STEMI and non-STEMI PCI, without notification of a focused review.

Staff Analysis and Conclusion

As shown in Table 8, MHCC staff compiled the results from AAMC's quarterly reports from the ACC-NCDR CathPCI for STEMI and non-STEMI PCI cases performed between January 2019 and December 2023. MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's risk-adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period. The national benchmark fell within the 95% confidence interval (CI) for AAMC for all 12-month reporting periods between January 2019 and December 2023.

Table 8: AAMC Adjusted Mortality Rates (AMR) in STEMI and NON-STEMI PCI Cases, by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs[4]

Reporting Period	NON-STEMI PCI Cases				STEMI PCI Cases			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2023q1-2023q4	1.55	[0.32, 4.47]	1.99	Yes	1.00	[0.03, 5.41]	1.88	Yes
2022q4-2023q3	0.72	[0.02, 3.99]	2.02	Yes	1.62	[0.09, 18.82]	1.91	Yes
2022q3-2023q2	0.00	[0.00, 3.25]	2.02	Yes	0.76	[0.02, 4.11]	1.89	Yes
2022q2-2023q1	0.00	[0.00, 3.48]	2.05	Yes	0.77	[0.02, 4.21]	1.89	Yes
2022q1-2022q4	0.00	[0.00, 2.66]	2.14	Yes	0.92	[0.02, 4.99]	2.00	Yes
2021q4-2022q3	0.00	[0.00, 3.16]	2.20	Yes	1.19	[0.03, 6.48]	2.11	Yes
2021q3-2022q2	0.00	[0.00, 3.35]	2.26	Yes	1.22	[0.03, 6.63]	2.18	Yes
2021q2-2022q1	0.00	[0.00, 3.46]	2.25	Yes	1.42	[0.04, 7.71]	2.82	Yes
2021q1-2021q4	0.00	[0.00, 4.87]	1.16	Yes	1.17	[0.03, 6.39]	2.74	Yes
2020q4-2021q3	0.00	[0.00, 2.20]	2.23	Yes	0.00	[0.00, 4.03]	2.18	Yes
2020q3-2021q2	N/A	[0.00, 1.95]	1.18	Yes	5.95	[2.76, 10.93]	7.51	Yes
2020q2-2021q1	N/A	[0.00, 2.01]	1.21	Yes	4.05	[1.33, 9.21]	7.55	Yes
2020q1-2020q4	N/A	[0.00, 1.70]	1.13	Yes	3.71	[1.02, 9.25]	6.89	Yes
2019q4-2020q3	0.88	[0.02, 4.84]	1.06	Yes	1.11	[0.03, 6.04]	6.37	Yes
2019q3-2020q2	0.51	[0.01, 2.78]	1.00	Yes	4.46	[1.46, 10.13]	6.06	Yes
2019q2-2020q1	0.85	[0.10, 3.04]	0.95	Yes	4.56	[1.69, 9.66]	5.99	Yes
2019q1-2019q4	0.97	[0.18, 37.73]	0.95	Yes	4.24	[1.84,15.43]	6.01	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.

[4] A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the National AMR or indicates statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or Non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI or non-STEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEMI and non-STEMI cases for each reporting period. N/A means not applicable. Prior to the period ending 2021q3, the ACC-NCDR CathPCI reports did not include an AMR rate when a hospital had zero deaths in a reporting period.

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.

AAMC provided documentation indicating that for each calendar year from 2019 through 2023, inclusive, each physician on its PCI roster completed at least 50 PCI procedures per year.

Staff Analysis and Conclusion

AAMC initiated its on-site cardiac surgery program in late December 2020. MHCC staff concludes that this standard does not currently apply to AAMC. To the extent that the standard did apply to AAMC from January 2019 through December 2020, MHCC staff concludes that AAMC complies with the standard.

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

Because AAMC initiated a cardiac surgery program in late December 2020, this standard is not applicable after January 2021. In CY 2020, each physician performed at least fifty PCI cases annually on average. MHCC staff concludes that this standard is not applicable to AAMC.

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

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

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

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

Staff Analysis and Conclusion

Because AAMC initiated a cardiac surgery program in late December 2020, this standard is not applicable after January 2021. In CY 2020, each physician performed at least 50 PCI cases annually, on average. MHCC staff concludes that this standard does not apply to AAMC.

10.24.17.07C(6)(e) and .07D(7)(e) Each physician shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or completed their training before 1998 and did not seek board certification before 2003.

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

AAMC provided a letter, dated November 20, 2023, from Dr. Scott M. Katzen M.D., Physician Director of Interventional Cardiology Services, stating that each physician providing primary PCI services at AAMC is board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff concludes that AAMC meets this standard based on the letter provided.

10.24.17.07C(6)(g) and .07D(7)(g) An interventionalist shall complete a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology during every two years of practice.

AAMC provided signed attestations dated in November and December 2023, from Drs. Czarny, Ginsberg, Reineck, Shkullaku and Katzen stating that each physician has completed a minimum of 30 hours of continuing education credits in the area of interventional cardiology during the last two years.

Staff Analysis and Conclusion

MHCC staff concludes that AAMC meets this standard based on the attestations provided.

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

The letter dated November 20, 2023, from Dr. Scott M. Katzen M.D., Physician Director of Interventional Cardiology Services, states that each physician providing primary PCI services at AAMC participates in the on-call schedule. Additionally, AAMC provided copies of recent on-call schedules displaying that each physician providing primary PCI services at AAMC participates in the on-call schedule.

Staff Analysis and Conclusion

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

Volume

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

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

AAMC provided the total PCI case volume for CY 2019 through CY 2023, as shown in Table 9.

Table 9: AAMC Total PCI Volume, CY 2019 – CY 2023

Calendar Year	Total PCI
2019	374
2020	321
2021	357
2022	339
2023	342

Source: AAMC's January 2024 PCI Certificate of Ongoing Performance renewal application, response to Question 25.

Staff Analysis and Conclusion

MHCC staff reviewed the table submitted by AAMC and analyzed the ACC NCDR CathPCI data for CY 2019 through CY 2022. Staff determined at least 200 PCI procedures were completed each year between CY 2019 and CY 2023. MHCC staff concludes that AAMC complies with the 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 127 to 143 cases each calendar year (Table 10) and confirms that AAMC exceeded the threshold of 49 cases annually referenced in the standard.

Table 10: AAMC Primary PCI Volume, CY 2019 - CY 2022

Calendar Year	Primary PCI Volume
2019	143
2020	132
2021	127
2022	136

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

Because AAMC performed greater than 49 primary PCI cases annually, MHCC staff determined that 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.

AAMC provided the number of primary PCI cases by quarter for each of four physician who performed primary PCI at AAMC between January 2019 and December 2023. Three of the four physicians only performed primary PCI cases at AAMC. One physician also performed primary PCI at other hospitals.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume data submitted by AAMC and analyzed the ACC-NCDR CathPCI data for CY 2019 through CY 2022. This analysis shows that between January 2019 and December 2022, each physician performed at least 11 primary PCI cases per year. MHCC staff determines that AAMC complies with the 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.

AAMC summarized the results of the MACPAQ external review reports completed for the period from CY 2019 to CY 2022. Between January 2019 and June of 2021, no cases were found to be inappropriate or rarely appropriate. Between July 2021 and December 2022 one case was found to be rarely appropriate according to two of three appropriateness criteria and an additional case was found to be rarely appropriate according to one of the three appropriateness criteria.

Staff Analysis and Conclusion

MHCC staff reviewed the MACPAQ reports for these time periods and minutes for the Interventional Cardiology Work Group meeting. Staff noted that the results of the MACPAQ reports were discussed, and follow-up planned, consistent with AAMC's description of the handling of the MACPAQ reports. MHCC staff determines that AAMC complies with the standard.

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

(a) Patients described as appropriate for primary PCI in the Expert Guidelines.

(b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) reasonably concludes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

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

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

AAMC stated that during the period from January 2019 through December 2023, there were no patients who received thrombolytic therapy in lieu of primary PCI. AAMC also stated that there were no patients who received primary PCI services inappropriately.

Staff Analysis and Conclusion

MHCC staff reviewed the MACPAQ reports for the period from January 2019 through December 2022 and concludes that AAMC complies with the standard.

RECOMMENDATION

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