

**IN THE MATTER OF
SAINT AGNES
HOSPITAL**

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

Docket No.: 19-24-CP015

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

June 18, 2020

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 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 was 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 (nonprimary) 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.

B. Applicant

Saint Agnes Hospital

Saint Agnes Hospital (SAH) is a 247-bed general hospital located in Baltimore City. SAH does not have a cardiac surgery program on site.

SAH initiated primary PCI services in 1996 under a research waiver granted to the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT). On September 18, 2008, MHCC granted a two-year research waiver to SAH permitting participation in the Atlantic Cardiovascular Patient Outcomes Research Team Trial: Elective Angioplasty Study (C-PORT E). Patient enrollment at SAH began on January 13, 2009 and MHCC granted an extension of the waiver beginning on December 16, 2010. The Commission released an application for hospitals with existing C-PORT E research waivers to seek continuation of the waivers through a follow-on elective PCI registry. SAH was granted this waiver on November 17, 2011. On December 15, 2011, MHCC approved a two-year waiver for SAH to continue providing primary PCI services without on-site cardiac surgery. SAH subsequently applied for renewal of its two-year primary PCI waiver, which was granted through January 17, 2016. SAH currently provides primary and elective PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. SAH is located in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Baltimore City, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, Talbot Counties. Fourteen hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; all of the other programs provide both primary and elective PCI services. Five of the fourteen hospitals provide cardiac surgery services, and one facility in this region has a Certificate of Need to establish a cardiac surgery program.

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 March 22, 2019. MHCC staff reviewed the application and requested additional information on February 6, 2020 (corrected February 7, 2020), April 3, 2020, and June 3, 2020. SAH submitted additional information and clarification on February 28, 2020, April 24, 2020, and June 8, 2020.

II. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

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

At the time of application, SAH stated it participated in NCDR ACTION-GWTG and CathPCI Registry. SAH also stated that the required data collection and outcome reports to the MHCC are submitted quarterly and that there were no data collection or reporting deficiencies identified by the MHCC. As of January 2018, SAH started submitting data to the AHA CAD-GWTG Registry to meet MEIMSS requirements. SAH reports that it has a chest pain accredited emergency department and submits data to the Chest Pain Society via its registry on all STEMI patients.

Staff Analysis and Conclusion

SAH has complied with the submission of ACC-NCDR CathPCI data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of ACC-NCDR CathPCI data to validate that hospitals submitted accurate and complete information. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of SAH's data reported during the audit period.

MHCC staff received duplicate data as required and 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 reported a downtime of the cardiac catheterization laboratory on June 5, 2015 from 2 a.m. to 6 a.m. due to a facilities upgrade on cooling units in the hospital. During this downtime,

SAH reported that no patients were diverted. SAH also submitted a log of work orders for April 2011 through February 2020.

Staff Analysis and Conclusion

MHCC staff reviewed the log of work orders submitted and observed that the log contained dates and times when work orders were completed. Additionally, staff determined that the closure on June 5, 2015 was unavoidable.

SAH 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.

SAH provided a signed statement from Keith Vander Kolk, the hospital President and Chief Executive Officer, stating that door-to-balloon (DTB) times at SAH will not exceed 90 minutes from patient arrival at the hospital, excluding transfer patients, for at least 75 percent of appropriate patients. Mr. Vander Kolk also stated that the program will continue to track DTB times for transfer cases to evaluate for opportunities for improvement. SAH reported DTB times by quarter from 2015 Q1 to 2019 Q2, as shown in Table 1.

Table 1: SAH Reported Compliance with DTB Benchmark for Primary PCI

Quarter	Number of Primary PCI Cases	Number of Cases With DTB <= 90 Minutes*	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	34	34	100%
CY2015 Q2	33	34	100%
CY2015 Q3	24	21	87.5%
CY2015 Q4	29	24	82.8%
CY2016 Q1	20	18	90%
CY2016 Q2	26	23	88.5%
CY2016 Q3	14	13	92.9%
CY2016 Q4	29	27	93.1%
CY2017 Q1	21	21	100%
CY2017 Q2	22	17	77.3%
CY2017 Q3	19	18	94.7%
CY2017 Q4	16	13	81.4%
CY2018 Q1	23	23	100%
CY2018 Q2	20	19	95%
CY2018 Q3	14	11	78.6%
CY2018 Q4	20	18	90%
CY2019 Q1	15	15	100%
CY2019 Q2	20	20	100%
Total*	399	369	92.5%

Sources: SAH Application, Updated Q4; *MHCC analysis of data provided by SAH.

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

SAH reported that in Quarter 2 of 2015, the hospital had only one transfer case from another facility. The STEMI diagnosis was discovered on admission to SAH. SAH reported that there was appropriate follow-up with both internal and external care providers with regards to the delayed diagnosis and case outcome.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data and found that SAH met the DTB time standard in all but one quarter, as shown in Table 2. MHCC staff's analysis differs 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. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, SAH complied with this standard, with between 78% and 84% of PCI cases meeting the door-to-balloon time standard, as shown in Table 2.

MHCC staff concludes that SAH complies with this standard.

Table 2: 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 8-Quarters		
	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes
2015q1	36	35	91.7%			
2015q2	33	32	81.8%			
2015q3	25	22	80.0%			
2015q4	32	24	88.2%			
2016q1	20	18	95.0%			
2016q2	25	21	77.3%			
2016q3	14	13	81.8%			
2016q4	35	29	72.2%	220	194	88%
2017q1	20	19	90.0%	204	178	87%
2017q2	22	17	84.0%	193	163	84%
2017q3	22	18	92.9%	190	159	84%
2017q4	18	13	82.9%	176	148	84%
2018q1	24	22	97.2%	180	152	84%
2018q2	22	18	97.0%	177	149	84%
2018q3	10	8	88.0%	173	144	83%
2018q4	17	15	75.0%	155	130	84%

Source: MHCC staff analysis of ACC-NCDR CathPCI registry data, CY 2015- CY 2018.

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

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

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

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

Staff Category	Number/FTEs	Cross Training
Physician	4.0	
Nurse	7.2 FTE	S/C/M
Technician	5.0 FTE	S/C/M

Source: SAH Application Question 6a

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

SAH also states that the level of staffing reported is consistent with typical staffing levels for hospitals with CCLs and similar case volumes. Staff full-time equivalents (FTEs) are reviewed

on an annual basis in collaboration with finance and department leadership. Factors considered include fluctuation of case volumes and on-call schedule requirements. If staffing changes are needed due to unforeseen circumstances (i.e., staff out for extended periods of time), SAH reported that the hospital utilizes contract agency services that specialize in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by SAH to information reported in SAH’s most recent waiver application and three other current applications for Certificate of Ongoing Performance for Primary and Elective PCI (Table 3B).

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

Program & Year Reported	Total PCI Volume in Year Prior	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
SAH 2013	Not Reported	N = 4	8.0	5.0
SAH 2019	465	N = 4	7.2	5.0
Anne Arundel Hospital 2019	447	3.4 FTEs	7.5	6.0
University of Maryland Baltimore Washington Medical Center 2019	315	N = 3	5.0	5.0
Frederick Memorial Hospital 2019	418	N = 6	7.4	5.3

Sources: SAH 2019 PCI Certificate of Ongoing Performance Application, SAH 2013 Primary PCI Waiver Application, Anne Arundel Hospital 2019 PCI Certificate of Ongoing Performance Application, University of Maryland Baltimore Washington Medical Center 2019 PCI Certificate of Ongoing Performance Application, Frederick Memorial Hospital 2019 PCI Certificate of Ongoing Performance Application

SAH reported that the actual number of nursing staff has not decreased since the hospital’s 2013 waiver application, but the FTEs have changed to accommodate scheduling. The nurses’ shifts are either 12 or nine hours, and nurses typically work thirty-six hours per week (0.9 FTEs) instead of forty hours (1 FTE). If the nurse manager is included in staffing, that adds one FTE to the total number of nurse FTEs.

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 Keith Vander Kolk, Health System President and Chief Executive Officer, documenting SAH’s support for the renewal of its Certificate of Ongoing Performance for primary and elective PCI. Mr. Vander Kolk’s letter acknowledges that the hospital will provide primary PCI services in accord 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 a Coordinator for Cardiovascular Compliance who is a registered nurse and who is responsible for overseeing the NCDR Chest Pain/MI registry and submission to the AHA CAD GWTG registry. SAH reported that it has received the Platinum Award from the NCDR ACTION Registry for 2015, 2016, 2017, and 2018 in recognition of achieving 75% overall defect-free care for greater than 90% of STEMI and non-STEMI cases for the previous year. SAH also has an RN Coordinator for Cardiovascular Quality Assurance (QA). This person is responsible for overseeing the ACC-NCDR CathPCI Registry and 100% case review of all STEMI cases. Both the RN Coordinator for Cardiovascular Compliance and the RN Coordinator for Cardiovascular QA work with the Medical Director of Cardiovascular Units to review any discrepancies or adverse events in cases presented to the interdisciplinary Cath Lab Quality Assurance meeting and the interdisciplinary review team, respectively.

The position, Manager of Diagnostic and Interventional Cardiology Services, is responsible for overseeing departmental quality assurance and reports to the Quality Assurance and Patient Safety Council and Medical Staff Quality Assurance Committee on a quarterly basis. The manager also oversees the quarterly peer review meeting and is the contact for the quarterly review of elective PCI cases by an external review organization, which is also reviewed at a quarterly physician peer review meeting.

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 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' duties include working with the Chairman of Medicine to define and implement physician credentialing criteria (based on ACC guideline recommendations) and directing overall PCI program management. He works with nursing and administrative staff on purchasing equipment and pharmaceuticals, hiring and training personnel, as well as directing participation in quality assurance and improvement initiatives. These quality assurance and improvement initiatives include participating in both ACC-NCDR CathPCI registry

and the Maryland Academic Consortium for PCI Quality and Appropriateness (MACPAQ). Dr. Voss schedules and maintains both weekly multidisciplinary case review and case selection conferences, the internal quality assurance review conferences, physician scheduling for the cardiac catheterization laboratory, and the physician on call schedule. He is also responsible, along with the Chairman of Medicine, to monitor interventional physician ongoing professional practice evaluations, mortality and morbidity rates, and clinical case performance monitoring.

Staff Analysis and Conclusion

MHCC staff concludes that SAH is compliant with this standard.

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

For the period between January 2015 and July 2018, 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 intensive care unit. SAH also provided a list of annual hands-on competencies. Additionally, SAH provided a brief description of topics covered in training for new hires who are responsible for PCI patient care. This training is conducted through MyLearning Modules, the Clinical Nurse 1 Residents Class Series, and the Critical Care Consortium.

Staff Analysis and Conclusion

MHCC staff 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 shall have a formal, written agreement with a tertiary care center that provides for the unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

SAH submitted an agreement signed by Mary Kay Gardenier, Vice President Cardiovascular and Metabolic Institutes, SAH, and Cheryl L. Lunnen, Cardiovascular Vice President, MedStar Union Memorial Hospital, 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 transfer agreements with the University of Maryland (UM) Medical Center and with UM St. Joseph Medical Center.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that SAH meets this standard based on the copy of the transfer agreement provided with MedStar Union Memorial Hospital.

SAH was notified that the other two agreements were not in compliance because they do not contain language that clearly states each hospital will unconditionally accept patients. Additionally, the agreement with UM St. Joseph Medical Center, signed in January of 2013, stated that it is renewed automatically for successive one-year renewal terms, not to exceed a total of five years. While only one formal, written agreement with a tertiary care center that provides for the unconditional transfer of patients for any required additional care is required to satisfy 10.24.17.07D(4)(h), MHCC staff encouraged SAH to update these agreements. SAH has notified staff that it will update the agreements and submit copies to MHCC, when available.

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

Yolanda Copeland, Chief Nursing Officer, signed and dated an agreement with Pulse Medical Transportation stating that Pulse Medical Transportation will use its best efforts to respond to all unscheduled requests in a timely manner. The agreement states that the provider will meet the minimum overall on-time monthly performance standard of arriving within thirty minutes of the time the request is made. The agreement also contains a list of exceptions to the time frame targets (e.g. unusual adverse weather, official government-declared disasters, and abnormal circumstances).

Staff Analysis and Conclusion

MHCC staff reviewed the agreement with Pulse Medical Transportation (Provider) that was submitted with the original application and determined that it was not in compliance due to the response standards for emergency or immediate requests, which states that “Provider will immediately respond to all emergency requests. Provider will meet the minimum overall on-time monthly performance standard of arriving within thirty (30) minutes from the time of notification, ninety (90) percent of the time or better.” MHCC staff informed SAH that the agreement submitted did not meet the standard, and SAH submitted a modified agreement that no longer contained the language that the minimum overall on-time monthly performance standard would be met ninety percent of the time. MHCC staff determined that the revised agreement complies with the standard.

SAH meets this standard.

Quality

10.24.17.07D(5)(a) The hospital shall develop a formal, regularly scheduled (meetings at least

every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

SAH submitted Interventional Case Review Meeting dates and attendance records from 2015 through 2018. SAH responded that Interventional Case Review Meetings are held on a weekly basis. At these meetings, interventional cardiologists, administrative cardiologists, and CCL leadership or the data coordinator are required to attend. There is also a cardiac surgeon who attends most meetings in order to provide a full heart team approach to case reviews and management. The Chairman of the Department of Medicine attends a majority of these weekly meetings and CCL staff are encouraged to attend.

Staff Analysis and Conclusion

MHCC staff reviewed attendance records from 2015 through 2018 and determined that interventional case review meetings with these attendees were regularly scheduled such that the frequency of meetings did not fall less than every other month.

SAH complies with this standard.

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

SAH submitted attendance records for the STEMI Process Review Meetings from 2015 through 2018.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendance records submitted and determined that meetings were held between one and three times per month. Attendees at the meetings include staff from the emergency department, coronary care unit, and cardiac catheterization laboratory as required.

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 for MACPAQ from 2015 through 2019 Q2. SAH also described 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. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 3. Although only 5% of cases are required to be reviewed, beginning in the second half of 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. As shown in Table 4, between 5.1% and 9.4 % of cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed.

Table 3: SAH External Review Numbers By Year

Time Period	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard*
CY 2015	368	22	6.0%	Annual	Partially
CY 2016	366	21	5.7%	Semiannual	Yes
CY 2017	371	19	5.1%	Quarterly	Yes
CY 2018	388	23	5.9%	Quarterly	Yes
2019 Q1Q2	107	10	9.4%	Quarterly	Yes

Source: MHCC staff analysis of MACPAQ reports.

*Six cases per physician, or all cases if interventionalist performed fewer than three cases during the review period, were completed per calendar year.

Due to the lack of specificity in the requirements for external review in COMAR 10.24.17 prior to the update in November 2015, many hospitals delayed conducting the external review. In a bulletin issued in October 2015, MHCC staff advised hospitals to conduct an external review for all cases performed in CY 2015, and if the hospital had not conducted semiannual reviews on schedule, then the hospital should still review cases late, rather than not reviewing at all. Hospitals were advised that if the review cycle period ended after the effective date of the updated COMAR regulations, then the new standards for external review should be followed, and this approach was taken by SAH for CY 2015. SAH should have conducted semiannual reviews in CY 2015, which is why SAH only partially meets the standard for external review for this period. For the period between January 2015 and December 2018, MHCC staff verified that if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by MACPAQ, as required.

SAH complies with this standard.

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

- (i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or***
- (ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as***

provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than 3 cases during the relevant period, as provided in Regulation .08; or

- (iii) A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraphs .07C(4)(d)(i).*

10.24.17.07D(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 external review, PCI cases are reviewed on a weekly basis at the Interventional Review Committee meetings. Cases are reviewed and tracked by interventionalists

and the numbers are tallied at the end of each calendar year to ensure that at least 10% of PCI cases are reviewed annually. If any issues arise, the cases are reviewed at the bi-monthly CCL Quality Assurance Committee meeting and forwarded to the Department of Medicine Peer Review Committee.

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).¹

At least six 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 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).²

10.24.17.07D(5)(e) The chief executive officer of the hospital shall certify annually to the Commission 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 the Keith Vander Kolk, Health System 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 quarterly interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

¹https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

² Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the individual interventionalist review requirements.

Staff Analysis and Conclusion

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

10.24.17.07D (5)(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review cases.

- (i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.***
- (ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.***
- (iii) 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 a summary of the most recent quality assurance activities and submitted meeting minutes to support each quality assurance activity. Activities include improving in-house STEMI times, revising the heparin policy, addressing the impact of a specific drug for the acute coronary syndrome (ACS) protocol, and developing a protocol to reduce the likelihood of contrast-induced nephropathy. SAH has also created a STEMI crash course for new ED registered nurses as part of orientation.

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 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 by rolling 12-month reporting period for 2015 Q1 through 2019 Q2 when available, as shown in Table 4. These data are not available for any hospitals participating in the ACC CathPCI data registry for the rolling 12-month period of 2017 Q3 through 2018 Q2.

Table 4: SAH Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI				NONSTEMI			
	Hospital AMR	95% CI	National AMR	Meets MHCC Standard	Hospital AMR	95% CI	National AMR	Meets MHCC Standard*
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
2018q1-2018q4	7.85	[2.93, 16.37]	6.00	Yes	1.25	[0.54-2.43]	1.00	Yes
2017q4-2018q3	9.62	[3.59, 20.04]	6.54	Yes	1.24	[0.54-2.42]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	9.60	[4.24, 18.06]	6.91	Yes	0.56	[0.12, 1.63]	1.03	Yes
2017q1-2017q4	7.24	[2.39, 16.18]	6.85	Yes	0.45	[0.50, 1.62]	0.99	Yes
2016q4-2017q3	8.08	[3.31, 15.99]	6.75	Yes	0.24	[0.01, 1.31]	0.98	Yes
2016q3-2017q2	8.23	[2.71, 18.46]	6.64	Yes	0.73	[0.15, 2.12]	0.95	Yes
2016q2-2017q3	9.02	[2.97, 20.28]	6.77	Yes	1.39	[0.38, 3.54]	0.97	Yes
2016q1-2017q4	14.03	[6.18, 26.49]	6.82	Yes	1.93	[0.63, 4.47]	0.95	Yes
2015q4-2016q3	12.35	[5.45, 23.25]	6.71	Yes	2.91	[1.18, 5.94]	0.96	NO
2015q3-2016q2	12.89	[6.32, 22.70]	6.66	Yes	2.39	[0.88, 5.15]	0.93	Yes
2015q2-2016q1	12.4	[6.07, 21.87]	6.45	Yes	1.80	[0.59, 4.17]	0.90	Yes
2015q1-2015q4	10.48	[5.34, 18.04]	6.26	Yes	1.50	[0.40, 3.80]	0.90	Yes

Source: MHCC Staff compilation of results from the hospital's quarterly reports from the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between January 2015 and March 2018.

*Notes: This table provides information on whether SAH meets the current standard; however, note that the current standard only became effective in January 2019. Therefore, the standard is not applicable for the reporting periods shown. A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) included the National AMR or indicated 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.

Staff Analysis and Conclusion

This standard is not applicable for the majority of the review periods for SAH's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar standard that was adopted previously referenced a statewide average as the benchmark but MHCC staff was 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. However, MHCC staff has provided information below on how SAH performed over the period between January 2015 and June 2019.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for both STEMI and non-STEMI and determined that the hospital's adjusted mortality rate was statistically significantly different than the national benchmark in the 2015q4-2016q3 reporting period because the national benchmark did not fall within the 95% confidence interval. The 95% national benchmark did fall within the 95% confidence interval for all other 12-month reporting periods between 2015 Q1 and 2019 Q2. A report for the hospital's performance for the period ending December 2019, the first period for which the current standard applies, is not yet available.

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 Maryland Health Care Commission on a quarterly basis.

SAH submitted tables with the volume of primary and elective PCI cases performed by interventionalists at SAH as well as at other hospitals, by quarter for the period January 2015 through December 2018, for 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 the doctor's PCI volumes is true and correct to the best of the doctor's 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 January 2015 and December 2018.

SAH complies with this 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 MHCC. A hospital may be required to develop

a plan of correction based on the results of the physician's evaluation.

SAH responded that this regulation is not applicable.

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.

10.24.17.07D(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.***

SAH responded that this regulation is not applicable.

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.

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

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

SAH submitted a signed and dated statement from Dr. Matthew Voss, Medical Director of Interventional Cardiology, acknowledging that each physician performing primary PCI services at SAH is in compliance with standard of 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.

10.24.17.07D (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 Albornoz, 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.

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

SAH submitted a signed statement from Dr. Matthew Voss, Medical Director of the Cardiac Catheterization Laboratory, 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 submitted a copy of the on-call schedule for the period January 2018 through December 2018.

Staff Analysis and Conclusion

Staff examined the on-call schedule for January 2018 through December 2018 and observed that Drs. Drossner, Voss, Albornoz, and Plack were all scheduled to be on-call at different times during the month.

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 submitted total annual volume for CY 2014 through CY 2019, as shown in Table 5.

Table 5: SAH Total PCI Volume, CY 2015- CY 2019

Calendar Year	Total PCI
2015	488
2016	455
2017	449
2018	465
2019	405

Source: SAH application, question 28, and updated question 28.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for CY 2015 through CY 2018 and the volume information provided by SAH. This data shows that SAH exceeded the target volume of 200 PCI cases each year, from CY 2015 through CY 2019.

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.

SAH responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI volume data reported for individual interventionalists and the ACC-NCDR CathPCI data and determined over 49 primary PCI cases were performed per year. As shown in Table 6, the volume of primary PCI cases performed at SAH exceeded the threshold in the standard for triggering a focused review.

Staff concludes that this standard is not applicable.

Table 6: SAH Primary PCI Volume, CY 2015- CY 2018

Year	Number of Cases
CY 2015	126
CY 2016	98
CY 2017	85
CY 2018	89

Source: SAH application, response to question 22.

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

SAH submitted individual interventionalist volumes starting with the quarter ending on September 30, 2014 and ending with the quarter ending December 31, 2018.

Staff Analysis and Conclusion

MHCC staff reviewed PCI volume information submitted for the period between January 2015 and December 2018 and analyzed data in the ACC-NCDR CathPCI registry for this period. This information shows that each interventionalist performed at least 11 primary PCI cases annually.

SAH complies with this standard.

Patient Selection

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

(a) Patients described as appropriate elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.

(b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, are not suitable for elective PCI.

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 external review reports from 2015 through June 2019 and determined that there were no cases between January 2019 and June 2019 that were determined to be “rarely appropriate” with respect to clinical criteria, angiographic criteria, and ACC/AHA appropriateness criteria.

MHCC staff concludes that SAH complies with this standard

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

(a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.

(b) Patients with acute myocardial infarction in cardiogenic shock that the treating

physician (s) believes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

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

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

SAH responded that during the review period, there were no cases in which a patient received primary PCI inappropriately based on internal review. The hospital's STEMI Process and Quality Assurance Committee reviews 100% of primary PCI cases. Additionally, SAH responded that no STEMI patients received thrombolytic therapy during the review period.

Staff Analysis and Conclusion

MHCC staff determines that SAH complies with the standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff concludes that SAH meets all of 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.