

**IN THE MATTER OF
ASCENSION SAINT AGNES
HOSPITAL**

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

Docket No.: 24-24-CP046

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

July 18, 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 the co-location requirement. In the following decade, similar research evaluated the safety of providing elective PCI services at hospitals without on-site cardiac surgery.

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

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter (Cardiac 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 to the Cardiac Surgery Chapter 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 period of time specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must demonstrate that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide PCI services.

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 If the focused review identifies the hospital as failing to meet one or more of the requirements for a Certificate of Ongoing Performance, the hospital 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 does not 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

Ascension Saint Agnes Hospital

Ascension Saint Agnes Hospital (SAH) is a 181-bed general hospital located in Baltimore City. The Commission approved a waiver for SAH to provide primary PCI services without on-site cardiac surgery for the first time on May 18, 2006. SAH subsequently received renewals of this waiver on June 21, 2007, December 17, 2009, December 15, 2011, and December 13, 2013. SAH received a waiver for non-primary PCI services for the first time on September 18, 2008. The hospital's waiver for non-primary PCI services was subsequently renewed twice. In 2020, SAH received approval of its Certificate of Ongoing Performance for both primary and elective 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. SAH 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 the fourteen hospitals provide cardiac surgery services. Eight programs 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 SAH's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services. A description of SAH's documentation and MHCC staff's analysis follows.

PRODEDURAL HISTORY

SAH filed a Certificate of Ongoing Performance application on January 10, 2024. MHCC staff reviewed the application and requested additional information on March 27, 2024, June 24, 2024, and July 2, 2024. SAH submitted additional information on April 18, 2024, June 28, 2024, and July 4, 2024.

II. 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.

SAH stated that the hospital is not aware of any deficiencies in the data collection process and participates in the American College of Cardiology's (ACC's) National Cardiovascular Data Registry (NCDR) for CathPCI. SAH submitted the required data and outcomes reports to MHCC. SAH stated that its data entry processes were transitioned to Navion, a third-party vendor associated with Ascension Health, in January 2021, to streamline submissions to the ACC-NCDR CathPCI. Data for all ST-segment elevation myocardial infarction (STEMI)⁴ and non-STEMI (NSTEMI) patients are entered into the American Heart Association's Get with the Guidelines Coronary Artery Disease (AHA GWTG-CAD) registry in order to comply with the standards set by the Maryland Institute for Emergency Medical Services Systems (MIEMSS).

Staff Analysis and Conclusion

SAH has complied with the submission of ACC-NCDR CathPCI data to MHCC staff in accordance with the established schedule. In October 2022, MHCC staff identified that the quarterly reports lacked certain demographic data. Upon investigation, it was revealed that the omission stemmed from the reports provided by Navion, which inadvertently excluded the required demographic details. This issue was promptly addressed, and corrected reports were resubmitted to MHCC. Since this correction, there have been no further issues reported.

⁴ An ST-segment elevation myocardial infarction is a heart attack in which there is cardiac muscle damage resulting from an acute interruption of blood supply to a part of the heart that can be demonstrated by a change of ST-segment elevation on an electrocardiogram. An NSTEMI is a less common type of heart attack.

MHCC staff concludes that SAH 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.

SAH has two cardiac catheterization laboratories (CCLs). SAH provided information on routine maintenance performed in each CCL and the times when PCI services were not available in the CCLs for the period from January 2019 to June 2024. Table 1 indicates when PCI services were not available in either CCL. SAH explained that PCI services were not available on October 17, 2020, from 6 PM to 9 PM because an interventionalist was urgently required for an emergency case at University of Maryland Upper Chesapeake Medical Center (UMMC). PCI services were also not available on April 17, 2021, from 3 PM until 8 AM on April 18, 2021, because an interventionalist was unavailable due to illness; another interventionalist was not available to fill-in because it was a holiday weekend. Lastly, on May 27, 2023, from 3 PM to 7 PM, PCI services were not available because the on-call interventionalist was performing PCI at UMMC, and a back-up interventionalist was not available. SAH reported that at least one CCL was always available when routine maintenance was performed.

SAH reported that over the prior five years there was one day when an interventionalist was not available and, as a result, two patients were transferred to another facility. This occurred when two patients with STEMIs presented to the hospital’s emergency department within 25 minutes of each other on a weekend, and other interventional cardiologists were initially unavailable. The on-call interventional cardiologist, Dr. Voss, opted to triage the STEMI patients to other programs in town until he was available to resume call coverage. Although Dr. Drossner, another interventionalist, called back to offer assistance before the patients were transferred, the hospital decided to continue with the patient transfers to avoid delays or confusion. The hospital reported on the outcomes for the two patients transferred; neither patient died. One patient had a poor prognosis that was unrelated to any delay in providing PCI.

Table 1: SAH Reported CCL Downtime by Date, Time, and Reason, CY 2020 – CY 2023

Date/Time of Downtime	Downtime Reason
10/17/2020 / 6pm to 9pm	Physician Unavailable - Case at UMMC
4/17/2021- 4/18/2021 / 3pm to 8am	Physician Unavailable - Sick and holiday weekend
5/27/2023 / 3pm to 7pm	Physician Unavailable - Case at UMMC

Source: SAH’s Certificate of Ongoing Performance application 2024, Q2.

Staff Analysis and Conclusion

Although there were only a few times when PCI services were not available due to an interventionalist not being present, it is rare for other hospitals to report this problem at all. MHCC staff inquired about the availability of another physician when a physician was performing a case at UMMC and the frequency of having a second physician on-call as backup when the on-call

physician covers two hospitals. In response, SAH explained that it is extremely rare for another interventional cardiologist to be unavailable for backup. Typically, two interventionalists are available four out of seven days of the week. SAH's backup system, similar to other programs in Baltimore, involves coordinating with the other interventional cardiologists for additional weekend coverage. SAH explained that all staff for the CCL receive pages, whether on-call or not. In rare cases when someone who is part of the on-call team does not respond quickly, this approach is a faster way to identify someone else who can help. SAH explained that the staff also prefer this approach because it is less likely that a mistake in updating the on-call will negatively affect patient care.

MHCC staff recommends the Commission find that SAH complies with this standard and include the following condition on the Certificate of Ongoing Performance:

Beginning August 1, 2025, and on an annual basis until SAH is released from this condition, SAH shall report to MHCC dates and downtime for its CCL, including the start and end times for downtime, the reasons for downtime, and whether patient care was affected, by August 1 each year for the 12-month period ending June 30.

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.

SAH provided a signed statement from Beau Higginbotham, President and Chief Executive Officer (CEO), dated January 2, 2024, stating that SAH commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer patients, for at least 75% of appropriate patients. Furthermore, SAH commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement. SAH reported DTB times by quarter from 2019 Q1 to 2023 Q3, as shown in Table 2A. SAH reported that the hospital did not receive transfer cases from other facilities since its last application for a Certificate of Ongoing Performance.

Table 2A: SAH Reported Compliance with DTB Benchmark for Primary PCI by Quarter, January 2019 to September 2023

Quarter Ending	Number of Non-Transfer Primary PCI Patients	Number of Non-Transfer Patients with DTB Time ≤ 90 Minutes	
		Number	Percent
CY 2019 Q1	15	15	100.0%
CY 2019 Q2	20	20	100.0%
CY 2019 Q3	21	20	95.2%
CY 2019 Q4	21	19	90.5%
CY 2020 Q1	25	22	88.0%
CY 2020 Q2	14	12	85.7%
CY 2020 Q3	18	17	94.4%
CY 2020 Q4	15	11	73.3%
CY 2021 Q1	11	9	81.8%
CY 2021 Q2	19	17	89.5%
CY 2021 Q3	25	22	88.0%
CY 2021 Q4	26	21	80.8%
CY 2022 Q1	20	18	90.0%
CY 2022 Q2	22	17	77.3%
CY 2022 Q3	16	16	100.0%
CY 2022 Q4	15	13	86.7%
CY 2023 Q1	17	13	76.5%
CY 2023 Q2	25	22	88.0%
CY 2023 Q3	21	19	90.5%

Sources: SAH's Certificate of Ongoing Performance application 2024, Q3b, and additional information submitted on April 18, 2024.

Note: MHCC staff rounded the percent of cases with DTB<=90 minutes, provided by SAH.

Staff Analysis and Conclusion

MHCC staff examined the data submitted by SAH and analyzed the ACC-NCDR CathPCI data from CY 2019 through CY 2022. As shown in Table 2B, SAH did not achieve the DTB standard in five out of the 16 quarters from CY 2019 Q1 to CY 2022 Q4. MHCC staff's analysis differs from the information provided by the hospital in Table 2A in some cases, because the ACC-NCDR performance metric for DTB excludes certain cases, such as when there is a non-system reason for delay, while MHCC includes all cases in reviewing compliance with this standard.

Table 2B: SAH Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Quarter, CY 2019 – CY 2022

Quarter Ending	Number of Non-Transfer Primary PCI Patients	Number of Non-Transfer Patients with DTB Times ≤ 90 Minutes	
		Number	Percent
CY 2019 Q1	17	14	82.4%
CY 2019 Q2	18	17	94.4%
CY 2019 Q3	14	10	71.4%
CY 2019 Q4	23	19	82.6%
CY 2020 Q1	29	22	75.9%
CY 2020 Q2	14	12	85.7%
CY 2020 Q3	23	17	73.9%
CY 2020 Q4	19	11	57.9%
CY 2021 Q1	15	12	80.0%
CY 2021 Q2	21	17	81.0%
CY 2021 Q3	27	22	81.5%
CY 2021 Q4	28	21	75.0%
CY 2022 Q1	25	18	72.0%
CY 2022 Q2	25	17	68.0%
CY 2022 Q3	19	16	84.2%
CY 2022 Q4	16	13	81.3%

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

In response to MHCC staff's request for additional information on the reasons why the DTB standard was not met in the five quarters, SAH explained that during the STEMI process review and quality assurance meetings, each case is examined according to a standard format, covering specific segments of the care process, such as the time from door-to-EKG. SAH reported that from Q1 2019 to Q4 2022, most delays were during the door-to-EKG interval, where the standard is 10 minutes. The hospital observed that many of these delays were prevalent during the initial phase of the COVID-19 pandemic, a period marked by uncertainty that led to staffing challenges, high staff turnover, and the employment of unconventional staffing models. These models included increased use of agency staff and a team nursing approach, where critical care and emergency department nurses were assisted by med-surg nurses and other disciplines.

To address the delays in door-to-EKG times, the hospital began stationing an advanced practice provider along with the registered nurse in the triage area during peak hours from 11 AM to 8 PM. The hospital also updated networking cables in the emergency department to enhance connectivity for the EKG machines, which would allow for better scanning of patient identification and reduce the need for manual data entry. This update took several months to complete but successfully improved scanning capabilities. The hospital also noted that patients were delayed in getting to the CCL because nurses were attempting to secure a second intravenous site for all patients, which the hospital deemed unnecessary.

During the COVID pandemic, it was noted that fewer Emergency Medical Services (EMS) personnel were available to observe cases and receive feedback. In response, SAH began inviting EMS providers from each jurisdiction to the virtual STEMI process review and quality assurance meetings that are held twice a month. The hospital also started electronically sending STEMI case summary reports to EMS, which included first-medical-contact to device times. The hospital also provided EKGs and before-and-after patient outcome photos, thus ensuring that EMS providers received comprehensive feedback. This initiative aimed to improve the response time to STEMIs

outside the hospital, as explained in the STEMI process review and meeting minutes from October 27, 2022.

MHCC staff requested detailed information on the reasons for delays in DTB times for individual cases in the five quarters in which the DTB standard was not met, CY 2019 Q2, 2020 Q3 and Q4, and CY 2022 Q1 and Q2. Staff reviewed this information and noted that in many cases the reason for delays was due to the patient’s condition and the need for additional testing or treatment before PCI. In other cases, the hospital was able to identify barriers and take action to reduce the chances of DTB time delays for the same reason in the future.

As shown in Table 2C, MHCC staff also considers a hospital’s performance over longer periods that include multiple quarters. Over rolling eight- quarter periods between CY 2019 and CY 2022, SAH met the door to balloon time standard for between 74% and 78% of PCI cases.

Table 2C: SAH Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period

Time Period	Quarter			Rolling Eight-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
CY 2019 Q1	17	14	82.4%			
CY 2019 Q2	18	17	94.4%			
CY 2019 Q3	14	10	71.4%			
CY 2019 Q4	23	19	82.6%			
CY 2020 Q1	29	22	75.9%			
CY 2020 Q2	14	12	85.7%			
CY 2020 Q3	23	17	73.9%			
CY 2020 Q4	19	11	57.9%	157	122	77.7%
CY 2021 Q1	15	12	80.0%	155	120	77.4%
CY 2021 Q2	21	17	81.0%	158	120	75.9%
CY 2021 Q3	27	22	81.5%	171	132	77.2%
CY 2021 Q4	28	21	75.0%	176	134	76.1%
CY 2022 Q1	25	18	72.0%	172	130	75.6%
CY 2022 Q2	25	17	68.0%	183	135	73.8%
CY 2022 Q3	19	16	84.2%	179	134	74.9%
CY 2022 Q4	16	13	81.3%	176	136	77.3%

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

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

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

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

As shown in Table 3A, SAH provided the number of physicians, nurses, and technicians who were available to provide cardiac catheterization services to acute myocardial infarction (MI) patients in the week before the due date of the application.

Table 3A: Total Number of Cardiac Catheterization Laboratory Physician, Nursing, and Technical Staff

Staff Category	Number/FTEs	Cross Training
Physician	4.0	
Nurse	8.3 FTE	S/C/M
Technician	5.0 FTE	S/C/M

Source: SAH's Certificate of Ongoing Performance application 2024, Q4a.

*S – Scrub; C – Circulate; M – Monitor

SAH also stated that the level of staffing reported is consistent with typical staffing levels for hospitals with CCLs and similar PCI case volumes. If staffing changes are needed due to unforeseen circumstances, SAH reported that the hospital utilizes contract agency services that specialize in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff compared the staffing levels described by SAH to information reported in the Certificate of Ongoing Performance applications for three other programs with similar PCI volumes: Frederick Health Hospital (FHH), University of Maryland Upper Chesapeake Medical Center (UMCM), and UPMC Western Maryland. As shown in Table 3B, SAH reported a similar number of nurses to UPMC Western Maryland, but almost four FTEs less than UCMC and FHH which reported 12.6 and 11.95 nurse FTEs respectively. SAH reported a similar number of technicians to FHH and about two less technician FTEs than UCMC and UPMC Western Maryland.

Table 3B: SAH and Other PCI Programs Cardiac Catheterization Laboratory Staff

Program & Year Staffing Reported	Total PCI Volume	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
SAH 2023	429	N = 4	8.3	5.0
UMCM 2023	365	N = 4	12.6	6.8
FHH 2024	368	N = 4	11.95	6.05
UPMC Western Maryland 2019	348	N = 3	6.1	7.3

Sources: Total PCI Case Volume is from ACC-NCDR CathPCI registry reports for the period ending September 30, 2023; SAH PCI Certificate of Ongoing Performance Application, January 2024; UCMC PCI Certificate of Ongoing Performance application, January 2024; Fredrick Health Hospital response to MHCC questions March 20, 2024, p2; UPMC Western Maryland's June 2019 PCI COP application.

MHCC staff concludes that SAH staffing is comparable to other PCI programs with similar volume and that SAH meets this standard.

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

SAH provided a signed letter of commitment from Beau Higginbotham, President and CEO, documenting SAH's support for the renewal of its Certificate of Ongoing Performance for primary and elective PCI. Mr. Higginbotham's letter states that the hospital will provide primary PCI services in accordance with the requirements established by MHCC.

Staff Analysis and Conclusion

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

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

SAH has allocated 1.9 FTEs for cardiovascular compliance and quality assurance monitoring. The clinical coordinators, who are registered nurses, collaborate with interdisciplinary teams to manage care processes for cardiovascular patients, including data entry and retrieval of information in the AHA GWTG-CAD Registry, ACC-NCDR CathPCI, and a quality management system called MIDAS. The clinical coordinators work closely with staff and a third-party vendor, Navion, to ensure accurate data entry. The clinical coordinators also teach and counsel staff on compliance requirements and conduct routine reviews of STEMI cases with interdisciplinary teams. The clinical coordinator for STEMI cases is responsible for overseeing data entry for the AHA GWTG CAD Registry and ACC-NCDR CathPCI for STEMI data, as well as working with the medical director of the CCL to prepare cases for review by the STEMI Process Review Committee. This coordinator also reports STEMI statistics to leadership in the emergency department, CCL, and cardiovascular unit and provides post-discharge follow-up calls to ensure patient compliance and communicate any issues to cardiologists.

SAH also has a clinical coordinator who is a registered nurse and who oversees data entry for the AHA GWTG CAD Registry and NCDR CathPCI for elective PCI data. This clinical coordinator works to prepare cases for review by various committees. This coordinator also communicates any documentation deficiencies to hospitalists, provides education on documentation and discharge guidelines for therapy as needed, and performs post-discharge follow-up calls to ensure patients understand the discharge instructions.

Additionally, SAH has a Manager of Diagnostic and Interventional Cardiology who oversees departmental quality assurance reporting to the Patient Safety and Quality Assurance Committee and Department of Medicine on a quarterly basis. The person also manages quarterly interventional physician peer review meetings and serves as the contact for the quarterly MACPAQ external reviews of elective PCI cases.

Staff Analysis and Conclusion

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

10.24.17.07D(4)(f) The hospital shall identify a physician director of interventional cardiology

services responsible for defining and implementing credentialing criteria for the cardiac catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

Dr. Matthew Voss, an interventional cardiologist, is the medical director of the cardiac catheterization laboratory at SAH. Dr. Voss's duties include working with the Chief Medical Officer to define and implement physician credentialing criteria and directing overall PCI program management. He works with nursing and administrative staff on equipment and pharmaceutical purchasing, personnel hiring and training. He also directs participation in quality assurance and quality improvement initiatives, including participation in the ACC-NCDR CathPCI, AHA CAD GWTG Registry, and MACPAQ external review process. Dr. Voss oversees both weekly multidisciplinary case review and case selection meetings, the internal quality assurance review process, and publishes the physician on-call schedule. Dr. Voss is also responsible, along with the Chief Medical Officer, to monitor interventional physician ongoing professional practice evaluations, mortality and morbidity rates, and clinical case performance monitoring.

Staff Analysis and Conclusion

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

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

SAH reported that the hospital reviews education and training annually. Training on regulatory compliance is updated as regulations change, while department-specific training is revised based on needs and outcomes. In the CCL, a competency-based training model focusing on three low-volume, high-risk pieces of equipment with annual competency demonstrations were adopted. Annual training for chest pain/heart attack and stroke is conducted via myLearning, along with other cardiovascular care training. During COVID in 2020 and 2021, in-person training was limited, but efforts were revitalized in late 2022 and 2023, guided by patient outcomes and chart audits. All registered nurses in the cardiovascular unit, intensive care unit (ICU), and CCL staff are certified in Basic Life Support and Advanced Cardiac Life Support.

For the period between January 2019 and December 2023, SAH provided a list of continuing education for interventional cardiology staff, a list of in-service education programs for staff of the cardiovascular unit, and a list of in-service education programs for staff of the adult ICU. Additionally, SAH provided a list of annual hands-on competencies and a brief description of topics covered in training for new hires responsible for PCI patient care.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation provided and notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that SAH complies with this standard.

10.24.17.07D(4)(h) The 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.

SAH submitted a written agreement with the University of Maryland Medical Center to accept unconditionally the transfer of patients who have undergone cardiac catheterization or primary angioplasty procedures at SAH, for any required additional care, including emergent or elective cardiac surgery or PCI, and to provide timely transmission of required follow-up data on transferred patients. SAH also submitted a transfer agreement with the Medstar Union Memorial Hospital to accept unconditionally the transfer of any primary or non-primary PCI patients for any required additional care.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreements and concludes that SAH meets this standard.

10.24.17.07D(4)(i) A 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.

Yolanda Copeland, Chief Nursing Officer, signed and dated a written agreement with Pulse Medical Transportation stating that Pulse Medical Transportation will meet the minimum overall on-time monthly performance standard of arriving within 30 minutes of the time the request is made.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement between the hospital and Pulse Medical Transportation and determined that SAH meets this standard.

Quality

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

SAH submitted the dates and attendance records for interventional case review meetings held weekly from January 2019 through December 2023. The attendees at these meetings included interventional cardiologists, nurses, technicians, administrative cardiologists, CCL leadership, and data coordinators.

Staff Analysis and Conclusion

MHCC staff reviewed attendance records for interventional case review meetings held from CY 2019 through CY 2023 and determined that meetings included the required attendees and were held at least every other month. In response to the MHCC staff's inquiry about why only one technician attends the interventional case review meetings, SAH explained that the technologist who attends is responsible for reporting back on any issues or findings to other technologists. Previously, attendance was randomly assigned, leading to varying levels of engagement.

MHCC staff concludes that SAH 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 that meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

SAH submitted the dates and attendance records for the STEMI Process Review meetings from CY 2019 through CY 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendance records submitted and determined that meetings were held between one and two times per month. Attendees at the meetings include staff from the emergency department, coronary care unit, and CCL, as required. MHCC staff reviewed minutes for these meetings.

MHCC staff concludes that SAH 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.

SAH submitted external review reports from MACPAQ for CY 2019 through CY 2023 Q1. The hospital also noted that a Physician Peer Review Committee meets to review the results of the MACPAQ external review reports.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted by SAH. The volume of elective PCI cases for each year, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 4. Although only 5% of cases are required to be reviewed externally, between 5.8% and 7.1% of cases were reviewed each year for CY 2019 through CY 2022. In CY 2023 Q1, 7.5% of cases were reviewed. MHCC staff confirmed that at least three cases per

physician were reviewed every two quarters, the equivalent of three cases semiannually, as specified in COMAR 10.24.17.

MHCC staff concludes that SAH complies with this standard.

Table 4: SAH External Review Numbers CY 2019 – CY 2022

Time Period	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard*
CY 2019	266	19	7.1%	Quarterly	Yes
CY 2020	297	18	6.1%	Quarterly	Yes
CY 2021	296	19	6.4%	Quarterly	Yes
CY 2022	311	18	5.8%	Quarterly	Yes

Source: MHCC staff analysis¹, SAH's Certificate of Ongoing Performance application 2024, Q13, and MACPAQ reports CY 2019 – CY 2022.

*Every six months, at least three cases per physician were reviewed or all cases if an interventionalist performed fewer than three cases during the review period.

10.24.17.07C(4)(d) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

- (i) *An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or*
- (ii) *A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than three cases at the hospital during the relevant period, as provided in Regulation .08; or*
- (iii) *A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraph .07C(4)(d)(i).*

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

- (i) *An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or*
- (ii) *For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual*

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

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

10.24.17.07D(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.*

In addition to the external review reports, SAH provided information regarding its internal review processes, including the number of cases reviewed internally for each interventionalist from CY 2019 through CY 2022. The Interventional Cardiology Peer Review Committee meets quarterly to discuss select cases and any outstanding cases for review during the meeting. PCI cases are reviewed on a weekly basis at the Interventional Review Committee meetings to ensure that at least 10% of PCI cases are reviewed annually.

Staff Analysis and Conclusion

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

At least five cases per interventionalist were reviewed per year, as applicable, and additional cases were reviewed via internal review. Through the additional internal review of cases at least 10% of cases per interventionalist were reviewed annually, as required. The external review

⁵https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

conducted by MACPAQ meets the requirements of 10.24.17.07D(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.

MHCC staff concludes that SAH satisfactorily conducts individual interventionalist review as provided in COMAR 10.24.17.07C(4)(d) and described in the October 2015 bulletin, with respect to COMAR 10.24.17.07D(5)(c).⁶

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.

SAH submitted an affidavit from Beau Higginbotham, President and CEO, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist reviews consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

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

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

- (i) All individually identifiable patient information submitted to the Commission for the purpose 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.***

SAH provided copies of the quality assurance activities related to PCI services, including comprehensive measures and ongoing monitoring efforts. These activities are documented in the quality and patient safety committee minutes and include internal peer reviews. There is also a focus on compliance with guidelines directed medications at discharge and aiming to ensure adherence to ACC/AHA guidelines for medication therapy at admission and discharge. The hospital plans to reinstate in-house mock STEMI drills in 2024, which were paused due to the COVID pandemic and staff turnover. This is part of an ongoing performance improvement project to maintain high standards in STEMI response metrics, with an average of three to four in-house STEMI cases per year.

⁶ Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the individual interventionalist review requirements.

Guideline-directed medication therapy remained stable before and after the process change in October 2022, when cardiology transitioned to a consulting basis. Now, hospitalists in consultation with cardiology staff handle patient admissions and discharges, ensuring adherence to proper order sets and ACS discharge plans. Cardiology physician assistant and nurse coordinators review patient records to ensure compliance. Nurse coordinators also call PCI patients the day after discharge to review medications and answer questions.

Staff Analysis and Conclusion

MHCC staff reviewed the meeting minutes and description of quality assurance practices provided and concludes that SAH complies with this standard.

Patient Outcome Measures

10.24.17.07C(5)

- (a) An elective PCI program shall meet all performance standards established in statute or in State regulations.*
- (b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.*
- (c) A hospital shall be subject to a focused review if it has a risk-adjusted mortality rate for non-STEMI PCI cases that exceeds an established benchmark beyond the 95 percent confidence interval calculated for the hospital's all-cause in-hospital risk-adjusted mortality rate for non-STEMI PCI cases.
 - (i) The primary benchmark is the national median in-hospital risk-adjusted mortality rate for non-STEMI PCI cases, calculated from the CathPCI Registry data; and*
 - (ii) If the statewide median risk-adjusted mortality rate for elective PCI cases is obtained by the Commission within twelve months of the end of the reporting period, then the statewide median in-hospital risk-adjusted mortality rate for elective PCI cases will be used as a second benchmark.**

10.24.17.07D(6)

- (a) A primary PCI program shall meet all performance standards established in statute or in State regulations.*
- (b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.*
- (c) A hospital with a risk-adjusted mortality rate for STEMI PCI cases that exceeds the*

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

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

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

SAH submitted adjusted mortality rates by rolling 12-month reporting period for 2018 Q2 through 2023 Q4, as shown in Table 5.

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

Reporting Period	STEMI				NSTEMI			
	Hospital AMR	95% Confidence Interval	National AMR	Meets MHCC Standard	Hospital AMR	95% Confidence Interval	National AMR	Meets MHCC Standard*
2023q1-2023q4	1.59	[0.04, 8.55]	1.88	Yes	1.59	[0.42, 2.98]	1.99	Yes
2022q4-2023q3	1.66	[0.04, 8.93]	1.91	Yes	1.35	[0.44, 3.12]	2.02	Yes
2022q3-2023q2	1.99	[0.05, 10.70]	1.89	Yes	1.29	[0.42, 2.99]	2.02	Yes
2022q2-2023q1	0.00	[0.21, 1.98]	1.89	Yes	0.78	[0.21, 1.98]	2.05	Yes
2022q1-2022q4	0.00	[0.00, 7.48]	2.00	Yes	0.44	[0.05, 1.59]	2.14	Yes
2021q4-2022q3	1.78	[0.05, 9.59]	2.11	Yes	0.90	[0.29, 2.07]	2.20	Yes
2021q3-2022q2	1.68	[0.04, 9.11]	2.18	Yes	0.85	[0.28, 1.96]	2.26	Yes
2021q2-2022q1	3.47	[0.42, 12.12]	2.82	Yes	1.18	[0.39, 2.73]	2.25	Yes
2021q1-2021q4	3.60	[0.99, 8.81]	2.74	Yes	1.20	[0.44, 2.59]	2.23	Yes
2020q4-2021q3	3.69	[1.02, 8.91]	2.18	Yes	0.56	[0.07, 2.02]	2.23	Yes
2020q3-2021q2	11.19	[4.96, 20.83]	7.51	Yes	0.62	[0.07, 2.20]	1.18	Yes
2020q2-2021q1	9.72	[4.01, 18.89]	7.55	Yes	0.42	[0.01, 2.33]	1.21	Yes
2020q1-2020q4	4.76	[1.57, 10.68]	6.89	Yes	N/A	N/A	1.13	N/A
2019q4-2020q3	3.62	[1.00, 8.95]	6.37	Yes	0.77	[0.09, 2.76]	1.06	Yes
2019q3-2020q2	4.58	[1.51, 10.28]	6.06	Yes	0.66	[0.08, 2.38]	1.00	Yes
2019q2-2020q1	6.35	[2.97, 11.54]	5.99	Yes	0.67	[0.08, 2.41]	0.95	Yes
2019q1-2019q4	9.37	[4.99, 15.52]	6.01	Yes	0.82	[0.1, 2.95]	0.95	Yes
2018q4-2019q3	10.34	[5.69, 16.70]	6.06	Yes	0.42	[0.01, 2.32]	0.98	Yes
2018q3-2019q2	9.12	[4.50, 15.89]	6.38	Yes	1.32	[0.36, 3.33]	1.00	Yes
2018q2-2019q1	8.19	[3.36, 16.07]	6.13	Yes	1.37	[0.55, 2.80]	0.99	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports from the American College of Cardiology for the ACC-NCDR CathPCI data for PCI cases performed between April 2018 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 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

This standard is not applicable for the review periods that were included in SAH's Certificate of Ongoing Performance prior to CY 2019, because the current standard did not become effective until January 14, 2019. A similar, earlier standard referenced a statewide average as the benchmark. However, MHCC staff were not able to obtain a valid statewide average for all-cause 30-day risk-adjusted mortality for the period between January 2015 and December 2018.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and NSTEMI patients, as shown in Table 5, and determined that the hospital has performed statistically significantly similar to the national benchmark in all reporting periods. The national benchmark fell within the 95% confidence interval for SAH's adjusted mortality rates in all reporting periods for STEMI cases, indicating that the hospital's performance was not statistically significantly different from the national benchmark. In most reporting periods for NSTEMI cases, the national benchmark also fell within the 95% confidence interval for SAH's adjusted mortality rates. However, in five reporting periods, those ending in 2021Q3, 2022 Q2, 2022 Q3, 2022Q4, and 2023 Q1, the hospital performed statistically significantly better than the national average.

MHCC staff concludes that SAH complies with this standard.

Physician Resources

10.24.17.07C(6)(a) and .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.

SAH submitted the volume of primary and elective PCI cases performed by each interventionalist at SAH, as well as at other hospitals, by quarter for the period from CY 2019 through CY 2023. SAH reports volumes for the following four interventionalists: Dr. Michael Drossner, Dr. Matthew Voss, Dr. Martin Albornoz, and Dr. Raymond Plack. Each of these physicians also signed and dated an affidavit affirming under penalties of perjury that the information regarding his PCI volume is true and correct to the best of his knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed the reported PCI volume for the interventionalists, and the ACC-NCDR CathPCI data submitted by the hospital. Staff determined that current interventionalists performed, on average, at least 50 PCI procedures on a rolling eight-quarter basis between CY 2019 and CY 2023.

MHCC staff concludes that SAH complies with this 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.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to SAH. While SAH does not have on-site cardiac surgery, each physician performing primary PCI performed over 50 PCI procedures annually, on average, over a 24-month period.

10.24.17.07C(6)(c) and .07D(7)(c) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI procedures annually averaged over a 24-month period, and who took a leave of absence of less than one year during the 24-month period measured, may resume the provision of primary PCI provided that:

- (i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;*
- (ii) The physician continues to satisfy the hospital's credentialing requirements; and*
- (iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.*

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to SAH. While SAH does not have on-site cardiac surgery, each physician performing primary PCI performed over 50 PCI procedures annually, on average, over 24-month periods between CY 2019 and CY 2023.

10.24.17.07C(6)(e) and .07D(7)(e) Each physician shall be board-certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or who completed training before 1998 and did not seek board certification before 2003 or physicians who completed a fellowship in interventional cardiology less than three years ago.

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

SAH submitted a signed and dated statement from the medical director of the CCL, Dr. Matthew Voss, acknowledging that each physician performing primary PCI services at SAH is in compliance with COMAR 10.24.17.07C(6)(e) and .07D(7)(e). Each physician is currently board-certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that SAH meets these standards.

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.

SAH submitted signed and dated individual attestations from Dr. Michael Drossner, Dr. Raymond Plack, Dr. Martin Alborno, and Dr. Matthew Voss, stating that each completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC staff concludes that SAH meets this standard based on the statements provided.

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

SAH submitted a signed statement from the medical director of the CCL, Dr. Matthew Voss, acknowledging that each physician who has performed primary PCI services during the performance review period has participated in an on-call schedule, and all physicians currently performing primary PCI services are participating in the on-call schedule. SAH also provided the on-call schedule for every month in CY 2023

Staff Analysis and Conclusion

Staff examined the on-call schedules provided and observed that Drs. Drossner, Voss, Alborno, and Plack were all scheduled to be on-call at different times during every month in CY 2023.

MHCC staff concludes that SAH meets this standard.

Volume

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

(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.

SAH provided the number of primary PCI, elective PCI, and total PCI cases for the period from CY 2019 to CY 2023. The total number of PCI cases ranged from a low of 379 cases in CY 2020 to a high of 429 cases in 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the case volume information provided by SAH and analyzed the ACC-NCDR CathPCI data. As shown in Table 6, the annual volume of PCI cases ranged from 376 in CY 2020 to 395 cases in CY 2022. The volume of PCI cases performed at SAH is well above the target minimum volume of 200 cases.

Table 6: SAH PCI Case Volume

Calendar Year	Primary PCI Cases	Elective PCI Cases	Total PCI Cases
2019	87	294	381
2020	99	277	376
2021	105	275	380
2022	95	300	395

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

MHCC staff concludes that SAH meets 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

Because SAH performed greater than 49 primary PCI cases annually between CY 2019 and CY 2022, 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.

SAH provided the number of primary PCI cases completed by each interventionalist quarterly, from CY 2019 to CY 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by SAH and analyzed the ACC-NCDR CathPCI data. This analysis shows that between January 2019 and December 2023, at least 11 primary PCI procedures were completed per year for each interventionalist. Staff’s analysis of the data in the ACC-NCDR CathPCI confirms that all the interventionalists performed at least 11 primary PCI procedures annually.

MHCC staff finds that SAH complies with this standard.

Patient Selection

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

SAH responded that during the review period, there were no cases in which a patient received elective PCI inappropriately based on an internal or external review.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports for cases performed between January 2019 and March 2023. In one report, there was one case in which PCI was identified as "rarely appropriate" per ACC/AHA criteria and clinical criteria. MHCC staff asked SAH how it responded to that information. SAH noted that "rarely appropriate" does not mean never appropriate. SAH's peer review committee deemed the case within standards of care.

MHCC staff concludes SAH complies with this standard.

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

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

SAH reported that during the review period, there were no cases in which a patient received primary PCI inappropriately based on internal review. SAH also stated that no STEMI patients received thrombolytic therapy during the review period.

Staff Analysis and Conclusion

MHCC staff analysis of the ACC-NCDR Cath PCI data for CY 2019 through CY 2022 is consistent with the information reported by the applicant on use of thrombolytic therapy. MHCC staff determines that SAH complies with the standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff recommends the Commission find that SAH meets all the requirements for a Certificate of Ongoing Performance for its PCI program. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a Certificate of Ongoing Performance that permits SAH to continue providing primary and elective percutaneous coronary intervention services for four years subject to the following condition:

Beginning August 1, 2025, and on an annual basis until SAH is released from this condition, SAH shall report to MHCC dates and downtime for its CCL, including the start and end times for downtime, the reasons for downtime, and whether patient care was affected, by August 1 each year for the 12-month period ending June 30.