IN THE MATTER OF	*	**BEFORE THE**
MEDSTAR SOUTHERN MARYLAND	*	**MARYLAND**
HOSPITAL CENTER	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 19-16-CP027	*	

* *

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

April 18, 2024

I. INTRODUCTION

A. Background

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

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

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

The Commission engaged in extensive discussion with the CAG, comprised of national and regional experts, who, along with stakeholders provided recommendations for the new regulations. 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 new Cardiac Surgery Chapter changed the benchmark used to evaluate hospitals' risk-adjusted mortality rates for PCI programs. 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 (non-primary) PCI services, for a given number of years specified by the Commission that cannot exceed five years. At the end of the period, the hospital must renew its authorization to provide PCI services by demonstrating that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance.

B. Applicant

MedStar Southern Maryland Hospital Center

MedStar Southern Maryland Hospital Center (MSMHC) is a 197-bed general hospital located in Clinton, Maryland (Prince George's County). MSMHC does not have a cardiac surgery program on site.

Health Planning Region

The Cardiac Surgery Chapter defines four health planning regions for adult cardiac services. MSMHC is in the Metropolitan Washington health planning region. This region includes Calvert, Charles, Frederick, Montgomery, Prince George's and Saint Mary's Counties and the District of Columbia. Seven hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; all the other programs provide both primary and elective PCI services. Three of the seven hospitals also provide cardiac surgery services.

C. Staff Recommendation

MHCC staff recommends that the Commission approve MSMHC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services with several conditions regarding auditing of documentation in PCI cases and a condition regarding attendance by technicians at case review meetings held at least every other month. A description of the information submitted by MSMHC and MHCC staff's analysis and recommendations follows.

II. PROCEDURAL HISTORY

MSMHC established its primary PCI program under a waiver prior to August 18, 2014, and as provided in COMAR 10.24.07A(2) and (3), the hospital may continue to provide primary and elective PCI services when it has not yet completed a scheduled review to consider the grant of its first Certificate of Ongoing Performance. MSMHC filed a Certificate of Ongoing Performance application on September 21, 2019, in accordance with the review schedule determined by the Commission. MHCC staff reviewed the application and requested additional information on September 28, 2020, January 14, 2021, and July 28, 2023. MHCC staff received additional information on October 26, 2020, January 22, 2021, January 29, 2021, October 3, 2023, and March 18, 2024. The gaps in requesting additional information were due to a lack of MHCC staff resources in late 2019 and 2020, and the time it took to complete a focused review. MHCC

staff concluded that updated information for the hospital's application should be requested due to the amount of time that had passed since the hospital first submitted an application.

MHCC staff also requested and received information as part of a focused review that was conducted, based on the hospital's mortality rates for ST Elevated Myocardial Infarction (STEMI) PCI cases in the 12-month reporting periods ending on December 31, 2019, June 30, 2020, and September 30, 2020 (Table 7). The focused review report was finalized and provided to MSMHC on September 6, 2023, and MHCC staff received an initial response from MSMHC on September 15, 2023, that addressed the quality concerns raised in the focused review. Following a meeting between MSMHC and MHCC staff on November 8, 2023, MSMHC provided additional information to MHCC staff on November 28, 2023, regarding steps it had taken and would take to address issues raised regarding documentation in the cases reviewed. Based on MSMHC's explanation of actions taken in response to quality issues identified in the focused review and the hospital's subsequent performance on mortality metrics, MHCC staff concluded a plan of correction was not required to address the hospital's mortality rate.

III. 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 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.

MSMHC responded that the hospital is not aware of any deficiencies in the data collection process. MSMHC stated that in 2018, the hospital transitioned from direct data entry to the ACC-NCDR CathPCI registry to using a third-party vendor for submission of information, which resulted in submission delays. MSMHC noted that appropriate notifications were given to the Maryland Institute for Emergency Medical Services Systems and MHCC staff. As of the date of this report, data submission to the ACC–NCDR CathPCI registry and MHCC is current.

Staff Analysis and Conclusion

MSMHC has complied with the submission of ACC-NCDR CathPCI data to MHCC in accordance with the established schedule. There are no reporting periods for which the hospital's performance is unavailable due to a failure to meet deadline for submission to the ACC-NCDR CathPCI registry.

MHCC staff concludes that MSMHC 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.

MSMHC responded that there were no times in which cardiac catheterization laboratory (CCL) downtime prevented delivery of PCI services. MSMHC explained that the hospital operates two interventional and one electrophysiology suite. MSMHC noted that both CCL 1 and CCL 2 remain ready to always accept patients, with the electrophysiology suite available for use if both CCL 1 and 2 are in use. MSMHC advised that equipment logs of downtime by CCL for calendar year (CY) 2015 through 2019 were not available because the hospital was not maintaining tracking. However, when MSMHC submitted updated data in September 2023, the hospital provided a log with the downtimes for each CCL from January 2021 through May 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the downtime logs provided by the hospital. There was only one day when both CCL 1 and CCL 2 had downtime on the same day, June 16, 2022. It is unclear if the downtime overlapped, but the amount of downtime for one room was only 11 minutes in one instance and three minutes in another instance that day, which is brief.

MHCC staff concludes that MSMHC 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 DTB times for transfer cases and evaluate areas for improvement.

MSMHC provided a signed statement, dated August 7, 2023, from Stephen Michaels, M.D., the President for MSMHC, stating that MSMHC commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer patients, for at least 75% of appropriate patients. Furthermore, MSMHC commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement.

MSMHC provided DTB times from January 2015 through March 2023 for non-transfer cases, as shown below in Table 2a.

Table 2a: MSMHC Reported Compliance with DTB Time Standard by Quarter for Non-Transfer Cases, January 2015 - March 2023

Quarter	Non-Transfer Primary PCI Volume	Number of Cases with DTB <= 90 Minutes	Percent of Cases with DTB <=90 Minutes
2015 Q1	41	33	80.5%
2015 Q2	40	35	87.5%
2015 Q3	25	23	92.0%
2015 Q4	27	20	74.1%
2016 Q1	22	20	90.1%
2016 Q2	25	21	84.0%
2016 Q3	23	19	82.6%
2016 Q4	28	27	96.4%
2017 Q1	29	25	86.2%
2017 Q2	33	29	87.9%
2017 Q3	35	33	94.3%
2017 Q4	19	17	89.5%
2018 Q1	36	32	88.9%
2018 Q2	35	32	91.4%
2018 Q3	25	20	80.0%
2018 Q4	34	34	100.0%
2019 Q1	22	20	90.1%
2019 Q2	28	23	82.1%
2019 Q3	29	24	82.8%
2019 Q4	43	32	74.4%
2020 Q1	37	30	81.1%
2020 Q2	31	28	90.3%
2020 Q3	30	26	86.7%
2020 Q4	35	29	82.9%
2021 Q1	32	31	96.9%
2021 Q2	33	24	72.7%
2021 Q3	25	22	88.0%
2021 Q4	24	22	91.7%
2022 Q1	25	21	84.0%
2022 Q2	30	19	63.3%
2022 Q3	26	22	84.6%
2022 Q4	37	36	97.3%
2023 Q1	24	22	91.7%

Source: MSMHC supplementary data submitted to MHCC staff in January 2021 and September 2023.

MSMHC also provided information on its performance on DTB times for transfer cases, as shown in Table 2b. MSMHC explained that a significant number of the hospital's referrals are from rural neighborhoods, which has affected transport times. MSMHC held meetings with MedStar St. Mary's Hospital and MedStar Transport and developed an action plan to help improve the transport process. A key recommendation was to use flight instead of ground transportation for patients requiring primary PCI.

Table 2b: MSMHC Reported DTB Performance by Quarter for Transfer Cases, January 2015 - March 2023

Quarter	Transfer Primary PCI Volume	Cases With DTB <= 120 Minutes	Percent of Cases with DTB <=120 Minutes
2015 Q1	0	0	n/a
2015 Q2	2	1	50.0%
2015 Q3	4	2	50.0%
2015 Q4	1	1	100.0%
2016 Q1	3	0	0%
2016 Q2	5	1	20.0%
2016 Q3	1	0	0%
2016 Q4	0	0	n/a
2017 Q1	2	1	50.0%
2017 Q2	2	0	0%
2017 Q3	3	2	66.7%
2017 Q4	1	0	0%
2018 Q1	0	0	n/a
2018 Q2	2	0	0%
2018 Q3	1	1	100.0%
2018 Q4	4	0	0%
2019 Q1	9	1	11.1%
2019 Q2	9	4	44.4%
2019 Q3	10	2	20.0%
2019 Q4	3	2	66.7%
2020 Q1	4	0	0%
2020 Q2	5	3	60.0%
2020 Q3	6	3	50.0%
2020 Q4	4	0	0%
2021 Q1	4	0	0%
2021 Q2	6	4	66.6%
2021 Q3	3	1	33.3%
2021 Q4	6	1	16.7%
2022 Q1	5	0	0%
2022 Q2	5	0	0%
2022 Q3	7	2	28.6%
2022 Q4	7	2	28.6%
2023 Q1	4	1	25.0%

Source: Supplementary data submitted by MSMHC in January 2021 and September 2023.
Note: n/a means not applicable.

Staff Analysis and Conclusion

MHCC staff reviewed the information reported by MSMHC which indicates that the quarterly percentage of non-transfer primary PCI patients with a DTB time of 90 minutes or less ranged from 63% to 97% between January 2015 and March 2023. Staff's analysis of DTB times, as shown in Table 3a, indicates that the DTB standard was not met in eight of the thirty-two quarters between 2015 and 2022.

Table 3a: MSMHC Compliance with DTB Standard by Quarter for Non-Transfer Primary PCI Cases, January 2015 – June 2022

Time Period	Total Primary PCI Volume	Number of Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes
2015 Q1	38	28	73.7%
2015 Q2	39	31	79.5%
2015 Q3	20	20	100.0%
2015 Q4	25	20	80.0%
2016 Q1	21	17	81.0%
2016 Q2	21	18	85.7%
2016 Q3	22	18	81.8%
2016 Q4	27	26	96.3%
2017 Q1	25	22	88.0%
2017 Q2	28	25	89.3%
2017 Q3	31	29	93.5%
2017 Q4	16	14	87.5%
2018 Q1	31	27	87.1%
2018 Q2	32	29	90.6%
2018 Q3	23	18	78.3%
2018 Q4	33	31	93.9%
2019 Q1	19	19	100.0%
2019 Q2	27	22	81.5%
2019 Q3	29	21	72.4%
2019 Q4	40	27	67.5%
2020 Q1	41	28	68.3%
2020 Q2	35	26	74.3%
2020 Q3	30	26	86.7%
2020 Q4	34	28	82.4%
2021 Q1	37	32	86.5%
2021 Q2	34	23	67.6%
2021 Q3	30	22	73.3%
2021 Q4	24	22	91.7%
2022 Q1	24	19	79.2%
2022 Q2	23	17	73.9%
2022 Q3	28	21	75.0%
2022 Q4	41	35	85.4%

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2015 - CY 2022.

Since failure to meet this standard in each quarter may be due to factors outside of a hospital's control, MHCC staff also considers a hospital's performance over longer time periods. Over rolling eight quarter periods, MSMHC complied with this standard, with between 75.4% and 90.1% of primary PCI cases meeting the DTB time standard, as shown in Table 3b.

Table 3b: MSMHC Non-Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period, CY 2015 – CY 2022

	Quarter			Rolling 8-Quarters		
Time Period	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes
2015 Q1	38	28	73.7%			
2015 Q2	39	31	79.5%			
2015 Q3	20	20	100.0%			
2015 Q4	25	20	80.0%			
2016 Q1	21	17	81.0%			
2016 Q2	21	18	85.7%			
2016 Q3	22	18	81.8%			
2016 Q4	27	26	96.3%	213	178	83.6%
2017 Q1	25	22	88.0%	200	172	86.0%
2017 Q2	28	25	89.3%	189	166	87.8%
2017 Q3	31	29	93.5%	200	175	87.5%
2017 Q4	16	14	87.5%	200	172	86.0%
2018 Q1	31	27	87.1%	189	166	87.8%
2018 Q2	32	29	90.6%	200	175	87.5%
2018 Q3	23	18	78.3%	191	169	88.5%
2018 Q4	33	31	93.9%	219	195	89.0%
2019 Q1	19	19	100.0%	213	192	90.1%
2019 Q2	27	22	81.5%	212	189	89.2%
2019 Q3	29	21	72.4%	210	181	86.2%
2019 Q4	40	27	67.5%	234	194	82.9%
2020 Q1	41	28	68.3%	244	195	79.9%
2020 Q2	35	26	74.3%	247	192	77.7%
2020 Q3	30	26	86.7%	254	200	78.7%
2020 Q4	34	28	82.4%	255	197	77.3%
2021 Q1	37	32	86.5%	273	210	76.9%
2021 Q2	34	23	67.6%	280	211	75.4%
2021 Q3	30	22	73.3%	281	212	75.4%
2021 Q4	24	22	91.7%	265	207	78.1%
2022 Q1	24	19	79.2%	248	198	79.8%
2022 Q2	23	17	73.9%	236	189	80.1%
2022 Q3	28	21	75.0%	234	184	78.6%
2022 Q4	41	35	85.4%	241	191	79.3%

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2015 - CY 2022.

MHCC staff concludes that MSMHC complies with this standard.

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

As shown in Table 4a, MSMHC provided the number of physicians, nurses, and technicians who can provide cardiac catheterization services to acute myocardial infarction patients as of September 13, 2023.

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

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	2 FT, 3 PT, 1 after hours PRN call	
Nurse	11 (FTE)	1 = S; 11 = C; 11 = M
Technician	5 (FTE)	5 = S; 5 = C; 5 = M

Source: September 2023 Supplementary data submitted by MSMHC
*Scrub (S), circulate (C), monitor (M).

Staff Analysis and Conclusion

MHCC staff compared the reported staffing levels at MSMHC to the staffing levels for programs at three other hospitals with similar PCI case volume. A comparison of volume and staffing levels for MSMHC, UPMC Western Maryland, Adventist HealthCare (AHC) Shady Grove, and University of Maryland Baltimore Washington Medical Center (UM BWMC), is shown in Table 4b. UM BWMC and MSMHC have a similar volume of PCI cases, and the FTEs for technical staff are similar for both hospitals, but MSMHC reported a much higher number of nurses FTEs, 11 FTEs compared to six for UM BWMC. Although MSMHC reports five interventionalists, it also noted that three are part-time staff. MSMHC also has many more nurse FTEs than AHC, almost twice as many nurses, even though the PCI volume for AHC is only 20% higher than MSMHC. Both hospitals have the same number of technicians. UPMC Western Maryland and MSMHC have a similar PCI case volume, but UPMC Western Maryland has fewer interventionalists than MSMHC. UPMC Western Maryland has a greater number of technician FTEs than MSMHC, but the combined FTEs for nurses and technicians together is closest to MSMHC compared to the other two hospitals.

Table 4b: CCL Staffing for MSMHC and Other Select PCI Programs

Program - Year Reported	Total PCI Cases	Interventionalists	Nurse FTEs	Technician FTEs
MSMHC - 2023	318	5	11.0	5.0
UM BWMC – 2019	315	3	6.0	6.0
AHC Shady Grove - 2019	263	5	6.0	5.0
UPMC Western MD - 2019	348	3	6.1	7.3

Sources: MSMHC's September 2023 supplemental data submission and MSMHC's PCI volume from ACC-NCDR CathPCI registry report for period ending September 30, 2023; University of Maryland's Baltimore-Washington Medical Center's March 2019 PCI COP application and March 2020 supplemental data submission; AHC Shady Grove's September 2019 PCI COP application and application addendum March 23, 2021; and UPMC Western MD's June 2019 PCI COP application.

Based on this analysis of the number of staff reported at other hospitals with comparable PCI volumes, MHCC staff concludes that there are adequate nursing and technical staff to provide services 24 hours per day, seven days per week.

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.

MSMHC provided a signed letter of commitment, dated August 7, 2023, from Stephen Michaels, M.D., President, Medstar Southern Maryland Hospital Center, acknowledging that

MSMHC will provide primary PCI services in accordance with the requirements established by the Commission.

Staff Analysis and Conclusion

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

MSMHC provided a list of the staff involved with these functions. As shown in Table 5, there are two positions with some responsibility for data management and quality, and a total of three FTEs.

Table 5: MSMHC Data Management and Quality Improvement Staff FTEs

Position/ Title	FTEs
Director, Cardiology Service Line	1
Nurse Data Abstractors	2
Total	3

Source: MSMHC September 2023 supplemental data submission, p5.

Staff Analysis and Conclusion

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

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

Brian C. Case, M.D., was appointed as the medical director of the CCL at MSMHC in July 2023. Dr. Case is responsible for the elements listed in the standard. In addition, Dr. Case provides leadership and mentoring to the other medical professionals working in the CCL.

Staff Analysis and Conclusion

MHCC staff concludes that MSMHC complies with this standard.

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

MSMHC provided a list of the continuing educational programs and activities in which staff in the CCL and critical care unit participated between 2019 and 2022. MSMHC stated that

annual competencies are assigned through the human resources department. Additionally, CCL staff have hands-on specific competencies for the CCL that must be completed annually. MSMHC also stated that all competencies are tracked by the learning management system, which records and monitors staff compliance.

Staff Analysis and Conclusion

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

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

Stephen T. Michaels, M.D., MSMHC President, signed a Memoranda of Understanding with both MedStar Union Memorial Hospital (Union Memorial) and Medstar Washington Hospital Center (Medstar Washington) wherein Union Memorial and Medstar Washington agree to receive unconditionally, patients for any required additional care including emergent or elective cardiac surgery or PCI from MSMHC.

Staff Analysis and Conclusion

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

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

MSMHC provided a signed agreement, dated August 30, 2023, between MSMHC and Medstar Transport. The agreement states that Medstar Transport agrees to respond to the sending hospital within 30 minutes for patients in need of emergency transport services.

Staff Analysis and Conclusion

MHCC staff reviewed the August 2023 agreement and concludes that the transport agreement is acceptable and that MSMHC complies with this standard.

Quality

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

MSMHC reported that its Department of Interventional Cardiology held Mortality and Morbidity meetings every month from January 2015 through 2019 when the frequency was switched to every other month. The hospital also provided attendance records for these meetings, from January 2015 through May 2023, which indicate that the attendees include interventional cardiologists, electrophysiologists, nurses, hospital leadership, data abstractors and representatives from the quality/patient safety team.

Staff Analysis and Conclusion

The documentation submitted by the hospital shows that meetings were held every other month as required and were attended by physicians and nurses, as required. However, the attendance sheets do not show that technicians attended these meetings.

Staff recommends that Staff recommends that the Commission find that MSMHC complies with this standard and include the following condition on the Certificate of Ongoing Performance:

> MSMHC shall hold bi-monthly interventional case review meetings that include technicians, as required in COMAR 10.24.17.07D(5)(a) and shall submit to Commission staff attendance lists for each of these meetings held between May and October by Dec 1 of each year and attendance lists for meetings held between November and April by June 1 of each year until at least December 1, 2025. After this date, the Executive Director may release MSMHC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

(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.

MSMHC reported that it held monthly "*Chest Pain / PCI Case Review / Statistics*" meetings between January 2015 and May 2023 except for April 2020. The hospital explained that in that month no meeting was held in compliance with the hospital's COVID-19 policy. MSMHC submitted attendance records for all but six meetings; the hospital could not provide these records for one meeting in 2021 and five meetings in 2022. MSMHC explained that the attendance records are probably missing due to a software malfunction. The attendance records indicate that meetings were attended by cardiologists, nurses, data abstractors, ICU staff, and representatives from the quality/patient safety team.

Staff Analysis and Conclusion

The hospital was able to provide documentation for most meetings and meetings were attended by physician and nursing leadership, as required. Based on the statements made by MSMHC in its application and supplemental submissions, and the attendance records submitted,

MHCC staff recommends that the Commission find that MSMHC 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.

MSMHC has submitted copies of the external review reports for PCI cases performed between January 2015 and December 2021 by Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ).

Staff Analysis and Conclusion

MHCC 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 6. As shown in Table 6, although only 5% of cases are required to be reviewed externally, between 9.1% and 20.1% of cases were reviewed each year.

Table 6: MSMHC External Review of PCI Cases by Year, CY 2016 - CY 2021

Calendar Year	Elective PCI Cases Forwarded to MACPAQ	Number of Cases Reviewed	Percentage of Cases Reviewed	Timing of external reviews	Meets Standard*
2016	200	37	18.5%	Semi-annual	Yes
2017	215	31	14.4%	Semi-annual	Yes
2018	285	27	9.4%	Semi-annual	Yes
2019	263	24	9.1%	Semi-annual	Yes
2020	190	25	13.1%	Semi-annual	Yes
2021	178	37	20.1%	Semi-annual	Yes

Source: MHCC staff analysis of MACPAQ reports; and MHCC staff analysis of 2015 NCDR CathPCI data.
*Each semiannual review cycle included 3 cases per physician or all cases if the interventionalist performed fewer than three cases during the review periods.

For the period between January 2016 and June 2021, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that at least five percent of elective PCI cases were reviewed and the required minimum number of cases per physician. A minimum number of three cases per interventionalist was not specified in COMAR 10.24.17 until late 2015. Staff verified the appropriate percentage of cases was reviewed in 2015 overall for the year. For 2015, the first external review of cases for the hospital included eight months of cases and the second review included four months. The second review included only one or two cases per physician, which would be acceptable, if for the next eight months a total of six cases were reviewed per physician. However, MHCC staff cannot readily confirm this, given the hospital subsequently had reviews for six-month periods.

MHCC staff recommends the Commission find that MSMHC 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 the external reviews described above, MSMHC stated that the internal review of cases with morbidity and mortality conducted during closed sessions, are administered in accordance with the Phase of Care Mortality Analysis form provided by the Cleveland Clinic Alliance. MSMHC stated that ten percent of the total PCI cases are reviewed during the monthly PCI meetings. Cases are also selected for review using multiple review indicators including internal incident reporting and PCI activation outcomes. The internal review process includes a comprehensive review of all the available components of patients' medical records including but not limited to, angiographic images, diagnostic studies, and medical test results. Cases are routinely reviewed at bimonthly peer review meetings.

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 provide 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] This guidance continues to be applicable to case reviews.

The documentation and information provided by MSMHC indicates that MSMHC reviewed at least 10% of cases interventionalist for CY 2016 through CY 2021. The external reviews conducted by MACPAQ for PCI cases performed from January 2015 through December 2021 meet the requirements of COMAR 10.24.17.07D(5)(c) 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.

Based on the documentation and information provided, MHCC staff concludes that MSMHC meets the standards in both COMAR 10.24.17.07D(5)(c) and 10.24.17.07D(5)(d).

10.24.17.07D(5)(e) and C(4)(f). 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.

[1] https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

MSMHC submitted an affidavit from its president, Dr. Stephen Michaels, dated March 12, 2024, certifying 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.

Staff Analysis and Conclusion

MHCC staff concludes that MSMHC complies with this standard.

10.24.17.07C(4)(g) and 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.

In its original, 2019, application, MSMHC provided descriptions of two quality improvement practices. The first was the hospital's use of a Cerner product (MedConnect) to identify provider deficiencies in its electronic medical record system as well as a robust tracking and follow-up process, led by Health Information Management staff, to track and fix those deficiencies.

The second quality improvement practice described by the hospital is its protocol for reviewing PCI cases. MSMHC submitted meeting minutes from its PCI Performance Committee for 2015 through 2022. This committee meets monthly and reviews PCI cases. During these meetings data from previous months are reviewed, with attention to outliers and performance relative to benchmarks.

The hospital provided information on additional initiatives that it has undertaken to improve the quality of its PCI services and enhance patient outcomes. In 2021, MSMHC began using additional intravascular imaging catheters to optimize stent implantation and reduce the risk of periprocedural complications. In 2022, MSMHC's cardiac catheterization laboratory incorporated the *Abbott Corventis CoroFlow* system into the tools that it uses for invasive physiology. MSMHC explained that this platform enables cardiac catheterization laboratory staff to evaluate for coronary microvascular dysfunction, a known etiology for acute coronary syndrome (ACS) patients presenting with MINOCA (myocardial infarction with non-obstructive coronary artery disease). This additional capability allows for a more complete evaluation of patients. Finally, MSMHC noted that consistent with the most recent industry knowledge that radial access is preferable to femoral access for PCI treatment, MSMHC's rate of radial access

has continued to increase annually. Radial access reduces risks of bleeding, vascular complications, and mortality.

Additionally, MHCC staff commissioned a focused review of MSMHC's PCI program due to certain time periods in which the hospital's adjusted mortality rate (AMR) was statistically significantly worse than the national average. MHCC staff concluded that the hospital had taken appropriate action to address this issue, as described later in this report.

Another issue identified through the focused review regarding documentation is one that MHCC staff wants to validate has been successfully addressed. On November 28, 2023, MSMHC provided MHCC staff with a formal plan to address the documentation issues noted by the reviewer. MSMHC stated that by March 1, 2024, it would develop comprehensive onboarding training for all monitoring and circulating technicians and nurses to ensure that staff know the correct way to document patient care for patients undergoing cardiac catheterization procedures. In its November 28, 2023, response, MSMHC also noted that in October 2023, the hospital had initiated random monthly audits of ten PCI cases per month to assess compliance with the institution's documentation requirements. The audits were planned to cover a six-month period from October 2023 through March 2024. Finally, MSMHC stated that it would present audit data at monthly PCI meetings for leadership follow-up and report progress to the Quality, Safety and Professional Affairs Committee between November 2023 and April 15, 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the information on quality assurance activities and concludes that MSMHC complies with this standard. Staff recommends that the hospital report to MHCC staff the auditing it has completed and that additional auditing and reporting on documentation potentially be conducted. Staff recommends the following condition be included on the hospital's Certificate of Ongoing Performance to verify the hospital has improved its documentation in PCI cases:

1) Demonstrate that documentation of PCI cases accurately captures all patient care through the following:

    a) Provide MHCC staff with a copy of its revised training materials aimed at ensuring proper documentation during cardiac catheterization procedures on or before May 31, 2024.

    b) Provide MHCC staff with records of which CCL staff have undergone the revised training and the dates when the training took place on or before May 31, 2024.

    c) Provide MHCC staff with documentation of the findings from the random monthly documentation audits for October 2023 – March 2024, and actions taken to resolve problems identified through the audits on or before May 31, 2024.

d) Complete additional auditing of documentation for PCI cases after May 31, 2024, for additional six-month periods, if requested by MHCC staff, and report the results within 30 days of the end of the audit period.

Patient Outcome Measures

10.24.17.07C(5)(a). An elective PCI program shall meet all performance standards established in statute or in State regulations.

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

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

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

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

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

MSMHC's adjusted mortality rates, by rolling 12-month reporting period, for 2015 Q1 through 2023 Q3, are shown below in Table 7.

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

	STEMI				NON-STEMI			
Reporting Period	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2022q4-2023q3	*0.00	[0.00, 4.78]	*1.91	Yes	1.46	[0.18, 5.18]	2.02	Yes
2022q3-2023q2	*.0.00	[0.00, 4.63]	*1.89	Yes	1.40	[.017, 4.98]	2.02	Yes
2022q2-2023q1	*0.00	[0.00, 4.65]	*1.89	Yes	0.94	[0.02, 5.16]	2.05	Yes
2022q1-2022q4	*0.00	[0.00, 4.47]	*2.00	Yes	1.07	[0.03, 5.87]	2.14	Yes
2021q4-2022q3	*0.00	[0.00, 5.13]	*2.11	Yes	0.99	[0.03, 5.44]	2.20	Yes
2021q3-2022q2	*0.00	[0.00, 6.09]	*2.18	Yes	1.92	[0.23, 6.82]	2.26	Yes
2021q2-2022q1	*0.00	[0.00, 4.05]	*2.19	Yes	1.55	[0.19, 5.55]	2.25	Yes
2021q1-2021q4	*0.00	[0.00, 3.71]	*2.17	Yes	0.82	[0.02, 4.51]	2.23	Yes
2020q4-2021q3	*1.04	[0.03, 5.70]	*2.18	Yes	0.70	[0.02, 3.85]	2.23	Yes
2020q3-2021q2	9.17	[3.73, 18.38]	7.51	Yes	0.00	[0.00, 3.70]	1.18	Yes
2020q2-2021q1	13.21	[6.71, 22.89]	7.55	Yes	0.75	[0.02, 4.10]	1.21	Yes
2020q1-2020q4	11.76	[5.73, 21.02]	6.89	Yes	1.35	[0.16, 4.83]	1.13	Yes
2019q4-2020q3	12.47	[6.55, 21.15]	6.37	No	2.18	[0.45, 6.29]	1.06	Yes
2019q3-2020q2	11.79	[6.19, 19.99]	6.06	No	1.72	[0.35, 4.95]	1.00	Yes
2019q2-2020q1	12.12	[5.90, 21.68]	5.99	Yes	1.41	[0.17, 5.03]	0.95	Yes
2019q1-2019q4	14.01	[6.82, 24.96]	6.01	No	0.74	[0.02, 4.10]	0.95	Yes
2018q4-2019q3	11.79	[4.38, 24.96]	6.06	Yes	NR			Yes
2018q3-2019q2	9.23	[3.43, 19.49]	6.38	Yes	NR			Yes
2018q2-2019q1	7.07	[2.63, 14.94]	6.13	Yes	NR			Yes
2018q1-2018q4	5.71	[2.12, 12.06]	6.00	Yes	NR			Yes
2017q4-2018q3	7.17	[2.93, 14.26]	6.54	Yes	0.52	[0.01, 2.89]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry							
2017q2-2018q1	4.43	[0.92, 12.63]	6.91	Yes	1.35	[0.16, 4.82]	1.03	Yes

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

	STEMI				NON-STEMI			
Reporting Period	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2017q1-2017q4	5.61	[1.16, 16.00]	6.86	Yes	1.46	[0.18, 5.20]	0.99	Yes
2016q4-2017q3	5.13	[1.06, 14.66]	6.75	Yes	1.76	[0.21, 6.28]	0.98	Yes
2016q3-2017q2	6.91	[1.90, 17.21]	6.64	Yes	1.15	[0.03, 6.32]	0.95	Yes
2016q2-2017q1	9.83	[3.23, 22.23]	6.77	Yes	1.15	[0.03, 6.31]	0.97	Yes
2016q1-2016q4	8.39	[3.12, 17.62]	6.82	Yes	1.00	[0.03, 5.49]	0.95	Yes
2015q4-2016q3	9.68	[4.25, 18.36]	6.71	Yes	NR			
2015q3-2016q2	9.65	[4.50, 17.62]	6.66	Yes	NR			
2015q2-2016q1	9.66	[5.10, 16.24]	6.45	Yes	NR			
2015q1-2015q4	8.92	[4.70, 15.07]	6.26	Yes	NR			

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 2015 and March 2023.

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

*Reporting on STEMI cases in the ACC-NCDR CathPCI reports changed beginning in the period ending 2021q3; for this period and later, the performance metric excludes cases with cardiogenic shock.

Staff Analysis and Conclusion

As shown in Table 7, the hospital's adjusted mortality rate was not statistically significantly different from the national benchmark for NSTEMI cases in any reporting period from 2015 Q1 to 2023 Q3 periods because the national benchmark fell within the 95% confidence interval for MSMHC. For STEMI cases, the hospital's adjusted mortality rate was not statistically significantly different from the national benchmark in most reporting periods, except in three reporting periods. For the reporting periods ending December 31, 2019, June 30, 2020, and September 30, 2020, the hospital performed statistically significantly worse than the national average, as shown in Table 7.

The hospital's statistically significantly worse than average performance on the morality metric for STEMI cases triggered a focused review of STEMI patient deaths during those periods to evaluate the quality of care provided and whether the hospital responded appropriately to issues identified. MHCC staff contracted with an organization to provide an independent review by a board certified interventionalist. A total of eighteen cases were reviewed. The reviewer provided his conclusions about the cases, an assessment of the hospital's own peer review of the cases, and recommendations. One of the conclusions was that MSMHC needs to improve its recordkeeping for the CCL. For details regarding the focused review, Commissioners should refer to Appendix 1. This information is confidential and protected by the Maryland Health Care Commission's status as a medical review committee.

The focused review report was provided to MSMHC on September 6, 2023. The hospital initially responded on September 15, 2023. MSMHC first emphasized that its PCI program had improved substantially for several metrics, since the time periods incorporated in the focused review (January 2019 – September 2020), including with respect to mortality. The hospital also explained why it disagreed with the reviewer's conclusions in some cases. MHCC staff and MSMHC met to discuss the focused review on November 8, 2023.

Considering the hospital's performance on mortality metrics for the 12-month periods ending 2020 Q3 through 2023 Q3, MHCC staff recommends that the Commission find that MSMHC meets this standard.

<u>Physician Resources</u>

10.24.17.07D(7)(a) and 10.24.17.07C(6)(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.

MSMHC submitted information on the volume of primary and elective PCI cases at MSMHC and other hospitals, by physician and quarter, for January 2015 through July 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the reported physician volumes for the interventionalists who performed primary PCI services at MSMHC from 2015 through 2023 and determined that each interventionalist performed at least 50 PCI procedures annually on average, even in years when the standard was waived. The requirement to perform at least 50 PCI procedures annually average over a 24-month period was waived for 2020 and 2021, due to the COVID-19 pandemic.[2]

MHCC staff concludes that MSMHC 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.

Staff Analysis and Conclusion

This regulation is not applicable since MSMHC's physicians perform 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.

Staff Analysis and Conclusion

This standard does not apply to MSMHC.

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].

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[2] https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/documents/MHCC%20bulletin_cardiac_covid19_20200331.pdf

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

MSMHC submitted a signed and dated statement from Dr. William O. Suddath, Medical Director of CCL, acknowledging that all physicians performing primary PCI services at MSMHC are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that MSMHC meets these standards based on the letter provided.

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.

MSMHC submitted signed and dated attestations from Drs. Case, Samtani, Leiboff, Temesgan and Addala stating that each physician has completed a minimum of 30 hours of continuing medical education credits in interventional cardiology during the last two years.

Staff Analysis and Conclusion

MHCC staff reviewed the attestations provided and concludes that MSMHC meets this standard.

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

MSMHC submitted a signed statement from Dr. William O. Suddath, Medical Director of the CCL, acknowledging that each physician who has performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. MSMHC also submitted a copy of the on-call schedule for August 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the on-call schedule submitted, and observed that Drs. Suddath, Al-Omari, Leiboff, and Addala were all scheduled to be on-call at different times during the month. Staff requested additional information regarding a physician that did not appear on the schedule. MSMHC explained that the physician no longer provides cardiac interventional services at MSMHC. MHCC staff concludes that MSMHC 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.

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

Table 8: MSMHC PCI Volume

Calendar Year	Total PCI Volume
2015	325
2016	310
2017	360
2018	368
2019	435
2020	373
2021	363
2022	327

Sources: ACC-NCDR CathPCI Registry reports for CY 2015- CY 2017 and CY 2019-CY 2022; MSMHC PCI COP Application (September 2019), Form B, for CY 2018.

Staff Analysis and Conclusion

In addition to reviewing the information in the ACC-NCDR CathPCI reports submitted by MSMHC, MHCC staff also analyzed the ACC-NCDR CathPCI registry's patient level data. Both staff's analysis of the patient level data and the information in the ACC-NCDR CathPCI reports indicates that MSMHC exceeded the target volume of 200 PCI procedures annually, during each year of the review period. MSMHC complies with this standard.

10.24.17.07D(8)(a). For primary PCI cases, if a program falls below 36 cases for rural PCI providers and 49 cases for non-rural providers, a focused review will be triggered.

This regulation is not applicable to MSMHC. MSMHC performed greater than 49 primary PCI cases annually between 2015 and 2022.

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

MSMHC submitted primary PCI volume for each interventionalist by calendar year for 2015 through 2023. MHCC staff reviewed the primary PCI case volume information submitted by MSMHC, and it shows that between January 2019 and December 2023, at least eleven primary PCI procedures were completed per year for each interventionalist, except for one physician. This physician performed primary PCI at MSMHC eight times in 2020 and five times in 2021.

Staff Analysis and Conclusion

MHCC staff analyzed the data in the ACC-NCDR CathPCI registry for the period 2015 and 2022 and observed that, all MSMHC interventionalists performed at least eleven primary PCI

procedures per year, except for one physician. Because the standard refers to eleven primary cases per year as a target and not an absolute requirement, it is acceptable that one physician did not meet the target of 11 primary PCI cases annually. MHCC staff concludes that MSMHC 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.

MSMHC stated that according to the ACCF/AHA AUC appropriateness criteria, no cases were identified by internal or external reviews as unsuitable or inappropriate for elective PCI.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from January 2015 through December 2021 and determined that there were no cases determined to be "inappropriate" with respect to clinical criteria, angiographic criteria, and ACC/AHA/AUC appropriateness criteria. During that same period, only 2 of the 65 cases reviewed (3%) were determined to be rarely appropriate according to clinical criteria only. There were no cases determined to be inappropriate by two or more of the three criteria used to evaluate appropriateness. MHCC staff determines that MSMHC complies with the standard.

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

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

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

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

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

In its March 2024 supplemental data submission MSMHC stated that during the period January 2015 through June 2019, zero patients received thrombolytic therapy that subsequently failed because the primary PCI system was unavailable. In its September 2023 supplemental data submission, MSMHC stated that between January 2020 and December 2022, two patients received thrombolytic therapy that subsequently failed.

Staff Analysis and Conclusions

Thrombolytic therapy was not provided due to PCI being unavailable during the review period, January 2015 through December 2022. MHCC staff analysis of the ACC-NCDR Cath PCI data for CY 2015 through CY 2022 is consistent with the information reported by the applicant. MHCC staff concludes that MSMHC complies with the standard.

RECOMMENDATION

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

MSMHC shall:

1) Demonstrate that documentation of PCI cases accurately captures all patient care through the following:

    a) Provide MHCC staff with a copy of its revised training materials aimed at ensuring proper documentation during cardiac catheterization procedures on or before May 31, 2024.

    b) Provide MHCC staff with records of which CCL staff have undergone the revised training and the dates when the training took place on or before May 31, 2024.

    c) Provide MHCC staff with documentation of the findings from the random monthly documentation audits for October 2023 – March 2024, and actions taken to resolve problems identified through the audits on or before May 31, 2024.

d) Complete additional auditing of documentation for PCI cases after May 31, 2024, for additional six-month periods, if requested by MHCC staff, and report the results within 30 days of the end of the audit period.

2) Demonstrate the hospital is holding bi-monthly interventional case review meetings that include technicians, as required in COMAR 10.24.17.07D(5)(a) through the following:

MSMHC shall submit to the Commission attendance lists for each of these meetings held between May and October by Dec 1 of each year and attendance lists for meetings held between November and April by June 1 of each year until at least December 1, 2025. After this date, the Executive Director may release MSMHC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.