

**IN THE MATTER OF
MERITUS MEDICAL
CENTER**

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**BEFORE THE MARYLAND
MARYLAND HEALTH
CARE COMMISSION**

Docket No.: 19-21-CP028

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

June 17, 2021

I. INTRODUCTION

A. Background

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

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

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

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter (Cardiac Surgery Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Surgery Chapter was subsequently revised in November 2015 and again in January 2019. The main change in these revisions to the Cardiac Surgery Chapter that affects PCI programs has been a change to the benchmark used to evaluate hospitals' risk-adjusted mortality rates. Commission staff was unable to obtain benchmark information for risk-adjusted mortality rates consistent with the regulations adopted in November 2015 that reflected the recommendations of the CAG. As a result, the standard was determined to be inapplicable; however, information on how hospitals performed relative to the newly adopted mortality standard is included in staff reports.

The Cardiac Surgery Chapter contains standards for evaluating the performance of established PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or both primary and

elective (non-primary) PCI services, for a period 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 obtaining a Certificate of Ongoing Performance demonstrating that it continues to meet the applicable requirements in COMAR 10.24.17.

B. Applicant

Meritus Medical Center

Meritus Medical Center (MMC) is a 237-bed general hospital located in Hagerstown (Washington County). MMC does not have a cardiac surgery program on site.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. MMC is in the Western Maryland health planning region. This region includes Allegany, Garrett, and Washington Counties. Two hospitals in this health planning region provide primary and elective PCI services. Only one hospital in the region, UPMC Western Maryland, provides cardiac surgery services.

C. Staff Recommendation

MHCC staff recommends that the Commission approve MMC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services. The information provided by MMC and MHCC staff's analysis of that information are detailed in this Staff Report.

II. PRODEDURAL HISTORY

MMC filed a Certificate of Ongoing Performance application on September 21, 2019. MHCC staff reviewed the application and requested additional information on February 4, 2021, and April 7, 2021. MHCC received additional information on March 12, 2021, May 27, 2021, and June 1, 2021.

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 ACCF NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

MMC responded that there are currently no deficiencies in data collection or reporting that have been identified by MHCC staff. MMC stated that it has participated in NCDR's CathPCI registry since 2008 and with the Acute Coronary Treatment and Intervention Outcomes Network–Get with The Guidelines (ACTION-GWTG) since 2010. MMC also noted that the hospital currently participates in the NCDR's CathPCI and Chest Pain/Myocardial Infarction Registry and has participated in the American Heart Association's GWTG Coronary Artery Disease registry since 2018. At the time the application was submitted, MMC noted that there were 2.0 full-time equivalent (FTE) registered nurses who serve as data coordinators and who regularly attend the quarterly cardiac data coordinator meetings.

Staff Analysis and Conclusion

MMC has complied with the requirement to submit the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) CathPCI data set to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of ACC-NCDR CathPCI data to validate that hospitals submitted accurate and complete information to the ACC-NCDR registry. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of MMC's data reported during the audit period.

MHCC staff concludes that MMC 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.

MMC indicated that the hospital's PCI services have always been available for both elective and emergency PCI cases during the review period. MMC has four cardiac catheterization laboratories (CCL) equipped to provide PCI services. MMC noted that individual rooms may occasionally be offline for scheduled maintenance or repair; however, at least one fully functioning CCL always remains available. As shown in Table 1, MMC provided a report of downtime for each CCL between January 2015 and June 2020.

Table 1: MMC Reported Frequency of CCL Downtime by CCL and Time Period, January 2015- June 2020

Time Period	Number of Downtime Occurrences				Overlapping Downtime
	CCL 1	CCL 2	CCL 3	CCL 4	
CY 2015	5	0	2	8	No
CY 2016	3	2	6	5	No
CY 2017	1	2	3	6	No
CY 2018	1	1	7	6	No
CY 2019	8	8	4	8	No
Jan – June 2020	2	6	1	2	No

Source: MHCC staff analysis of MMC application Q2, updated Q2

*Overlapping downtime refers to downtime reported that overlaps for all three rooms on the same date.

Staff Analysis and Conclusion

MHCC staff reviewed the information on CCL room downtime and determined that it is unlikely that all four CCLs were unavailable simultaneously.

MHCC staff concludes that MMC complies with this standard.

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

MMC provided a signed statement from Dr. Maulik S. Joshi, President and Chief Executive Officer (CEO) of MMC, stating that MMC commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, and that it commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement. Additionally, MMC provided DTB times for the period from January 2015 through June 2019, as shown in Table 2A. MMC reported that it did not routinely receive any PCI transfer cases from other hospitals.

**Table 2A: MMC Reported Compliance with DTB Benchmark by Quarter,
January 2015- December 2019**

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	29	26	89.6%
CY2015 Q2	23	21	91.3%
CY2015 Q3	21	16	76.1%
CY2015 Q4	17	16	94.1%
CY2016 Q1	22	21	95.4%
CY2016 Q2	14	12	85.7%
CY2016 Q3	23	20	86.9%
CY2016 Q4	26	26	100.0%
CY2017 Q1	22	20	90.9%
CY2017 Q2	24	20	83.3%
CY2017 Q3	17	15	88.2%
CY2017 Q4	16	15	93.7%
CY2018 Q1	17	16	94.1%
CY2018 Q2	19	17	89.4%
CY2018 Q3	13	12	92.3%
CY2018 Q4	19	16	84.2%
CY2019 Q1	22	20	90.9%
CY2019 Q2	27	24	88.8%
CY2019 Q3	30	28	93.3%
CY2019 Q4	21	16	76.1%

Source: MMC Application, updated Q4.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases, as shown in Table 2B. MHCC staff found that the quarterly percentage of patients with a DTB time of 90 minutes or less ranged from 76.1% to 100.0%. 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, whereas MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods. Over rolling eight quarter periods, MMC complied with this standard, with between 79.0% and 93.0% of primary PCI cases meeting the DTB time standard, as shown in Table 2B. Staff also noted that MMC did not perform primary PCI on any transfer patients during the review period based on analysis of the ACC-NCDR CathPCI data.

MHCC staff concludes that MMC complies with this standard.

Table 2B: MMC Non-Transfer Primary PCI Case Volume and Percentage of Cases With DTB Less Than or Equal to 90 Minutes, by Time Period

Quarterly Performance				Rolling 8-Quarter Performance		
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
2015q1	28	25	89.3%			
2015q2	27	21	77.8%			
2015q3	24	17	70.8%			
2015q4	16	15	93.8%			
2016q1	25	22	88.0%			
2016q2	15	12	80.0%			
2016q3	25	21	84.0%			
2016q4	26	24	92.3%	186	157	84.4%
2017q1	24	20	83.3%	182	152	83.5%
2017q2	23	20	87.0%	178	151	84.8%
2017q3	22	16	72.7%	176	150	85.2%
2017q4	19	15	78.9%	179	150	83.8%
2018q1	20	15	75.0%	174	143	82.2%
2018q2	20	17	85.0%	179	148	82.7%
2018q3	19	16	84.2%	173	143	82.7%
2018q4	20	16	80.0%	167	135	80.8%
2019q1	24	18	75.0%	143	133	93.0%
2019q2	29	24	82.8%	173	137	79.2%
2019q3	28	24	85.7%	179	145	81.0%
2019q4	21	13	61.9%	181	143	79.0%

Source: MHCC analysis of ACC-NCDR CathPCI data CY 2015- CY 2019.

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

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

As shown in Table 3A, below, MMC reported the number of physicians, nurses, and technicians who were available to provide cardiac catheterization services to acute myocardial infarction patients, one week prior to the due date of the application.

Table 3A: Total Number of CCL Physician, Nursing, and Technical Staff

Staff Category	Number/FTEs	Cross Training (S/C/M)*
Physician	N = 6	Interventional Cardiologist
Nurse	8.5 (FTE); 1 PRN	C, M
Technician	5.0 (FTE); 2 PRN	S, C, M

Source: MMC Application, Q6a.

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

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by MMC to information reported by three other existing PCI programs in their applications for a Certificate of Ongoing Performance, which reported a similar volume of PCI cases. MHCC staff observed that MMC has a slightly greater number of full-time equivalent (FTE) nurses than Johns Hopkins Bayview Medical Center and University of Maryland (UM) Prince George's Hospital Center, and a higher number of nurse FTEs than AHC Shady Grove. MMC had one less technician FTE than UM Prince George's Hospital Center. However, MMC reported the same number of technician FTEs as AHC Shady Grove, which had a similar case volume of PCI cases in 2018, as shown in Table 3B.

Table 3B: CCL Staffing for MMC and Other Select PCI Programs

Program	2018 Total PCI Volume*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
MMC	290	N = 6	8.5	5.0
Johns Hopkins Bayview Medical Center	200	N = 10	6.0	5.8
UM Prince George's Hospital Center	247	N = 5	10.0	6.0
AHC Shady Grove	269	N = 5	6.0	5.0

Sources: MMC 2019 PCI Certificate of Ongoing Performance Application, Johns Hopkins Bayview Medical Center 2019 PCI Certificate of Ongoing Performance Application, UM Prince George's Hospital Center 2019 PCI Certificate of Ongoing Performance Application, AHC Shady Grove 2019 PCI Certificate of Ongoing Performance Application.

*Volumes for either fiscal or calendar year (CY)

MHCC staff concludes that there is adequate nursing and technical staff to provide services. MMC complies with this standard.

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

MMC provided a signed letter of commitment from Dr. Joshi acknowledging that MMC 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 MMC 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.

MMC provided a list of the staff involved with these functions. As shown in Table 4, there are five positions with direct responsibility for data management and quality and a total of six FTEs.

Table 4: MMC Data Management and Quality Improvement Staff FTEs

Position Title	FTEs
Clinical Manager	1.0
CCL Registered Nurse Staff 1	1.0
CCL Registered Nurse Staff 2	1.0
Radiology Technologist	1.0
CCL Data Coordinators	2.0
Total	6.0

Source: MMC application Q8.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that MMC 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.

Robert Marshall, M.D., is the medical director for MMC’s interventional cardiology services. He has held this position since 2008 and is responsible for physician on-call schedules providing around the clock coverage. Dr. Marshall is also responsible for reviewing selected cases with CCL personnel during routine conferences, as well as STEMI cases in Interventional Cardiology Committee meetings. As described by MMC, the Medical Staff Office and the Vice President of Medical Affairs are responsible for granting or terminating PCI privileges and, along with Dr. Marshall, for completing annual performance reviews and follow-up on any cases where medical management was deemed to be less than optimal. The director is also expected to review CCL lab policies. In addition, the director has final authority on granting privileges for cardiologists practicing in the CCL, among many other responsibilities.

Staff Analysis and Conclusion

MHCC staff concludes that MMC 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.

MMC provided a list of the continuing educational programs and activities in which staff in the CCL and Critical Care Unit (CCU) participated between January 2015 and August 2019. MMC stated that staff participate in educational activities and services throughout the year as needed or required. These educational activities may include independent assigned learning, staff meetings, clinical inquiry meetings, best practice meetings, and PCI performance meetings. Additionally, MMC requires all registered nurses and radiologic technologists (RT) to complete a CCL- and CCU-specific skills validation competency test annually as part of their yearly evaluation. The competency tests include but are not limited to written skills, presentations, and verbal tests that nurses and RTs must meet yearly. If a staff member fails to demonstrate competency in an area, an action plan is developed.

MMC also notes that on September 1, 2018, MMC converted to the EPIC Electronic Health Record System. During the preceding four months, staff education was centered on completing the training on the new electronic record system. The CCL staff, in addition, were trained on the EPIC CUPID Invasive Cardiovascular module. Each staff member participated in education activities that ranged from eight to greater than thirty hours, and several members of the CCL staff became subject matter experts in navigating EPIC. MMC attributed the hospital's successful transition to EPIC, in part, on the promotion of a long-time radiology tech in the CCL to the EPIC analyst role. The analyst understood MMC's workflow and was able to integrate MMC's imaging, hemodynamics, and documentation systems efficiently.

Staff Analysis and Conclusion

MHCC staff notes that MMC's continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that MMC complies with this standard.

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

Dr. Joshi signed and dated a transfer agreement with University of Maryland St. Joseph Medical Center in Towson. The agreement provides that the respective institutions agree to accept from each other patients who need additional medical services that are offered by it, but not offered by or available at the other hospital.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that MMC 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.

Dr. Joshi signed and dated an agreement with Butler Medical Transport, LLC (Butler) that covers transportation to MMC. The agreement provides that, for emergent transport requests, Butler is required to arrive at the sending facility for pick-up within 30 minutes of a request.

Staff Analysis and Conclusion

MHCC staff reviewed the transport agreement and concludes that MMC meets this standard.

Quality

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

MMC provided attendance records for interventional cardiology meetings held between January 2015 and June 2019. MMC holds interventional cardiology meetings at least bi-monthly unless the regular meeting date is cancelled due to a lack of staff availability or unforeseen circumstances. MMC noted that if a meeting is canceled, information regarding the meeting is sent to participants electronically. Additionally, MMC provided attendance records for MMC's catheterization (cath) conference meetings held from January 2015 through November 2020. MMC initially stated that CCL nurses and technologists are invited to attend the bi-monthly interventional cardiology meetings, but generally do not attend. MMC subsequently stated that nurses and technologists regularly participate in case review at MMC's cath conference meetings with the Medical Director, Dr. Marshall, in the CCL during business hours.

MMC noted that the cath conference meetings are ad-hoc and occur whenever any staff member requests a review of a case. MMC noted that the cath conference meetings differ from the regularly held interventional cardiology meetings. For example, during these cath conferences, cases are discussed using all the images and all clinical data available to review the course of treatment and outcomes specific to the patients' time in the CCL. MMC noted that the interventional cardiology meetings and strategy care group meetings generally do not focus on CCL images, product selection, or clinical techniques as much as continuum of care treatment decisions, processes, and outcomes. Another distinction cited is that cath conferences are held during the downtime of regular business hours, when all the staff is available. The other two meetings are either held after business hours when the CCL staff would have to stay over, or they occur during a pre-scheduled time regardless of the case volume in the CCL at that time. MMC noted that this approach allows all staff members to attend and participate in cath conference meetings.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for the interventional cardiology meetings and cath conference meetings. The documentation submitted by MMC for interventional cardiology meetings included attendance records and meeting minutes for five meetings in 2015, four meetings in 2016, five meetings in 2017, three meetings in 2018, and two meetings in 2019.

Although nurses and technologists do not generally attend these formal interventional cardiology meetings, nurses and technologists participate in the ad-hoc case review meetings with the medical director. The documentation submitted by MMC for cath conference meetings included attendance records for thirteen meetings in 2015, eleven meetings in 2016, nine meetings in 2017, two meetings in 2018, nine meetings in 2019, and eight meetings in 2020. Because nurses and technologists are not required to participate in the formal interventional case review meetings but participate in the ad-hoc cath conference meetings with the medical director, MHCC staff concludes that MMC plans to fully comply with this standard in future years.

MHCC staff recommends that the Commission find that MMC complies with this standard and that a condition be added to the Certificate of Ongoing Performance requiring semiannual submission to MHCC staff of meeting dates and documentation of attendance for each meeting.

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

MMC provided a list of meeting dates, invited participants, and meeting notes that included attendance for meetings held between January 2015 and July 2019. MMC also stated that the team members for the strategy of care group include interventional cardiologists, emergency medicine physicians, emergency medical services providers, hospitalists, patient care services nurses, clinical resource nurses, clinical quality specialists, CCL technologists, cardiac rehabilitation staff, emergency department nurses, and pharmacists.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for MMC's Strategy of Care team meetings. Ten meetings were held in both 2015 and 2016, twelve meetings were held in 2017, ten meetings were held in 2018, and ten meetings were held in 2019. MMC reported a total of five meeting cancellations during the review period. The reasons for cancellations included meeting participants not being available, CCL manager's scheduling conflicts, and surveyors from The Joint Commission being on-site. MMC noted that whenever a meeting was cancelled, the relevant information was sent to participants electronically.

MHCC staff concludes that MMC 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.

MMC submitted copies of the external review reports for PCI cases performed between January 2015 and December 2019. MMC explained that external review of cases is performed by the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), an MHCC-approved peer review system. MMC noted that PCI procedures were selected randomly

for review and the minimum number of cases per physician were reviewed, in accordance with COMAR regulations.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 5. As shown in Table 5, although only 5% of cases are required to be reviewed externally, between 12.2% and 16.9% of cases were reviewed each year.

Table 5: MMC External Review, January 2015- December 2019

Time Period	Reported PCI Case Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2015	196	24	12.2%	Annually	Yes
CY 2016	206	28	13.5%	Semi-annually	Yes
CY 2017	189	30	15.8%	Semi-annually	Yes
CY 2018	183	31	16.9%	Semi-annually	Yes
CY 2019	213	28	13.1%	Semi-annually	Yes

Source: MHCC staff analysis of MACPAQ reports.

* Each semiannual review included at least three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

Beginning in the second half of 2015, a minimum number of three cases per interventionalist must be reviewed for each semiannual review or all cases if fewer than three cases were performed, as required by COMAR 10.24.17. For the period between January 2015 and June 2019, MHCC staff verified that, when an interventionalist performed fewer than three cases in an applicable review period, MACPAQ reviewed all cases, as required.

MMC 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, MMC stated that quarterly internal review consists of additional random selection of PCI cases including primary and non-primary PCI cases for all interventionalists, in accordance with COMAR 10.24.17.09. MMC's Interventional Cardiology Peer Review group meets quarterly to conduct internal review of cases selected both randomly and on a non-random basis. Approximately 20 cases are reviewed internally each quarter. If an operator performs less than two cases per quarter, all cases are reviewed internally. In addition, MMC noted that MACPAQ conducts semiannual reviews of randomly selected non-primary PCI cases, in compliance with the Commission's requirement for external review of PCI cases.

Staff Analysis and Conclusion

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number of cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of cases to be reviewed to satisfy the requirements for review of individual interventionalists. The bulletin states that a semi-annual review of at least three cases or 10% of cases, whichever is greater, per interventionalist, as part of an external review meets the standard for the review of individual interventionalists, and the requirements in COMAR 10.24.17.07D(5)(c) are equivalent to those in COMAR 10.24.17.07C(4)(d).¹

The information provided by MMC documents that at least six cases or 10 percent of cases (or all cases if fewer than six cases were performed annually) are reviewed for each interventionalist. As required, these reviews include information on patient history, patient presentation, medical imaging, medical test results, and patient disposition. The external reviews conducted by MACPAQ meet the requirements of 10.24.17.07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records.

MHCC staff concludes that MMC satisfactorily conducts individual interventionalist review as provided in COMAR 10.24.17.07C(4)(d) and described in the October 2015 bulletin, with respect to COMAR 10.24.17.07D(5)(c).²

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

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

Staff Analysis and Conclusion

MHCC staff concludes that MMC complies with this standard.

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

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

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.***

MMC's Interventional Cardiology Quality Committee (ICQC) is responsible for evaluating and analyzing the medical necessity and appropriateness of interventional procedures performed in the Cardiac Catheterization Lab. This committee meets at least monthly to review and oversee the Interventional Cardiology Peer Review process. MMC's ICQC consists of the medical director of Interventional Cardiology, who serves as Chair of the Committee, the Chair of Cardiology, and medical staff representatives from the Department of Cardiology and Interventional Cardiology. In addition, a Performance Improvement Facilitator serves as support staff to the Committee. To serve on the Committee, members are required to sign a confidentiality statement at least annually.

MMC also provided examples of recent quality assurance activities related to PCI patients. For example, in 2015, there were issues that occurred when some of the on-call STEMI team were not receiving alerts on their pagers. New pagers were procured, and a dual-alert system utilizing both staff pagers and cell phones was implemented. Through case discussions during CCL staff meetings, staff determined that a registered nurse needed to be in the patient's room during femoral sheath pulls. Education was provided to both the post-anesthesia care unit and critical care staff. A second quality assurance initiative was established when one of the CCL nurses designed a new STEMI documentation form. The new form included critical data fields, specifically for the timing of calling a STEMI case and medication administration times. All staff were educated on use of the new form.

MMC stated that a third quality initiative was prompted by the review of two cases in the fall of 2015 where there was a delay in calling the code STEMI after performing the qualifying electrocardiogram (EKG). Going forward, the Critical Care educator encouraged nurses to be proactive when obtaining an EKG, either directly consulting with the intensivist in critical care or sending the EKG to the interventionalist on call if there was a call delay. Additionally, to minimize errors and delays, updated phone numbers and FAX numbers for all the interventionalists were made readily available in the units and the emergency department.

Staff Analysis and Conclusion

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

Patient Outcome Measures

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

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

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

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

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

MMC submitted risk-adjusted mortality rates by rolling 12-month reporting period for 2015 Q1 through 2020 Q3 when available, as shown in Table 6. These data are not available for any hospitals participating in the ACC-NCDR CathPCI data registry for the rolling 12-month period of 2017 Q3 through 2018 Q2.

Table 6: MMC 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
2019q4-2020q3	8.16	[3.05, 17.05]	6.37	Yes	2.57	[0.95, 5.49]	1.06	Yes
2019q3-2020q2	6.54	[1.80, 16.17]	6.06	Yes	2.36	[0.77, 5.41]	1.00	Yes
2019q2-2020q1	10.37	[3.86, 21.79]	5.99	Yes	2.11	[0.69, 4.84]	0.95	Yes
2019q1-2019q4	10.37	[4.24, 20.60]	6.01	Yes	1.45	[0.30, 4.17]	0.95	Yes
2018q4-2019q3	9.34	[3.48, 19.62]	6.06	Yes	0.93	[0.11, 3.32]	0.98	Yes
2018q3-2019q2	11.11	[4.55, 21.95]	6.38	Yes	1.27	[0.26, 3.67]	1.00	Yes
2018q2-2019q1	9.71	[3.63, 20.22]	6.13	Yes	1.83	[0.38, 5.27]	0.99	Yes
2018q1-2018q4	7.98	[3.27, 15.68]	6.00	Yes	1.76	[0.36, 5.09]	1.00	Yes
2017q4-2018q3	6.51	[2.43, 13.44]	6.54	Yes	2.29	[0.47, 6.61]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	5.33	[1.75, 11.97]	6.91	Yes	1.18	[0.14, 4.21]	1.03	Yes
2017q1-2017q4	4.73	[0.98, 13.39]	6.86	Yes	0.95	[0.12, 3.39]	0.99	Yes
2016q4-2017q3	5.59	[1.84, 12.63]	6.75	Yes	1.29	[0.27, 3.71]	0.98	Yes
2016q3-2017q2	6.25	[2.32, 13.16]	6.64	Yes	1.59	[0.43, 4.0]	0.95	Yes
2016q2-2017q3	5.74	[1.89, 12.96]	6.77	Yes	1.65	[0.34, 4.75]	0.97	Yes
2016q1-2017q4	6.68	[2.49, 14.02]	6.82	Yes	2.35	[0.64, 5.92]	0.95	Yes
2015q4-2016q3	6.91	[2.28, 15.51]	6.71	Yes	1.38	[0.38, 3.48]	0.95	Yes
2015q3-2016q2	5.46	[1.5, 13.46]	6.66	Yes	1.05	[0.22, 3.02]	0.93	Yes
2015q2-2016q1	4.78	[1.57, 10.78]	6.45	Yes	0.79	[0.1, 2.81]	0.90	Yes
2015q1-2015q4	4.34	[1.42, 9.8]	6.26	Yes	0.57	[0.07, 2.02]	0.90	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and December 2019.

Notes: A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark for ST-elevation 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 STEMI and non-STEMI cases for each reporting period.

Staff Analysis and Conclusion

This standard is not applicable for most of the review periods included in MMC's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar earlier standard referenced a statewide average as the benchmark, as recommended by MHCC's Clinical Advisory Group in 2012. However, MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk-adjusted mortality for the period between January 2015 and December 2018. MHCC staff has provided information in Table 6 that shows MMC's performance relative to the current standard over the period between January 2015 and September 2020.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different from the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for MMC for all 12-month reporting periods between January 2015 and September 2020, when an adjusted mortality rate was reported. MHCC staff concludes that MMC would have met this standard if it had been applicable for the period January 2015 through September 2019. The hospital meets the benchmark for both STEMI and non-STEMI cases for the periods ending December 2019, March 2020, June 2020, and September 2020.

MHCC staff concludes that MMC complies with this standard.

Physician Resources

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

MMC submitted information on the volume of primary and elective PCI cases at MMC and other hospitals, by physician and quarter, from 2015 through 2019 for Drs. Padder, Hashim, Flyer, Quash, Zirvi, Ahmad, Marshall, and Fallahi. The interventionalists each signed and dated an affidavit affirming under penalties of perjury that the information contained in the table on their form is true and correct to the best of their knowledge, information, and belief.

Staff Analysis and Conclusion

Staff determined that the interventionalists performing PCI procedures at MMC performed at least 50 PCI procedures, on average, for each of two 24-month periods, between 2015 and 2019. Dr. Mansoor Ahmad did not receive his privileges from MMC until July 1, 2019. His PCI case volume reflects his Interventional Cardiology fellowship at Christiana Care in Delaware.

MHCC staff concludes that MMC 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.

MMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

This standard does not apply to MMC. While MMC does not have on-site cardiac surgery, staff notes that each physician performing primary PCI procedures at MMC performed at least 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.***

MMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to MMC.

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

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

MMC submitted a signed and dated statement from Dr. Marshall acknowledging that all physicians performing primary PCI services at MMC are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that MMC meets this standard.

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

MMC submitted signed and dated attestations from Drs. Ahmad, Fallahi, Flyer, Marshall, Padder, and Zirvi stating that each has completed a minimum of 30 hours of continuing medical education credits in interventional cardiology in the last two years. Additionally, MMC noted that Dr. Quash resigned his privileges at MMC on February 8, 2021.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that MMC meets this standard.

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

MMC submitted a signed statement from Dr. Marshall acknowledging that each physician who 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. MMC also submitted a copy of its on-call schedule for January through June 2019 and September 2020.

Staff Analysis and Conclusion

Staff examined the on-call schedule for January through June 2019 and observed that all current physicians appeared on the schedule except Dr. Flyer. MMC advised that Dr. Flyer has been participating yearly in the MMC on-call schedule since April 2012. MMC noted that his on-call participation is intermittent at the request of the CCL director, Dr Marshall. MMC provided a recent schedule that included Dr Flyer for September 2020.

MHCC staff concludes that MMC 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.

MMC provided PCI case volume information for FY 2015 through FY 2019, as shown in Table 7. This information shows that MMC performed between 280 and 308 cases annually.

**Table7: MMC Total PCI Volume,
FY 2015- FY 2019**

Fiscal Year	Total Number of PCI Cases
2015	308
2016	305
2017	280
2018	290
2019	308

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

Staff Analysis and Conclusion

MHCC staff reviewed the PCI case volume information submitted by MMC and analyzed the ACC-NCDR CathPCI data submitted. Staff determined at least 200 PCI cases were performed on an annual basis over the five fiscal years reviewed (FY 2015-FY 2019).

MHCC staff concludes that MMC meets this standard.

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

MMC provided the number of primary PCI cases by quarter between January 2015 and December 2019.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI case volume for CY 2015 through CY 2019. This analysis shows primary PCI case volume ranged from 79 to 102 cases in each year and confirmed that MMC exceeded the threshold of 49 cases annually referenced in the standard.

Table 8: MMC Primary PCI Case Volume

Calendar Year	Number of Primary PCI Cases
2015	95
2016	91
2017	88
2018	79
2019	102

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2015- CY 2019.

MHCC staff determined that this standard does not apply to MMC.

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

MMC provided the number of primary PCI cases by interventionalist for 2015 through 2019 for all physicians except one.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by MMC. It shows that between January 2015 and December 2019, each interventionalist completed at least 11 primary PCI procedures per year for, except for one physician. This physician had recently completed a fellowship and only began providing primary PCI services at MMC in July 2019. Staff also analyzed the data in the ACC-NCDR CathPCI registry for CY 2015 through CY 2019 and concluded that each interventionalist met the target of 11 or more primary PCI cases annually, except for one physician in 2019, as previously noted.

MHCC staff concludes that MMC meets 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.***

MMC noted that MACPAQ reports were reviewed for calendar years 2015 through 2019 for appropriateness in the categories of angiographic appropriateness, clinical appropriateness, and ACC/AHA Guideline appropriateness (AUC-Guideline). MACPAQ reviews rated one patient as being rarely appropriate under the category of angiographic appropriateness for the review period of July 1, 2018-December 31, 2018.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports from January 2015 through June 2019 and determined that there was only one case between January 2015 and June 2019 that was determined to be “rarely appropriate” with respect to one or more of the following: clinical criteria; angiographic criteria; and ACC/AHA appropriateness criteria. MMC provided additional information about the follow-up on this case. MMC stated that the case was reviewed during an internal Peer Review meeting, and the physician who performed the case was counseled. The results of the review were shared with the Outcomes Analyst in the medical staff office who then followed up with the Professional Practice Evaluation Committee.

MHCC staff concludes that MMC complies with this standard.

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

- (a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.***
- (b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician (s) believes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.***
- (c) Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.***
- (d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believes that transfer to a tertiary institution may be harmful to the patient.***

MMC stated that, over the review period, there were no patients who received thrombolytic therapy. MMC also reported that no patients received primary PCI services inappropriately based on internal or external review.

Staff Analysis and Conclusion

MHCC staff has determined that MMC complies with the standard.

RECOMMENDATION

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

MMC shall hold meetings at least every other month for the purpose of conducting interventional case review that include physicians, technicians, and nurses who care for primary PCI patients, as required in COMAR 10.24.17.07D(5)(a), and shall submit to Commission staff attendance lists for each of these hospital staff meetings held between January and June by August 1 of each year and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2022. After this date, the Executive Director may release MMC from the reporting requirement if the Executive Director concludes that the hospital has achieved substantial compliance with this condition.