

IN THE MATTER OF

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BEFORE THE

MEDSTAR FRANKLIN SQUARE

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MARYLAND

MEDICAL CENTER

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HEALTH CARE

Docket No.: 24-03-CP051

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COMMISSION

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

November 21, 2024

I. INTRODUCTION

A. Background

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

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

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

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter (Cardiac Services Chapter) of the State Health Plan for Facilities and Services 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 given number of years 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 Cardiac Services Chapter authorizes 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 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

MedStar Franklin Square Medical Center

MedStar Franklin Square Medical Center (MFSMC) is a 357-bed general hospital located in Baltimore, Maryland. MFSMC does not have a cardiac surgery program on site.

MFSMC received approval to provide primary PCI services under a waiver on May 18, 2006. MFSMC subsequently received renewals of its waiver to provide primary PCI services in June 2007, May 2009, and May 2011. MFSMC received its first Certificate of Ongoing Performance for primary PCI services on July 16, 2020, for a four-year period.

MFSMC received approval to provide elective PCI services on April 21, 2022 and began providing elective PCI services in September of 2022. Its Certificate of Ongoing Performance was extended for a period of six months in June 2024 because staff required additional time to review the application. This is MFSMC's first renewal of its Certificate of Ongoing Performance for primary PCI services.

Health Planning Region

The Cardiac Services Chapter defines four health planning regions for adult cardiac services. MFSMC is in the Baltimore/Upper Shore health planning region. This region includes Baltimore City and Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot counties. Fourteen hospitals in this health planning region provide PCI services. Six of these hospitals also provide cardiac surgery services. Eight hospitals provide only PCI services.

C. Staff Recommendation

MHCC staff recommends that the Commission approve MFSMC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services with

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).

two conditions. A description of the information submitted by MFSMC and MHCC staff's analysis and recommendations follows.

II. PROCEDURAL HISTORY

MFSMC applied for renewal of its Certificate of Ongoing Performance for PCI services on January 12, 2024. MHCC staff requested additional information on May 17, 2024 and October 18, 2024. The hospital responded on June 10, 2024, and October 21, 2024.

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.

The hospital has submitted the data and reports required by MHCC. MFSMC stated that it is not aware of any deficiencies in data collection or reporting.

Staff Analysis and Conclusion

MFSMC has complied with the submission of data to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI to MHCC in accordance with the established schedule. MHCC staff concludes that MFSMC 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.

MFSMC reported that there were no instances in which it had to divert patients due to maintenance or downtime. While there were some brief periods of downtime due to scheduled preventative maintenance, the facility's hybrid operating room was available for PCI procedures. A copy of MFSMC's planned preventative maintenance schedule for the interventional cardiac room was provided and this information is summarized below in Table 1.

Table 1: MFSMC Reported CCL Downtimes, Dec. 2019 – Dec. 2023

Date	Duration	Reason
12/10/2019	4.0	Planned Maintenance
05/29/2020	4.5	Planned Maintenance
11/27/2020	4.5	Planned Maintenance
05/13/2021	5.0	Planned Maintenance
11/30/2021	4.0	Planned Maintenance
06/09/2022	4.0	Planned Maintenance
11/09/2022	4.0	Planned Maintenance
12/27/2022	5.0	Planned Maintenance
06/27/2023	7.0	Planned Maintenance
12/20/2023	5.5	Planned Maintenance

Source: MHCC staff summary of information provided in MFSMC's Certificate of Ongoing Performance application (February 2024), Appendix A and Response to MHCC staff questions on June 10, 2024, Appendix X.

Staff Analysis and Conclusion

Based on the continuous availability of PCI services during the review period, MHCC staff concludes that MFSMC 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.

MFSMC provided a signed statement from its president, Stuart M. Levine, MD, FACP, dated November 27, 2023, affirming that MFSMC commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital for at least 75% of cases. Additionally, MFSMC provided quarterly information on its door-to-balloon (DTB) times for the period January 2019 through December 2023 as shown below in Table 2. MFSMC reported that it does not receive transfer cases from other facilities.

Table 2: MFSMC Reported Compliance with DTB Time Standard by Quarter for Non-Transfer Cases, January 2019 – December 2023

Quarter	Non-Transfer Primary PCI Volume	Number of Cases with DTB <= 90 Minutes	Percent of Cases with DTB <=90 Minutes
2019 Q1	25	22	88.0%
2019 Q2	27	22	81.5%
2019 Q3	20	18	90.0%
2019 Q4	20	17	85.0%
2020 Q1	19	19	100.0%
2020 Q2	21	20	95.2%
2020 Q3	21	20	95.2%
2020 Q4	26	26	100.0%
2021 Q1	20	20	100.0%
2021 Q2	21	20	95.2%
2021 Q3	19	19	100.0%
2021 Q4	25	25	100.0%
2022 Q1	21	21	100.0%
2022 Q2	15	15	100.0%
2022 Q3	16	15	93.8%
2022 Q4	26	26	100.0%
2023 Q1	17	17	100.0%
2023 Q2	20	19	95.0%
2023 Q3	17	17	100.0%
2023 Q4	15	13	86.7%

Sources: 2019 - 2020: MFSMC application for Certificate of Conformance (July 2021); 2021 – 2023, Response to MHCC staff on October 21, 2024.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer PCI cases and found that MFSMC met the DTB standard in all but the third quarter of 2022, as shown in Table 3A. MHCC staff’s analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and the DTB metric used by MHCC includes all cases. MHCC staff asked MFSMC to explain the DTB delays in the third quarter of 2022. MFSMC responded with information that indicates in six of the seven cases in which the DTB standard was not met, the root cause was attributable to the patient’s condition, which is outside the control of the hospital. These reasons included cardiac arrest for two patients, difficulty crossing the culprit lesion in three cases and the need for additional testing based on symptoms in one instance.

MHCC staff also considers the hospital’s performance on the DTB standard over longer periods that include multiple quarters. Over rolling eight quarter periods MFSMC complied with this standard, with between 86.4% and 90.0% of PCI cases meeting the door-to-balloon time standard, as shown in Table 3B.

**Table 3A: MFSMC's Compliance with DTB Benchmark
by Quarter, CY 2020 - CY 2023**

Time Period	Non-Transfer Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes
2019q1	25	23	92.00%
2019q2	24	21	87.50%
2019q3	20	17	85.00%
2019q4	20	17	85.00%
2020q1	23	20	87.00%
2020q2	22	19	86.40%
2020q3	28	21	75.00%
2020q4	25	25	100.00%
2021q1	26	23	89.00%
2021q2	20	17	85.00%
2021q3	21	19	90.50%
2021q4	25	25	100.00%
2022q1	25	21	84.00%
2022q2	18	16	88.90%
2022q3	22	15	68.20%
2022q4	27	25	92.60%
2023q1	20	17	85.00%
2023q2	27	22	81.50%
2023q3	15	14	93.30%
2023q4	17	13	76.50%

Source: MHCC analysis of ACC-NCDR CathPCI data, January 1, 2019 – Dec. 31, 2023.

Table 3B: MFSMC Non-Transfer Primary PCI Case Volume and Percentage of Cases With DTB Less Than or Equal to 90 Minutes, by Time Period

Time Period	Quarter			Rolling 8-Quarters		
	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes
2019q1	25	23	92.0%			
2019q2	24	21	87.5%			
2019q3	20	17	85.0%			
2019q4	20	17	85.0%			
2020q1	23	20	87.0%			
2020q2	22	19	86.4%			
2020q3	28	21	75.0%			
2020q4	25	25	100.0%	187	163	87.2%
2021q1	26	23	89.0%	188	163	86.7%
2021q2	20	17	85.0%	184	159	86.4%
2021q3	21	19	90.5%	185	161	87.0%
2021q4	25	25	100.0%	190	169	90.0%
2022q1	25	21	84.0%	192	170	88.5%
2022q2	18	16	88.9%	188	167	88.8%
2022q3	22	15	68.2%	182	161	88.5%
2022q4	27	25	92.6%	184	161	87.5%
2023q1	20	17	85.0%	178	155	87.1%
2023q2	27	22	81.5%	185	160	86.5%
2023q3	15	14	93.3%	179	155	86.6%
2023q4	17	13	76.5%	171	143	83.6%

Source: MHCC analysis of ACC-NCDR CathPCI data, January 1, 2019 – Dec. 31, 2023.

Based on MHCC staff’s analysis of the ACC NCDR CathPCI data, which shows that the hospital met the DTB standard in all quarters except one between 2019 Q1 and 2023 Q4, the hospital’s performance over rolling 8-quarter periods which demonstrates compliance in all periods, and MHCC staff’s review of reasons for delays in the third quarter of 2022, which were for reasons outside the control of MFSMC, MHCC staff concludes that MFSMC 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 4, MFSMC provided the number of physicians, nurses, and technicians who can provide cardiac catheterization services to acute myocardial infarction patients as of the filing of its application in January 2024.

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

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	5	
Nurse	9 (FTE)	S/C/M = 9 FTE
Technician	4.5 (FTE)	S/C/M = 4.5 FTE

Source: MFSMC application (February 2024), p. 5

*Scrub (S), circulate (C), monitor (M).

Staff Analysis and Conclusion

MHCC staff compared the reported staffing levels at MFSMC to the staffing levels for programs at three other hospitals with similar PCI case volume. A comparison of volume and staffing levels for MFSMC, UPMC Western Maryland (UPMC WMD), Medstar Southern Maryland (MSMHC) and University of Maryland Baltimore Washington Medical Center (UM BWMC), is shown below in Table 5. MFSMC and UPMC WMD have a very similar volume of PCI cases, and the number of interventionalists are similar for both hospitals, but MFSMC reported a higher number of nurse FTEs, nine FTEs compared to six for UPMC WMD, while UPMC WMD utilizes more technicians, 7.3 compared to 4.5, than MFSMC. Although MSMHC reports five interventionalists, compared to MFSMC’s four, it also noted that three are part-time interventionalists. While MSMHC has more nurse FTEs than MFSMC, 11 compared to nine, it also has a case volume that is 14% higher than MFSMC’s. UM BWMC and MFSMC have similar PCI case volume, but BWMC has fewer interventionalists than MSMHC and the combined FTEs for nurses and technicians together is comparable to MFSMC’s.

Table 5: CCL Staffing for MFSMC and Other Select PCI Programs

Program	Total 2023 PCI Cases	Interventionalists	Nurse FTEs	Technician FTEs
MFSMC	261	4	9	4.5
UM BWMC	248	3	7.4	7.0
UPMC WMD	255	3	6.1	7.3
MSMHC	297	5	11	5.0

Sources: MFSMC’s COP application and PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2023; UPMC WMD’s June 2019 COP application and PCI volume from ACC-NCDR CathPCI registry report for the period ending December 31, 2023; MSMHC’s September 2023 supplemental information and PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2023; and UM BWMC’s January 2024 COP application and PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2023.

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

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.

MFSMC provided a signed letter of commitment, dated December 22, 2023, from Dr. Levine, President, Medstar Franklin Square Medical Center, acknowledging that MFSMC will provide primary PCI services in accordance with the requirements established by the Commission.

Staff Analysis and Conclusion

MHCC staff concludes that MFSMC meets this standard based on the letter of commitment provided.

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

MFSMC stated that Medstar employs a team, consisting of five FTEs that includes critical care RNs and a data analyst, dedicated to collecting, entering and managing the state and federally mandated data registries. Two nurses and the data analyst from the team attend monthly performance improvement meetings with representatives from both MedStar facilities providing PCI services in the Baltimore area.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and notes that the hospital appears to have been submitting complete and timely information to the ACC-NCDR CathPCI and engaging in quality insurance activities to address DTB times for PCI patients and other concerns. MHCC staff concludes that MFSMC 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.

John Wang, M.D. became the medical director of the CCL at MFSMC in March of 2023. Prior to that, Dr. Sahid Saeed was MFSMC's medical director. MFSMC provided a copy of Dr. Wang's Curriculum Vitae and job description.

Staff Analysis and Conclusion

MHCC staff reviewed the job description of Medstar's medical director for the CCL. The responsibilities include setting Medstar's regional policy for the use of drugs, devices, equipment and technical services for interventional cardiology; oversight of physician credentialing; interviewing potential new personnel and recommending hiring decisions; quality and patient outcomes; ensuring effective referral and communications systems and ensuring that appropriate reviews of the quality of all physicians' catheterization practices are undertaken. Based on the job description provided and designating Dr. Wang as the medical director of the CCL, MHCC concludes that MFSMC is compliant with this standard.

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

MFSMC provided a list of competencies that staff review every year, some of which include assessments to prove competency. Examples of competencies checked include radiation safety, glycemic management, how to open a sterile package, and capnography for end-tidal carbon dioxide monitoring. MFSMC also stated that staff participate in case reviews and performance improvement meetings.

Staff Analysis and Conclusion

MHCC reviewed documentation submitted, including the list of annual educational assessments and the training specific to CCL staff. The continuing medical education programming for MFSMC cardiac staff includes the following appropriate topics: patient safety, emergency preparedness, corporate compliance, infection prevention, glycemic management, capnography for end-tidal carbon dioxide monitoring, and radiation safety. Based on staff's review of the continuing education topics and competencies checked annually provided, MHCC staff concludes that MFSMC is compliant with this standard.

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

MFSMC provided a copy of its agreement, dated December 6, 2023, with Medstar Union Memorial Hospital (MUMH). In this document MUMH agrees to receive, unconditionally, patients from MFSMC for any required additional care including emergent or elective cardiac surgery or PCI.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that MFSMC is compliance 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.

MFSMC provided a signed agreement, dated December 12, 2014, between MUMH and Procare. MFSMC stated that although the hospital that is party to this agreement is MUMH, the contract includes cardiovascular transports for all the MedStar Baltimore hospitals including MFSMC.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement between ProCare and MUMH. The agreement automatically renews every five years, and it remains in effect. MHCC staff concludes that MFSMC complies with this standard because it has the required patient transport agreement.

Quality

10.24.17.07C(4)(a) and 10.24.17.07D(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.

MFSMC stated that its case review meetings occur jointly with MUMH on the third and fourth Tuesday of each month. MFSMC provided a list of the dates that case review meetings were held between January 2020 and December 2023 and attendance records. While the meetings are multidisciplinary, only MFSMC's physicians are contractually bound to 75% attendance. Nurses and technicians attend based on their work schedules. MFSMC explained that because the case review meetings do not provide continuing education credits, attendance records for nurses and technicians are not kept.

MFSMC reported that it has additional case review meetings that include reviews of angiographic images. The hospital holds these peer review meetings monthly that only include physicians. The hospital also holds performance improvement meetings; these meetings were held between seven and 11 times per year between January 2019 and December 2023, but attendance records were not provided.

Staff Analysis and Conclusion

Based on the documentation provided, there were over 18 joint meetings with MUMH with case review held each year, which is consistent with holding case review meetings at least every other month. However, there was not documentation provided that these meetings are attended by MFSMC's nurses and technicians who care for primary PCI patients. Staff was unable to confirm that nurses and technicians attend these meetings because attendance records are not kept by the hospital. Staff recommends that the Commission find the hospital meets this standard with the following condition:

MFSMC shall hold interventional case review meetings at least every other month that include physicians, nurses, and technicians, as required in COMAR 10.24.17.07D(5)(a). MFSMC shall submit to Commission staff attendance lists for each of these meetings held between May and October by December 1 of each year and attendance lists for meetings held between November and April by June 1 of each year beginning with meetings held after November 30, 2024, until at least December 31, 2026, to document compliance with this condition. After this date, the Executive Director may release MFSMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

(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 COMAR 10.24.17 51 any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

MFSMC reported that in addition to the case review and performance improvement meetings, MFSMC also holds Cardiovascular Service Line meetings. MFSMC provided a list of dates and attendees for the Cardiovascular Service Line meetings.

Staff Analysis and Conclusion

MHCC staff reviewed the attendance records for the Cardiovascular Service Line meetings. There were nine meetings in CY 2019, six meetings in CY 2020, eleven meetings in CY 2021, eight meetings in CY 2022 and ten meetings in 2023. The attendance records for these meetings indicate that physician and nurse leadership for the emergency department and CCL, hospital leadership and representatives from Procure, MFSMC's emergency transportation vendor, regularly attended these meetings. MHCC staff asked MFSMC to explain why its monthly Cardiovascular Service Line meeting was cancelled three times in CY 2019, six times in CY 2020, and four times in CY 2022. The hospital explained that the meetings were cancelled in 2019 because the Cardiology Chief was unavailable. The meetings in 2020 were cancelled due to lack of a quorum; most of the operational leaders were, due to the COVID pandemic, either taking patient assignments or acting as a charge nurse on a unit. The hospital did not provide explanations for the four meetings cancelled in 2022.

Based on the explanations and documentation provided, MHCC is unable to conclude that MFSMC convened multiple care area group at least monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

Staff recommends that the Commission find the hospital is meeting the standard with the following condition:

MFSMC shall convene its multiple care area group monthly. Meetings shall be attended by the physician and nursing leadership of each care area and include a review of all issues related to the primary PCI system, identify problem areas, and develop solutions, as required in COMAR 10.24.17.07D(5)(b). MFSMC shall submit to Commission staff meeting minutes and attendance lists for each meeting held between May and October by December 1 of each year and meeting minutes and attendance lists for each meeting held between November and April by June 1 of each year, beginning with meetings held after November 30, 2024, and continuing until at least December 31, 2026. After this date, the Executive Director may release MFSMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

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.

MFSMC submitted copies of the external review reports for elective PCI cases performed between January 2019 and December 2022. The Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ) conducted the external reviews of elective PCI cases.

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, between 8% and 22% of cases were reviewed each year.

Table 6: MFSMC External Review of PCI Cases by Year, CY 2019 - CY 2022

Calendar Year	PCI Cases Forwarded to MACPAQ	Number of Cases Reviewed	Percentage of Cases Reviewed	Timing of external reviews	Meets Standard
2019	126	10	8%	Semi-annual	Yes
2020	104	10	10%	Semi-annual	Yes
2021	99	11	11%	Semi-annual	Yes
2022	81	18	22%	Semi-annual	Yes

Source: MHCC staff review of MFSMC's MACPAQ reports for the period 2019 through 2022

For the period between January 2019 and December 2022, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that at least five percent of the facility's PCI cases were reviewed.

The standard also requires that the external review of elective PCI cases include at least three cases per physician, or all cases if the interventionalist performed fewer than three cases. The MACPAQ reports submitted by MFSMC indicate that for the period January 2019 through December 2021, one case was reviewed per physician per review period, or two cases per year. This is acceptable because the requirement for external review applies only to elective PCI cases. Prior to September 2022, no elective PCI procedures were performed at MFSMC. The MACPAQ report for the period July through December of 2022 included three cases per physician. MHCC staff concludes that MFSMC 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.*

MFSMC provided the number of cases reviewed internally for each physician for CY 2019 through CY 2023 for all physicians, as applicable. The hospital also provided MACPAQ reports with the number of cases reviewed for individual physicians.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and analyzed the ACC NCDR CathPCI data for the period from CY 2019 to CY 2023 to determine the number of PCI cases performed by each interventionalist and to calculate the number of cases required to be reviewed each year. MHCC staff compared the results of its analysis to the number of PCI cases reviewed internally and externally per physician as reported by the hospital. In years when MFSMC only had a primary PCI program, the hospital was permitted to meet the requirement for review of individual physicians through an external review of 10% of primary PCI cases for each interventionalist, as stated in COMAR 10.24.17.08B(1)(c).

MHCC staff's assessment of the hospital's compliance is as follows. In 2019, this standard was met for all but one physician through external review by MACPAQ; the standard was met for the remaining physician through a combination of internal and external review. In 2020 and 2021, the hospital met the standard for all physicians through the external review of cases by MACPAQ. In 2022, the hospital met the standard through a combination of internal and external review for three physicians. For two physicians, the standard was substantially met because nine instead of 10 cases were reviewed. For one physician, the standard was not met because only six cases were reviewed. In 2023, the hospital met the standard for all physicians except one through internal case review. For the other physician, the standard will be met through a combination of internal review and external review by MACPAQ. The 2023 MACPAQ reports are not available yet, but staff for MACPAQ provided the number of cases that will be reviewed for physicians, based on information already submitted. Based on the hospital's substantial level of compliance for most of the review period, as determined by MHCC staff's analysis of data and the information provided, MHCC staff recommends the Commission find that MFSMC complies with the standards for review of individual interventionalists.

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

MFSMC submitted an affidavit from its president, Dr. Levine, dated December 4, 2023, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in the Cardiac Services Chapter, including those regarding internal peer review of cases and external review of cases.

Staff Analysis and Conclusion

MHCC staff concludes that MFSMC complies with this standard.

10.24.17.07C(4)(g) and 10.24.17.07D(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) 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.

MFSMC provided the dates of its Performance Improvement meetings, which usually take place monthly. These meetings occurred between seven and 11 times annually for the period from CY 2019 to CY 2023. The hospital provided detailed meeting minutes from its December 2023

Performance Improvement and a cardiology service line meeting held in November 2023 to demonstrate quality assurance activities are taking place. In its June 2024 supplemental data submission, MFSMC also submitted examples of areas for quality improvement with respect to its PCI services and described the solutions implemented. In addition, the hospital described the improved outcomes it observed due to the implementation of process improvements.

Staff Analysis and Conclusion

MHCC staff reviewed the information on quality assurance activities and, based on the detailed information provided regarding both the hospital's quality assurance process and positive outcomes, concludes that MFSMC complies with this standard.

Patient Outcome Measures

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

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

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

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 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.

MFSMC's adjusted mortality rates, by rolling 12-month reporting period, for 2018 Q2 through 2024 Q1, are shown below in Table 7.

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

Reporting Period	STEMI				NON-STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2023q2-2024q1	2.45	[0.30, 8.46]	0.79	Yes	0.96	[0.12, 3.42]	2.00	Yes
2023q1-2023q4	3.37	[0.70, 9.38]	1.88	Yes	1.30	[0.27, 3.72]	1.99	Yes
2022q4-2023q3	4.81	[1.33, 11.78]	1.91	Yes	1.23	[0.25, 3.52]	2.02	Yes
2022q3-2023q2	5.25	[1.45, 12.86]	1.89	Yes	2.04	[0.42, 5.80]	2.02	Yes
2022q2-2023q1	5.36	[1.48, 13.11]	1.89	Yes	1.21	[0.03, 6.52]	2.05	Yes
2022q1-2022q4	3.67	[0.76, 10.31]	2.00	Yes	0.00	[0.00, 11.77]	2.14	Yes
2021q4-2022q3	1.56	[0.04, 8.43]	2.11	Yes	15.58	[0.39, 67.64]	2.20	Yes
2021q3-2022q2	1.38	[0.04, 7.46]	2.18	Yes				
2021q2-2022q1	2.65	[0.32, 9.24]	2.82	Yes				
2021q1-2021q4	1.56	[0.04, 8.44]	2.74	Yes				
2020q4-2021q3	1.84	[0.05, 9.89]	2.18	Yes				
2020q3-2021q2	8.33	[1.01, 28.78]	7.51	Yes				
2020q2-2021q1	8.89	[1.85, 25.03]	7.55	Yes				
2020q1-2020q4	5.46	[0.66, 19.09]	6.89	Yes				
2019q4-2020q3	7.41	[2.04, 18.21]	6.37	Yes				
2019q3-2020q2	7.79	[2.15, 19.13]	6.06	Yes				
2019q2-2020q1	6.51	[1.80, 16.02]	5.99	Yes				
2019q1-2019q4	5.88	[1.62, 14.47]	6.01	Yes				
2018q4-2019q3	7.27	[2.4, 16.25]	6.06	Yes				
2018q3-2019q2	8.00	[3.02, 16.32]	6.38	Yes				
2018q2-2019q1	8.18	[3.37, 15.93]	6.13	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 April 2018 and March 2024.

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.

*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 above, MHCC staff compiled the results from MFSMC's quarterly reports from the ACC-NCDR CathPCI for STEMI PCI cases performed between January 2019 and March 2024 and non-STEMI PCI cases performed between July 2022 and March 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 risk-adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period. The national benchmark fell within the 95% confidence interval (CI) for MFSMC for all 12-month reporting periods between April 2018 and March 2024. MHCC staff concludes that MFSMC meets the benchmark for both STEMI and non-STEMI cases and complies with this standard.

Physician Resources

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 Commission on a quarterly basis.

MFSMC submitted information on the volume of primary and elective PCI cases at MFSMC and other hospitals, by physician and quarter, for the period October 2021 through March 2023. During each of the 12-month periods within that timeframe the physicians completed at least 50 PCI procedures.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for the interventionalists who performed primary PCI services at MFSMC from 2019 through 2023 and determined that each interventionalist performed at least 50 PCI procedures annually on average. Staff notes the requirement to perform at least 50 PCI procedures annually on average over a 24-month period was waived for 2020 and 2021, due to the COVID-19 pandemic.⁴ MHCC staff concludes that MFSMC 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

This regulation is not applicable since MFSMC's physicians performed 50 PCI procedures annually on average over a 24-month period.

⁴ https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/MHCC%20bulletin_cardiac_covid19_20200331.pdf

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 MFSMC since MFSMC's physicians performed 50 PCI procedures annually on average over a 24-month period.

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

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.

MFSMC submitted a statement, dated December 27, 2023, signed by Dr. Wang, the medical director of the hospital's CCL, stating that four of the five interventionalists at MFSMC are board certified in Interventional Cardiology, while the fifth is exempt because he completed his training before 1998, and he did not seek board certification prior to 2003.

Staff Analysis and Conclusion

MHCC staff reviewed the signed statement and concludes that MFSMC complies with 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.

MFSMC submitted signed and dated attestations from Drs. Wang, Siddiqi, Peichert, Iskander, and Kaliyadan 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 MFSMC complies with this standard.

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

MFSMC submitted a signed statement from Dr. Wang, the medical director of the CCL, acknowledging that each physician currently performing primary PCI services are participating in the on-call schedule. MFSMC also submitted a copy of the on-call schedule for December 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the on-call schedule submitted, and observed that Drs. Wang, Siddiqi, Peichert, Iskander and Kaliyadan were all scheduled to be on-call at different times during the month. MHCC staff concludes that MFSMC complies with 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.

MFSMC submitted volume information by fiscal year, as shown in Table 8.

Table 8: MFSMC Total PCI Volume

Fiscal Year	Total PCI Volume
2020	98
2021	104
2022	98
2023	222

Sources: MFSMC application, response to question 25

Note: The fiscal year is July 1 to June 30.

Staff Analysis and Conclusion

As noted previously, MFSMC did not perform elective PCI until September 2022. This standard does not apply to MFSMC for fiscal year (FY) 2020 and FY 2021. This standard applies to the hospital for ten of twelve months in FY 2023. During FY 2023, MFSMC reported completing more than 200 PCI cases. Based on the hospital performing greater than the target of 200 PCI cases in FY 2023 and CY 2023, MHCC staff recommends that the Commission find that MFSMC complied with the standard.

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

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2019 through CY 2023. As shown in Table 9, the hospital performed between 96 and 106 primary PCI cases annually between CY 2019 and CY 2022. Because MFSMC performed over 49 cases annually no focused review is required.

Table 9: MFSMC Primary PCI Volume

Calendar Year	Primary PCI Volume
2019	98
2020	106
2021	99
2022	96
2023	93

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2019 – CY 2023.

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

MFSMC submitted primary PCI volume for each interventionalist by calendar year from 2019 through 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by MFSMC, and it shows that between January 2019 and December 2023, at least eleven primary PCI procedures were completed per year for each interventionalist. MHCC staff also analyzed the data in the ACC-NCDR CathPCI registry for the period 2019 and 2023 and observed that all MFSMC interventionalists performed at least eleven primary PCI procedures per year. MHCC staff concludes that MFSMC complies 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.

MFSMC stated that according to the appropriateness criteria in Expert Guidelines, as applied to internal and external reviews of elective PCI cases, there were no patients who received elective PCI inappropriately.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from January 2019 through December 2022 and observed that there were no cases determined to be “rarely appropriate” with respect to clinical

criteria, angiographic criteria, or appropriateness criteria in Expert Guidelines. MHCC staff concludes that MFSMC complies with the standard.

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

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

MFSMC stated that during the review period there were no patients who received thrombolytic therapy in lieu of primary PCI. MFSMC also stated that there were no patients who received primary PCI services inappropriately.

Staff Analysis and Conclusions

MHCC staff analyzed the ACC-NCDR CathPCI data and noted that between CY 2019 and CY 2023, there were no PCI patients who received thrombolytic therapy except one patient in 2021. Staff also reviewed the hospital's ACC-NCDR CathPCI reports for the period from January 2019 to December 2023. For all reports during this period, staff noted zero primary PCI cases were determined to be "rarely appropriate." MHCC staff concludes that MFSMC complies with the standard.

RECOMMENDATION

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

1. MFSMC shall hold interventional case review meetings at least every other month that include physicians, nurses and technicians, as required in COMAR 10.24.17.07D(5)(a). MFSMC shall submit to Commission staff attendance lists

for each of these meetings held between May and October by December 1 of each year and attendance lists for meetings held between November and April by June 1 of each year beginning with meetings held after November 30, 2024, until at least December 31, 2026, to document compliance with this condition. After this date, the Executive Director may release MFSMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

2. MFSMC shall convene its multiple care area group monthly. These meetings shall be attended by the physician and nursing leadership of each care area and include a review of all issues related to the primary PCI system, identify problem areas, and develop solutions, as required in COMAR 10.24.17.07D(5)(b). MFSMC shall submit to Commission staff meeting minutes and attendance lists for each meeting held between May and October by December 1 of each year and meeting minutes and attendance lists for each meeting held between November and April by June 1 of each year, for meetings held after November 30, 2024, and continuing until at least December 31, 2026. After this date, the Executive Director may release MFSMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.