IN THE MATTER OF	*	**BEFORE THE**
ADVENTIST HEALTHCARE	*	**MARYLAND**
SHADY GROVE	*	**HEALTH CARE**
MEDICAL CENTER	*	**COMMISSION**
	*	
Docket No.: 25-15-CP062	*	

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STAFF REPORT AND RECOMMENDATION

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

April 16, 2026

I. INTRODUCTION

A. Background

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

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

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

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services Chapter (Cardiac Services Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Services Chapter was subsequently revised in November 2015 and again in January 2019.

The Cardiac Services Chapter contains standards for evaluating the performance of established cardiac surgery and PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or both primary and elective (non-primary) PCI services, for a time specified by the Commission that cannot exceed five years, unless an extension is granted by the Executive Director. At the end of the period, the hospital must demonstrate that it continues to meet the requirements in the Cardiac Services Chapter in order for the Commission to renew the hospital's authorization for a Certificate of Ongoing Performance.

In between renewals for a Certificate of Ongoing Performance, if a hospital is not in compliance with certain standards, a focused review shall be conducted. The regulations authorize Commission staff to conduct a focused review based on reported patient safety concerns, aberrations in data, or failure to meet quality standards established in State and federal regulations.[1] A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance must receive a detailed list of deficiencies from Commission staff and submit a plan of correction within 30 days of receipt of the list of deficiencies.[2] If a hospital does not submit a plan of correction that addresses the deficiencies cited or successfully complete a plan of correction, the hospital shall, upon notice of the Executive Director of the Commission, voluntarily relinquish its authority to perform cardiac surgery or emergency or elective PCI services, as applicable.[3]

B. Applicant

Adventist HealthCare Shady Grove Medical Center

Adventist HealthCare Shady Grove Medical Center (SGMC) is a 360-bed general hospital located in Rockville (Montgomery County) that is part of the Adventist HealthCare system. SGMC does not have a cardiac surgery program on site.

The hospital's most recent Certificate of Ongoing Performance for primary and elective PCI services was approved on July 15, 2021, for four years. On March 21 and October 20, 2025, six-month extensions were granted by the Executive Director of the Commission, to allow MHCC staff time to complete a thorough review of SGMC's current application for a Certificate of Ongoing Performance. This is the hospital's second renewal of its Certificate of Ongoing Performance.

Health Planning Region

Four health planning regions for adult cardiac services are defined in the Cardiac Services Chapter. The regions are defined by geographic areas. SGMC is located in the Metropolitan Washington health planning region. This region includes Calvert, Charles, Frederick, Montgomery, Prince George's, and St. Mary's counties, and the District of Columbia. Seven Maryland hospitals in this health planning region provide PCI services. Three of these hospitals provide both cardiac surgery and PCI services and four hospitals provide only PCI services.

C. Staff Recommendation

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

[1] COMAR 10.24.17.07B(2)(a), .07C(2)(a), and .07D(2)(a).
[2] COMAR 10.24.17.07B(2)(c), .07C(2)(c), and .07D(2)(c).
[3] COMAR 10.24.17.07B(2)(e), .07C(2)(e), and .07D(2)(e).

II. PRODEDURAL HISTORY

On March 7, 2025, SGMC filed its application for a Certificate of Ongoing Performance for primary and elective PCI services. Additional information was requested by MHCC staff on March 24, 2025, December 29, 2025, March 13, 2026, and March 30, 2026. Additional information was provided by SGMC on April 14, 2025, January 19, 2026, March 26, 2026, and March 31, 2026.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07C(3) and .07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACC-NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

SGMC stated the hospital submits data quarterly to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) CathPCI and to MHCC. Further, neither MHCC staff nor the hospital has identified data collection or reporting deficiencies.

Staff Analysis and Conclusion

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

SGMC reported that the facility in Rockville has two cardiac catheterization laboratories (CCLs) for PCI services. The hospital provided dates, times, and duration for preventative maintenance activities, as shown in Table 2. According to SGMC, there were nine incidents of downtime resulting in PCI service disruptions, delayed care, or diversion to other facilities.

Table 2. SGMC's Reported Downtime for CCLs, February 2021 – December 2024

Lab #	Date	Time	Duration
1	2/21/2021	12:00	3 hrs
1	4/13/2021	13:00	4 hrs
1	4/21/2021	8:00	4 hrs
2	4/21/2021	12:00	4 hrs
1	8/11/2021	8:00	2 hrs
2	8/11/2021	13:00	3 hrs
2	8/12/2021	8:30	2 hrs
1 and 2	10/8/2021	18:55	22 hrs 29 min
1	10/11/2021	7:00	10 hrs
1	12/7/2021	9:00	8 hrs
1	12/9/2021	7:00	10 hrs
1	12/10/2021	7:00	10 hrs
1	1/4/2022	8:00	7 hrs
1 and 2	2/6/2022	22:00	22 hrs
1 and 2	2/21/2022	19:00	1 hr 50 min
1 and 2	2/23/2022	9:15	35 min
2	3/17/2022	8:00	5 hrs
1	3/31/2022	7:00	10 hrs
1 and 2	6/11/2022	17:20	2 hrs 20 min
2	8/15/2022	8:00	8 hrs
1 and 2	10/22/2022	9:00	2 hrs
2	11/28/2022	17:20	2 hrs 20 min
1 and 2	12/26/2022	16:53	8 hrs 29 min
2	2/23/2023	8:30	8 hrs
1	3/10/2023	9:00	6 hrs 30 min
1	5/3/2023	9:00	4 hrs
1 and 2	6/14/2023	1:00	2 hrs 27 min
2	8/15/2023	7:00	11 hrs
1	10/11/2023	9:00	8 hrs
2	1/17/2024	8:00	6 hrs
2	3/12/2024	8:00	4 hrs
2	6/25/2024	8:00	4 hrs
1	6/25/2024	12:00	6 hrs
2	7/3/2024	8:00	5 hrs
2	7/12/2024	8:00	5 hrs
1 and 2	7/14/2024	13:09	26 min
2	8/7/2024	9:00	8 hrs
2	8/14/2024	9:00	8 hrs
1	9/11/2024	14:00	2 hrs
2	9/12/2024	10:00	2 hrs
1	9/25/2024	8:00	8 hrs

Source: SGMC's application for a Certificate of Ongoing Performance (pp. 2-4)

Staff Analysis and Conclusion

MHCC staff reviewed SGMC's reported CCL downtime for the period February 2021 through December 2024. MHCC staff reviewed the information submitted by SGMC on CCL room closures and noted that there were nine instances during the review period in which both cardiac catheterization laboratories were unavailable simultaneously. Of these nine instances, two resulted in patient diversion while the patient was en route to SGMC. In both instances, the patient being transported to SGMC for STEMI care was diverted to Suburban Hospital, resulting in an additional transport time of approximately ten minutes. SGMC reported that thrombolytic therapy was not administered as an alternative to primary PCI in these cases.

For the majority of the downtime cases listed in Table 2, one catheterization lab remained available for emergent PCI procedures. SGMC reported that its biomedical engineering team overseeing maintenance coordinates preventative maintenance activities with clinical staff and understands that maintenance would cease immediately if the laboratory were needed for an emergent PCI procedure.

In three instances in which both labs were unavailable, the unavailability resulted from multiple simultaneous emergencies occurring on a weekend. SGMC reported that both the primary and backup catheterization lab teams were engaged in active cases when an additional STEMI case arose. Although the hospital maintains an on-call backup team to address simultaneous emergencies, on-call administrative leadership determined that diversion to another PCI-capable hospital was the most appropriate course of action in those circumstances. SGMC reported that the importance of avoiding diversion when possible has subsequently been reinforced with catheterization laboratory staff and clinical leadership. Documentation of those discussions was provided in meeting minutes from the hospital's multiple-care group meetings in June 2023, August 2023, and December 2024. In addition, the hospital developed a process map describing decision making procedures for potential diversions, the most recent version of which was provided to MHCC.

On two occasions, SGMC reports that the decision was made to divert without consulting leadership. This was discussed in the hospital's multiple-care group meeting, as well as at a meeting of the Administrator on Call group to reinforce appropriate procedures before diversion decisions are made. The hospital shared with MHCC an excerpt of the presentation about this matter.

Two instances of CCL downtime were associated with equipment failures in October 2021 and February 2022. These events coincided with a construction project (from October 2021 to February 2022) to upgrade the primary catheterization lab. During construction, SGMC implemented a contingency plan intended to ensure one lab remained available for STEMI cases. Following the October 2021 equipment failure, SGMC revised its scheduling practices so that elective PCI procedures would not occupy the remaining laboratory if doing so could limit its ability to respond to an unexpected STEMI activation. SGMC reported that the February 2022 downtime event was caused by a hemodynamic monitoring system reconnection issue shortly after the newly upgraded lab returned to service. Staff were immediately summoned to correct the problem.

Finally, the hospital reported it had two instances where all three of its Intra-Aortic Balloon Pumps (IABPs) were in use. According to the hospital, these events occurred during a season of extremely high acuity of patients during the COVID pandemic. Catheterization lab medical leadership determined that it would be unsafe to perform primary PCI without the availability of an IABP. During those periods, the hospital diverted STEMI cases while maintaining thrombolytic care for walk-in patients if clinically appropriate. In both instances, catheterization lab management worked to obtain an additional balloon pump on loan from Adventist White Oak Medical Center.

MHCC staff reviewed SGMC's reported CCL downtime events and the hospital's explanations of the circumstances that resulted in temporary unavailability of PCI services. While there were limited instances in which both laboratories were unavailable simultaneously, the hospital has implemented operational and procedural changes intended to reduce the likelihood of future occurrences, including revised scheduling practices, enhanced diversion decision protocols, and equipment contingency planning.

Based on the information provided, staff find that SGMC maintains the institutional resources necessary to provide PCI services on a continuous basis and therefore concludes that SGMC complies with this standard.

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

SGMC submitted a signed statement from Daniel Cochran, President and Chief Executive Officer (CEO), dated January 22, 2025, committing the hospital to provide primary PCI services within 90 minutes and track the hospital's performance to identify opportunities for improvement. The hospital also provided door-to-balloon (DTB) times for non-transfer primary PCI cases for each quarter from CY 2020 through CY 2024, as shown in Table 3a. During this period, the hospital stated that 85.7 to 100 percent of cases met this standard.

Table 3a. SGMC's Reported Compliance with DTB Benchmark by Quarter, January 2020 – December 2024

Quarter	Total Primary PCI Volume	Cases with DTB ≤ 90 Minutes	Percent of Cases with DTB ≤ 90 Minutes
CY 2020 Q1	20	18	90.0%
CY 2020 Q2	24	22	91.7%
CY 2020 Q3	23	22	95.7%
CY 2020 Q4	24	23	95.8%
CY 2021 Q1	16	16	100.0 %
CY 2021 Q2	32	32	100.0%
CY 2021 Q3	30	29	96.7%
CY 2021 Q4	23	23	100.0%
CY 2022 Q1	30	27	90.0%
CY 2022 Q2	26	24	92.3%
CY 2022 Q3	25	23	92.0%
CY 2022 Q4	30	27	90.0%
CY 2023 Q1	18	18	100.0%
CY 2023 Q2	22	21	95.5%
CY 2023 Q3	28	24	95.7%
CY 2023 Q4	23	23	100.0%
CY 2024 Q1	27	26	96.3%
CY 2024 Q2	24	22	91.7%
CY 2024 Q3	35	32	91.4%
CY 2024 Q4	28	24	85.7%

Source: SGMC's application for a Certificate of Ongoing Performance 2025, pp. 5-6.

As shown in Table 3b, SGMC provided information about DTB times for primary PCI transfer cases between January 2020 and December 2024. During this period, the hospital reports that between 57 and 100 percent of transfer cases met the DTB time of 120 minutes or less, which is consistent with the guidelines of the ACC and American Heart Association (AHA).

Table 3b. SGMC's Reported Compliance with DTB Benchmark for Transfer PCI Cases by Quarter, January 2020 – December 2024

Quarter	Total Transfer Primary PCI Volume	Transfer Cases with DTB ≤ 120 Minutes	Percent of Transfer Cases with DTB ≤ 120 Minutes
CY 2020 Q1	5	5	100.0%
CY 2020 Q2	3	3	100.0%
CY 2020 Q3	4	4	100.0%
CY 2020 Q4	5	4	80.0%
CY 2021 Q1	4	3	75.0%
CY 2021 Q2	6	6	100.0%
CY 2021 Q3	7	7	100.0%
CY 2021 Q4	5	4	80.0%
CY 2022 Q1	4	4	100.0%
CY 2022 Q2	8	6	75.0%
CY 2022 Q3	5	5	100.0%
CY 2022 Q4	4	4	100.0%
CY 2023 Q1	6	4	**66.7%**
CY 2023 Q2	3	2	**66.7%**
CY 2023 Q3	5	5	100.0%
CY 2023 Q4	3	3	100.0%
CY 2024 Q1	7	4	**57.0%**
CY 2024 Q2	4	4	100.0%
CY 2024 Q3	4	4	100.0%
CY 2024 Q4	10	8	80.0%

Source: SGMC's application for a Certificate of Ongoing Performance 2025, pp. 6-7.

The hospital reported meeting the standard of 90 minutes or less for 75 percent of non-transfer primary PCI cases in nearly all quarters. The hospital provided an explanation for each case with a non-patient centered delay during the quarters where the standard was not met. Reasons for delays included ECG referral delay, unavailable immediate use of the CCLs, and delayed medical team arrival. Preventable delays were discussed at the hospital's multi-care group meeting.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases for the period from CY 2020 through CY 2024, as shown in Table 3c to evaluate the hospital's compliance with the requirement that primary PCI services be provided within 90 minutes of hospital arrival for at least 75 percent of non-transfer STEMI patients. Staff found that SGMC met this performance standard in the majority of quarters during the review period and consistently exceeded the required threshold when performance is evaluated over rolling eight-quarter periods. As shown in Table 3c, SGMC achieved DTB times of 90 minutes or less in between 69.2 percent and 96.2 percent of non-transfer primary PCI cases across the 20 quarters reviewed. The hospital fell below the 75 percent threshold in two quarters (CY 2022 Q3 and CY 2024 Q4).

Table 3c. SGMC's Compliance with DTB Benchmark for Non-Transfer Primary PCI Cases by Quarter, CY 2020 – CY 2024

Quarter	Non-Transfer Primary PCI Volume	Cases with DTB ≤ 90 Minutes	Percent of Cases with DTB ≤ 90 Minutes
CY 2020 Q1	20	18	90.0%
CY 2020 Q2	25	23	92.0%
CY 2020 Q3	25	21	84.0%
CY 2020 Q4	25	23	92.0%
CY 2021 Q1	21	17	81.0%
CY 2021 Q2	33	31	93.9%
CY 2021 Q3	33	31	93.9%
CY 2021 Q4	22	21	95.5%
CY 2022 Q1	31	26	83.9%
CY 2022 Q2	31	26	83.9%
CY 2022 Q3	29	21	**72.4%**
CY 2022 Q4	34	27	79.4%
CY 2023 Q1	20	18	90.0%
CY 2023 Q2	21	20	95.2%
CY 2023 Q3	32	25	78.1%
CY 2023 Q4	22	21	95.5%
CY 2024 Q1	26	25	96.2%
CY 2024 Q2	27	23	85.2%
CY 2024 Q3	35	28	80.0%
CY 2024 Q4	26	18	**69.2%**

Source: MHCC staff's analysis of ACC-NCDR CathPCI data for CY 2020 – CY 2024.

The hospital's reported performance differs slightly from MHCC staff's analysis because the hospital's calculations exclude certain cases identified by the ACC-NCDR as having non-system delays, while MHCC staff includes all cases when evaluating compliance with this regulatory standard. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers the hospital's performance over rolling eight-quarter periods, as shown in Table 3d. Over rolling eight-quarter periods from CY 2020 to CY 2024, between 83.6 and 90.7 percent of non-transfer primary PCI cases met the DTB time of 90 minutes, well above the regulatory requirement that at least 75 percent of cases meet the DTB time standard.

Table 3d. SGMC Non-Transfer Primary PCI Case Volume and Percentage of Cases with Door-to-Balloon (DTB) Time ≤ 90 Minutes

Time Period	Measure Type	Total Primary PCI Volume	Cases with DTB ≤ 90 Minutes	Percent with DTB ≤ 90 Minutes
CY 2020 Q1	Quarterly	20	18	90.0%
CY 2020 Q2	Quarterly	25	23	92.0%
CY 2020 Q3	Quarterly	25	21	84.0%
CY 2020 Q4	Quarterly	25	23	92.0%
CY 2021 Q1	Quarterly	21	17	81.0%
CY 2021 Q2	Quarterly	33	31	93.9%
CY 2021 Q3	Quarterly	33	31	93.9%
CY 2021 Q4	Quarterly	22	21	95.5%
CY 2021 Q4	Rolling 8-Quarter	204	185	90.7%
CY 2022 Q1	Quarterly	31	26	83.9%
CY 2022 Q1	Rolling 8-Quarter	215	193	89.8%
CY 2022 Q2	Quarterly	31	26	83.9%
CY 2022 Q2	Rolling 8-Quarter	221	196	88.7%
CY 2022 Q3	Quarterly	29	21	72.4%
CY 2022 Q3	Rolling 8-Quarter	225	196	87.1%
CY 2022 Q4	Quarterly	34	27	79.4%
CY 2022 Q4	Rolling 8-Quarter	234	200	85.5%
CY 2023 Q1	Quarterly	20	18	90.0%
CY 2023 Q1	Rolling 8-Quarter	233	201	86.3%
CY 2023 Q2	Quarterly	21	20	95.2%
CY 2023 Q2	Rolling 8-Quarter	221	190	86.0%
CY 2023 Q3	Quarterly	32	25	78.1%
CY 2023 Q3	Rolling 8-Quarter	220	184	83.6%
CY 2023 Q4	Quarterly	22	21	95.5%

Time Period	Measure Type	Total Primary PCI Volume	Cases with DTB ≤ 90 Minutes	Percent with DTB ≤ 90 Minutes
CY 2023 Q4	Rolling 8-Quarter	220	184	83.6%
CY 2024 Q1	Quarterly	26	25	96.2%
CY 2024 Q1	Rolling 8-Quarter	215	183	85.1%
CY 2024 Q2	Quarterly	27	23	85.2%
CY 2024 Q2	Rolling 8-Quarter	211	180	85.3%
CY 2024 Q3	Quarterly	35	28	80.0%
CY 2024 Q3	Rolling 8-Quarter	217	187	86.2%
CY 2024 Q4	Quarterly	26	18	69.2%
CY 2024 Q4	Rolling 8-Quarter	209	178	85.2%

Source: MHCC staff's analysis of ACC-NCDR data (CY 2020 – CY 2024.)

Table 3e. SGMC's Compliance with Primary PCI Transfer DTB Benchmark by Quarter, CY 2020 – CY 2024

Quarter	Transfer Primary PCI Volume	Cases with DTB ≤ 120 Minutes	Percent of Cases with DTB ≤ 120 Minutes
CY 2020 Q1	5	4	80.0%
CY 2020 Q2	3	3	100.0%
CY 2020 Q3	4	3	75.0%
CY 2020 Q4	5	4	80.0%
CY 2021 Q1	5	3	**60.0%**
CY 2021 Q2	8	4	**50.0%**
CY 2021 Q3	7	4	**57.1%**
CY 2021 Q4	6	2	**33.3%**
CY 2022 Q1	5	3	**60.0%**
CY 2022 Q2	8	6	75.0%
CY 2022 Q3	5	5	100.0%
CY 2022 Q4	4	3	75.0%
CY 2023 Q1	5	2	**40.0%**
CY 2023 Q2	3	2	**66.7%**
CY 2023 Q3	5	4	80.0%
CY 2023 Q4	3	2	**66.7%**
CY 2024 Q1	7	7	100.0%
CY 2024 Q2	4	4	100.0%
CY 2024 Q3	5	5	100.0%
CY 2024 Q4	9	9	100.0%

Source: MHCC staff's analysis of ACC-NCDR CathPCI data for CY 2020 – CY 2024.

For the period from CY 2020 through CY 2024, MHCC staff also reviewed the information reported by SGMC regarding the number and percentage of PCI transfer cases with a DTB time of 120 minutes or less. As shown in Table 3b, only three of 20 quarters had below 75 percent of transfer cases with a DTB time of 120 minutes or less. The percentage of cases achieving this DTB time ranged from 57 to 100 percent in each quarter. This data is consistent with MHCC staff's analysis of the ACC-NCDR CathPCI data, which is shown in Table 3e. The percentage of transfer cases achieving a DTB time of 120 minutes or less in each quarter ranged from 33.3 to 100 percent.

Although hospitals strive to achieve DTB times of 120 minutes or less in primary PCI transfer cases, many factors impacting the DTB times are outside of the hospital's control. For this reason, there is not the requirement for a certain percentage of cases to achieve a benchmark of 120 minutes or less each quarter. Instead, a hospital is required to track the DTB times for transfer cases and evaluate areas for improvement.

SGMC documented several efforts to improve DTB times for transfer cases. These include ongoing communication with referring facilities and EMS providers. One challenge the hospital identified was that private transport agencies were not meeting their contractual response time obligations, leading hospital senior leadership to pursue a solution with transport agency leadership, resulting in access to a more readily available unit for transport. The hospital also reports that it provides documentation to referring facilities which act as a checklist for streamlined patient care and to ensure the patient can be transferred quickly, as well as documenting critical timestamps. Finally, the hospital reports that it utilizes process maps in collaboration with referring facilities to ensure a standardized transfer process, and that those process maps are reviewed and

updated regularly.

Based on review of the ACC-NCDR CathPCI data and the information provided by SGMC, MHCC staff finds that the hospital consistently meets the requirement that at least 75 percent of non-transfer primary PCI cases achieve a door-to-balloon time of 90 minutes or less when evaluated over sustained time periods. In addition, SGMC tracks door-to-balloon times for transfer cases and has implemented multiple process improvements aimed at reducing delays associated with interfacility transfers.

MHCC staff concludes that SGMC meets this standard.

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

As shown in Table 4a below, SGMC reported the number of physicians, nurses, and technicians who are available to provide cardiac catheterization services to acute myocardial infarction patients as of the time that the hospital submitted its application for Certificate of Ongoing Performance. SGMC explained that these staffing levels demonstrate adequate physician, nursing, and technical staff for the CCL to provide coverage 24 hours per day, 7 days per week.

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

Staff Category	Number/FTEs	Cross Training (S/C/M*)
Physician	7	
Nurse	9.6 FTE	C/M
Technician	9.1 FTE	9.1 S / 9.1 C / 2.4 M

Source: SGMC's application for a Certificate of Ongoing Performance 2025, pp. 7-8.
*Scrub (S), Circulate (C), Monitor (M)

Staff Analysis and Conclusion

MHCC staff compared the staffing levels described by SGMC to information reported by three other existing PCI programs. A comparison of volume and staffing levels for SGMC, MedStar Southern Maryland Hospital Center (SMHC), Johns Hopkins Anne Arundel Medical Center (AAMC), and Meritus Medical Center (MMC) is shown in Table 4b. Staff observed that SGMC had similar case volumes to SMHC, AAMC, and MMC in 2023. The closest volume program was at AAMC, where there were five interventionalists compared to SGMC's seven. Although MMC had a slightly larger PCI volume than SGMC, it, too, had five interventionalists compared to SGMC's seven. Staff found that, compared to its peers, SGMC had a reasonable number of interventionalists for its total PCI case volume. SGMC had more nurse FTEs (9.6) than AAMC (8.5), and nearly as many as SMHC (11). With 9.1 FTE technicians, SGMC had higher staffing than any of its peers, with the closest being AAMC with seven FTE and one contract technician (CPT).

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

Program	Total PCI Volume 2023	Number of Interventionalists or FTEs	Nurse FTEs	Technicians FTEs
SGMC	333	7	9.6 FTE	9.1 FTE
SMHC	297	2 FT, 3 PT, 1 after hours PRN call	11 FTE	5 FTE
AAMC	330	5	8.5 FTE	7 FTE, 1 CPT
MMC	382	5	9 FTE, 5 Flex RNs, 2 Overfill Agency RNs	4.5 FTE, 3 Flex Techs, 2 Overfill Agency Techs

Sources: SGMC's application for Certificate of Ongoing Performance 2025, pp. 7-8; SMHC's Certificate of Ongoing Performance staff report 2024, p. 9; AAMC's application for a Certificate of Ongoing Performance 2024, p. 8; MMC's application for a Certificate of Ongoing Performance 2025, p. 6; PCI volumes for each hospital are from ACC-NCDR CathPCI registry reports for period ending December 31, 2023

Based on the information provided, MHCC staff determined that the hospital has adequate physician, nursing, and technical staff available to provide PCI services. Staff concludes that SGMC complies with this standard.

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

SGMC provided a written letter dated January 22, 2025, signed by President and CEO of the hospital Daniel Cochran, confirming that the hospital will provide primary PCI services in accordance with the requirements established by the MHCC and as outlined in the Cardiac Services Chapter.

Staff Analysis and Conclusion

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

SGMC stated that data management, reporting, and coordination with institutional quality improvement efforts for PCI services are appropriately managed under the leadership of the Chest Pain Center Coordinator.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and confirmed that the hospital has been submitting complete and timely information to the ACC-NCDR CathPCI and is engaging in

quality assurance activities for its PCI program. MHCC staff concludes that SGMC complies with this standard.

10.24.17.07D(4)(f) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the cardiac catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

SGMC reported that the Medical Director of the Cardiac Catheterization Lab Service is Dr. Dennis Friedman, and that he has held that position since May 1, 2002. According to the job description, Dr. Friedman: serves as a liaison with medical staff; reviews the performance of the Service and its staff; provides staff development; develops and implements quality assurance plans; ensures compliance with established standards; participates in performance improvement utilization review, discharge planning, peer review, and infection control activities; reviews and develops policies, procedures, and clinical pathways; reviews and revises medical staff guidelines and regulations; assists with recruitment, orientation, proctoring, and credentialing physicians; consults with the Service Director on the preparation of operating and capital budgets; and assists with the selection of capital equipment. These responsibilities demonstrate that the Medical Director provides oversight of several core elements of the primary PCI program, including quality management, policy development, equipment planning, and physician credentialing processes. The job description also indicates that the Medical Director participates in activities related to peer review and clinical performance monitoring.

In addition, Dr. Michael Chen serves as the section chair for Cardiology and Interventional Cardiology and develops the call schedule for primary PCI and Interventional Cardiology physician coverage.

Staff Analysis and Conclusion

Based on the information provided and MHCC staff's review of the description of job duties for the Medical Director of the CCL, staff concludes that SGMC complies with this standard.

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

SGMC provided a list of topics offered as a part of its required annual education for CCL staff. This includes moderate sedation and airway management; radiation safety; sterile technique; access site management; contrast induced nephropathy; and Intra-Aortic Balloon Pump. All hospital employees are required to complete learning modules for Early Heart Attack Care, and all nurses are required to complete modules on Acute Coronary Syndrome and Basic Dysrhythmias. In addition, an interventional cardiologist leads regular "Cath Conferences," which provide a review of cases with educational topics and discussion relative to the cases reviewed.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that SGMC complies with this standard.

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

SGMC submitted a signed transfer agreement with Adventist HealthCare White Oak Medical Center. The agreement was originally effective February 1, 2008, and it remains in effect.

Staff Analysis and Conclusion

MHCC staff reviewed the transfer agreement provided by SGMC and noted that the agreement provides for the unconditional transfer of patients, as required. MHCC staff concludes that SGMC complies with this standard.

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

SGMC provided an agreement between the hospital and Butler Medical Transport, LLC, executed on March 18, 2022. The hospital also provided a helicopter transport agreement with Washington Hospital Center's MedSTAR Transport Service, which was executed on July 1, 2008. The agreements remain in effect.

Staff Analysis and Conclusion

MHCC staff reviewed the transfer agreements provided by SGMC, noting that for time-critical transports, both Butler and MedSTAR will arrive within thirty (30) minutes of receiving the request for patient transport. MHCC staff concludes that the hospital complies with this standard.

Quality

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

SGMC provided dates and attendees for interventional case review meetings held from CY 2020 through CY 2024. The hospital reported that the case review is incorporated in the multiple care area group meeting, titled Cardiovascular Center of Excellence (CVCOE), held monthly.

Staff Analysis and Conclusion

SGMC submitted documentation that includes meeting dates and attendance records for twelve meetings in each year between CY 2020 and CY 2024. Review of meeting attendees shows that meetings are routinely attended by interventionalists, as well as other physicians, nurses, and technicians who care for primary PCI patients. MHCC staff concludes that SGMC complies with this standard.

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

SGMC provided meeting dates, minutes, and attendance records of the Cardiovascular Center of Excellence (CVCOE) meetings held from CY 2020 through CY 2024.

Staff Analysis and Conclusion

SGMC submitted documentation including dates, minutes, and attendance records for 12 meetings each year between CY 2020 and CY 2024. Meeting attendees include leadership and physicians from the CCL, CPC, PCU, Emergency Department, and Observation units, quality advising, and nursing supervision. Meetings took place monthly as required.

Staff review of the meeting minutes indicates that the CVCOE serves as a forum for reviewing issues related to the hospital's PCI system of care. Topics discussed during the review period included door-to-balloon time performance, catheterization laboratory availability, STEMI activation processes, diversion events, equipment issues, and coordination among emergency department, inpatient cardiac care units, and the catheterization laboratory. The minutes also document discussions of potential system improvements and follow-up actions related to these issues.

MHCC staff find that SGMC 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.

SGMC submitted copies of the external review reports for elective PCI cases performed between Q4 of CY 2020 and Q1 of CY 2025. The hospital contracts with the Cardiac Community Core Lab (CCCL), an MHCC approved review organization, to complete these external reviews according to standards established by the Commission. These semi-annual reviews include analysis of angiographic images, medical test results, and a patient's medical record.

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 5. Although only five percent of cases are required to be reviewed externally, between 16.9 and 26.8 percent of cases were reviewed each period.

Table 5. SGMC's External Review, October 2020 – March 2025

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
Oct 2020 – Mar 2021	58	12	20.7%	Semi-annually	Yes
Apr 2021 – Sept 2021	63	12	19.0%	Semi-annually	Yes
Oct 2021 – Mar 2022	58	12	20.7%	Semi-annually	Yes
Apr 2022 – Sept 2022	64	15	23.4%	Semi-annually	Yes
Oct 2022 – Mar 2023	89	15	16.9%	Semi-annually	Yes
Apr 2023 – Sept 2023	88	20	22.7%	Semi-annually	Yes
Oct 2023 – Mar 2024	92	16	17.4%	Semi-annually	Yes
Apr 2024 – Sept 2024	88	18	20.5%	Semi-annually	Yes
Oct 2024 – Mar 2025	56	15	26.8%	Semi-annually	Yes

Source: MHCC staff analysis of CCCL external review reports, October 2020 – March 2025.

For the period between Q4 of CY 2020 and Q1 of CY 2025, MHCC staff verified that at least three cases were reviewed for each interventionalist and, if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by CCCL.

MHCC staff concludes that SGMC complies with this standard.

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

(i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or

(ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has

performed fewer than three cases at the hospital during the relevant period, as provided in Regulation .08; or

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

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

(i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or

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

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

10.24.17.07C(4)(e) and .07D(5)(d) The external review of PCI cases and the performance review of an interventionalist referenced in Paragraphs .07C(4)(c) and .07C(4)(d) shall:

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

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

SGMC reported that, for non-primary PCI interventions, cases are reviewed semi-annually in accordance with COMAR 10.24.17.07D(5) by CCCL. In addition, all interventions are reviewed by the Medical Director of the Cardiac Catheterization Lab to ensure that primary PCI cases are reviewed as required in COMAR 10.24.17.07D(5).

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by SGMC and analyzed the ACC-NCDR CathPCI Registry data to determine the number of elective PCI cases performed by each interventionalist. Staff calculated the number of cases required to be reviewed for each interventionalist, per calendar year and compared the results of the analysis to the number of PCI cases reviewed internally and externally, per physician according to the hospital. MHCC staff observed that all physicians met the standard of ten percent, or ten cases reviewed, whichever was greater, for all reporting periods from October 2020 through March 2025.

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

MHCC staff concludes that SGMC complies with this standard.

10.24.17.07C(4)(f) and .07D(5)(e) The chief executive officer of the hospital shall certify upon request by Commission staff that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in this chapter, including those regarding internal peer review of cases and external review of cases.

SGMC submitted an affidavit from Daniel Cochran, President and CEO of SGMC, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for internal case review, multiple area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist review consistent with the Cardiac Services Chapter.

Staff Analysis and Conclusion

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

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

(i) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.

(ii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

The hospital reports that quality issues that pertain to patients undergoing PCI are discussed at its monthly CVCOE meeting, which serves as its multiple care area group meeting, for which the hospital provided minutes to MHCC. Internal peer review of cardiac cases is coordinated by the Quality Department, and the minutes from the peer review meeting are in turn submitted to the

Professional Practice Evaluation Committee (PPEC), with individual case reviews performed by the PPEC as circumstances dictate. Practice concerns identified through the internal peer review are referred to the appropriate clinical departments. No cases were referred for PPEC review or resulted in corrective actions or plans during the hospital's Certificate of Ongoing Performance review period.

During the review period, the hospital conducted performance improvement projects to improve care delivered to patients receiving PCI. Projects included decreasing Interventional Cardiologist arrival times for primary PCI, decreasing the time from patient arrival at the hospital to arrival in the catheterization lab for primary PCI, and decreasing the time to first device activation. The hospital was successful in decreasing the times for all of those measures.

Staff Analysis and Conclusion

MHCC staff reviewed the CVCOE meeting minutes and other information provided by the hospital. SGMC has undertaken quality assurance initiatives during the review period focused on ensuring appropriateness of elective interventions, as well as decreasing interventionalists' arrival times for primary PCI, decreasing door-to-catheterization lab time, and decreasing time to first device activation. MHCC staff concludes that the hospital complies with this standard.

Patient Outcome Measures

10.24.17.07D(6)(a) A primary PCI program shall meet all performance standards established in statute or in State regulations.

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

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

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

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

10.24.17.07C(5)(a) An elective PCI program shall meet all performance standards established in statute or 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 a reporting period, then the statewide median in-hospital risk-adjusted mortality rate for elective PCI cases will be used as a second benchmark.

SGMC submitted adjusted mortality rates by rolling 12-month reporting period, for 2019 Q2 through 2024 Q4, as shown in Table 6.

Table 6. SGMC Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI Hospital AMR	STEMI 95% CI	STEMI National AMR	STEMI Meets MHCC Standards	Non-STEMI Hospital AMR	Non-STEMI 95% CI	Non-STEMI National AMR	Non-STEMI Meets MHCC Standards
2024q1–2024q4	0.78	[0.02, 4.28]	0.74	Yes	0.81	[0.10, 2.88]	1.95	Yes
2023q4–2024q3	0.00	[0.00, 3.29]	0.75	Yes	1.35	[0.28, 3.89]	1.97	Yes
2023q3–2024q2	0.00	[0.00, 2.62]	0.78	Yes	1.29	[0.27, 3.72]	1.99	Yes
2023q2–2024q1	0.00	[0.00, 2.56]	0.79	Yes	1.52	[0.50, 3.49]	2.00	Yes
2023q1–2023q4	0.00	[0.00, 3.03]	1.88	Yes	2.01	[0.82, 4.07]	1.99	Yes
2022q4–2023q3	0.00	[0.00, 2.73]	1.91	Yes	2.21	[0.82, 4.71]	2.02	Yes
2022q3–2023q2	0.00	[0.00, 2.80]	1.89	Yes	2.70	[1.00, 5.75]	2.02	Yes
2022q2–2023q1	0.00	[0.00, 2.68]	1.89	Yes	1.92	[0.53, 4.80]	2.05	Yes
2022q1–2022q4	1.14	[0.14, 4.03]	2.00	Yes	1.10	[0.23, 3.13]	2.14	Yes
2021q4–2022q3	1.35	[0.16, 4.75]	2.11	Yes	1.28	[0.35, 3.20]	2.20	Yes
2021q3–2022q2	1.30	[0.16, 4.60]	2.18	Yes	0.91	[0.19, 2.59]	2.26	Yes
2021q2–2022q1	2.23	[0.61, 5.57]	2.19	Yes	1.64	[0.54, 3.74]	2.25	Yes
2021q1–2021q4	2.27	[0.47, 6.46]	2.17	Yes	1.51	[0.41, 3.76]	2.23	Yes
2020q4–2021q3	1.33	[0.16, 4.72]	2.18	Yes	2.81	[0.77, 6.97]	2.23	Yes
2020q3–2021q2	11.09	[5.86, 18.61]	7.51	Yes	1.04	[0.13, 3.68]	1.18	Yes
2020q2–2021q1	11.38	[6.02, 19.03]	7.55	Yes	0.00	[0.00, 2.92]	1.21	Yes
2020q1–2020q4	7.08	[3.30, 12.97]	6.92	Yes	0.00	[0.00, 2.69]	1.13	Yes

Reporting Period	STEMI Hospital AMR	STEMI 95% CI	STEMI National AMR	STEMI Meets MHCC Standards	Non-STEMI Hospital AMR	Non-STEMI 95% CI	Non-STEMI National AMR	Non-STEMI Meets MHCC Standards
2019q4–2020q3	7.24	[3.69, 12.48]	6.37	Yes	NR	[0.00, 2.68]	1.06	Yes
2019q3–2020q2	4.48	[1.83, 8.96]	6.06	Yes	NR	[0.00, 2.79]	1.00	Yes
2019q2–2020q1	3.83	[1.42, 8.09]	5.99	Yes	NR	[0.00, 2.54]	0.95	Yes

Source: MHCC staff compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data registry for PCI cases performed between January 2020 and December 2024.

Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval includes the national benchmark or indicates statistically significantly better performance than the national benchmark for ST-elevated myocardial infarction (STEMI) or non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs significantly worse than the national benchmark for STEMI or non-STEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEMI and non-STEMI cases for each reporting period.

Staff Analysis and Conclusion

As shown in Table 6, MHCC staff compiled the results from SGMC's quarterly reports from the ACC-NCDR CathPCI Registry for STEMI and non-STEMI PCI cases performed between March 2019 and December 2024. MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period for either STEMI or non-STEMI patients because the national benchmark fell within the 95 percent confidence interval for SGMC in all 12-month reporting periods between March 2019 and December 2024, when an adjusted mortality rate was reported.

MHCC staff concludes that SGMC meets the benchmark for both STEMI and non-STEMI cases and complies with this standard.

Physician Resources

10.24.17.07D(7)(a) Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24-month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight quarter basis and report the results to the Commission on a quarterly basis.

SGMC submitted information on the volume of primary PCI cases at SGMC and other hospitals, by physician and quarter, for the period from CY 2020 through CY 2024 for Drs. Chen, Finn, Friedman, Ghosh, Patel, Reddy, Wang, and Trujillo. Each interventionalist signed and dated an affidavit affirming under penalty of perjury that the information provided is true and correct to the best of their knowledge. The signed affidavits indicate that nearly every physician performed at least 50 PCI procedures over the 24-month period ending Q4 of CY 2024. The exception was Dr. Friedman, who in CY 2022 and CY 2023 performed fewer than 50 procedures annually, averaged over a 24-month period. The hospital attributed this to an increase in Dr. Friedman's administrative duties during this time; each of the PCI cases he performed during that timeframe was externally reviewed. This means that every PCI case performed in CYs 2022 and 2023 were evaluated by a blinded external interventional cardiologist who determined that quality standards were met. These standards included appropriateness; proper diagnosis of acute coronary syndrome; PCI success rate; complication rate; and consideration for alternative revascularization strategies.

Staff Analysis and Conclusion

MHCC staff reviewed the physician volumes reported by SGMC and analyzed data from the ACC-NCDR CathPCI. Staff confirmed that nearly every interventionalist who performed primary PCI services at SGMC from CY 2020 through CY 2024 performed a minimum of 50 procedures annually, averaged over a 24-month period, except for one physician in CYs 2022 and 2023. During the time when the physician missed the minimum volume requirement, each PCI case was externally reviewed, which provided an additional safeguard that quality standards were met in each case. Typically, external reviews are required for a proportion of a physician's elective PCI cases; in this situation, the review was applied to all cases, both primary and elective. All other

physicians met the standard during the time when it applied; therefore, MHCC staff recommends the finding that SGMC 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 the Commission. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Staff Analysis and Conclusion

MHCC staff's analysis showed that nearly all interventionalists at SGMC performed greater than 50 PCI procedures annually, averaged over a 24-month period, when that requirement applied. One physician did not meet this standard for CY 2022 and CY 2023, due to an increase in the physician's administrative duties during that time, according to the hospital. All of the physician's cases within that 24-month time period were externally reviewed and reported to the Commission. MHCC staff concludes that the hospital meets this standard.

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

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

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

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

Staff Analysis and Conclusion

During the review period, no physician took a leave of absence. Therefore, this standard does not apply to SGMC.

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.

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

SGMC submitted a signed and dated statement from CCL Medical Director, Dr. Dennis

Friedman, dated January 27, 2025, acknowledging that each physician performing primary PCI at the hospital is board-certified in interventional cardiology or exempt from this requirement. To be exempt from this requirement, the physician must have performed interventional procedures prior to 1998 and did not seek board certification before 2003, or the physician completed a fellowship in interventional cardiology less than three years ago.

Staff Analysis and Conclusion

MHCC staff reviewed the statement provided and concludes that SGMC meets this standard.

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

SGMC submitted signed and dated attestations from Drs. Michael Chen, Aloke Finn, Dennis Friedman, Bobby Ghosh, Rajeev Patel, and Sreeker Reddy stating that each has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC staff reviewed the attestations provided and determined that SGMC complies with this standard.

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

SGMC submitted a letter dated January 27, 2025, signed by Dr. Dennis Friedman, CCL Medical Director, acknowledging that each physician who performed primary PCI services from the start of the performance review period through the date of the letter has participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. The hospital also submitted the on-call schedule for March 2025.

Staff Analysis and Conclusion

MHCC staff reviewed the letter from Dr. Friedman and the on-call schedule for March 2025. All interventionalists who perform primary PCI at SGMC were included in the on-call schedule provided.

MHCC staff concludes that the hospital complies with this standard.

<u>Volume</u>

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

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

SGMC provided the total annual PCI case volume for each CY between 2020 and 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI case volume information submitted by SGMC. This data shows that the hospital consistently exceeds the target volume of 200 PCI cases annually. MHCC staff also calculated the volume of PCI cases, using the ACC-NCDR CathPCI Registry data for the period from CY 2020 to CY 2024. This analysis, shown in Table 7, indicates that SGMC performed between 254 and 337 PCI cases each year between CY 2020 and CY 2024.

Table 7. SGMC's
Total PCI Volume, CY 2020 – CY 2024

Year	Number of PCI Cases
CY 2020	254
CY 2021	262
CY 2022	292
CY 2023	312
CY 2024	337

Source: MHCC staff's analysis of ACC-NCDR CathPCI data \ Registry (CY 2020 – CY 2024).

MHCC staff concludes that SGMC 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.

SGMC provided the number of primary PCI cases that were completed at the hospital from CY 2020 through CY 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the number of primary PCI cases completed at SGMC and analyzed the ACC-NCDR CathPCI Registry data to calculate the volume of primary PCI cases performed at SGMC from CY 2020 through CY 2024. As shown in Table 8, the primary PCI volume ranged from 126 to 164 cases each year.

Table 8. Primary PCI Volume
at SGMC, CY 2020 – CY 2024

Year	Number of Primary PCI Cases
CY 2020	137
CY 2021	147
CY 2022	155
CY 2023	126
CY 2024	164

Source: MHCC staff's analysis of the ACC-NCDR CathPCI registry
Data, CY 2020 – CY 2024.

Because SGMC exceeded the threshold of 49 primary PCI cases annually during the review period, 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.

SGMC provided the number of primary PCI cases completed, by location and interventionist, for each quarter, from CY 2020 through CY 2024. The documentation submitted showed that nearly every physician performed at least 11 primary PCI cases annually during the review period. Exceptions included 2023 procedure counts for Drs. Friedman (3, due to an increase in administrative duties) and Reddy (9, in Q3-Q4 only).

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by SGMC and analyzed the ACC-NCDR CathPCI Registry data to verify the number of primary PCI cases performed by each interventional cardiologist between CY 2020 and CY 2024. MHCC staff determined that in most years, each interventionalist performed at least 11 primary PCI cases annually during the review period. In the case of the two exceptions (Drs. Friedman and Reddy in 2023), the physicians resumed operating at the target volume the following year. Additionally, the 11-case volume is a target, and not a mandate. MHCC staff recommends the Commission find that SGMC is in compliance with this standard.

Patient Selection

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

SGMC reports that based on internal and external reviews of elective PCI cases, no patients received elective PCI services inappropriately at the hospital.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from the Cardiac Community Core Lab (CCCL) for October 2020 through March 2025 and determined that no cases were identified as rarely appropriate across all angiographic, clinical, and AHA/ACC appropriate use criteria.

MHCC staff concludes that SGMC 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.

The hospital responded that there were no patients who received thrombolytic therapy that subsequently failed during the review period. Additionally, SGMC stated that, based on internal and external review of primary PCI cases, no patients received primary PCI procedures inappropriately.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR Cath PCI Registry data and noted that between CY 2019 and CY 2024, there were no patients who received thrombolytic therapy. In addition, the hospital's ACC-NCDR reports for the period reviewed indicate that no PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate.

MHCC staff concludes that SGMC complies with this standard.

RECOMMENDATION

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