IN THE MATTER OF	*	**BEFORE THE MARYLAND**
UNIVERSITY OF MARYLAND UPPER	*	**HEALTH CARE COMMISSION**
CHESAPEAKE MEDICAL CENTER	*	
Docket No. 24-12-CP047	*	

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STAFF REPORT AND RECOMMENDATION

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

September 18, 2025

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 PCI services, for a period of time 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 must be conducted. Staff has the authority to conduct a focused review based on reported patient safety concerns, aberrations in data identified by Commission staff, 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 does not 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

University of Maryland Upper Chesapeake Medical Center

The University of Maryland Upper Chesapeake Medical Center (UCMC) is a 253-bed general hospital that is located in Bel Air (Harford County). UCMC is part of the University of Maryland Medical System and does not have a cardiac surgery program on-site.

UCMC began providing primary PCI services on April 4, 2008. This approval authorized UCMC to provide primary PCI services for a one-year period. In March 2009, the Commission approved a two-year waiver for UCMC, allowing it to continue to provide primary PCI services without on-site cardiac surgery. UCMC subsequently received renewals of its waiver to provide primary PCI services in March 2011 and April 2013. UCMC obtained a Certificate of Conformance, allowing it to provide elective PCI services as well as primary PCI services, in December 2014. This authorization, based on the 2012 legislation outlined above, allows UCMC to provide elective PCI services subject to periodic review of its ongoing performance. The hospital received its first Certificate of Ongoing Performance to provide primary and elective PCI services on May 21, 2020. This is the first renewal of UCMC's Certificate of Ongoing Performance for its PCI program.

Health Planning Region

Four health planning regions for adult cardiac services are defined in the Cardiac Services Chapter. The regions are defined by geographic areas. Harford County is in the Baltimore/Upper Shore region, which also includes Baltimore City and Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Howard, Kent, Queen Anne's, and Talbot counties. Fourteen hospitals in this region provide PCI services. Five of these hospitals provide both cardiac surgery and PCI services and seven, including UCMC, provide only PCI services.

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[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).

Staff Recommendation

MHCC staff recommends that the Commission approve UCMC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services. A description of UCMC's documentation of its compliance with standards and the staff's analysis follows.

II. PROCEDURAL HISTORY

On January 11, 2024, UCMC applied to renew its Certificate of Ongoing Performance. Staff reviewed the application and requested additional information on March 12, 2024, and received a response on April 3, 2024. MHCC sent an additional request for information on April 25, 2024. Staff received responses on May 1 and May 3, 2024.

On May 15, 2024, MHCC notified the hospital that the hospital's current Certificate of Ongoing Performance would be extended for a year until May 21, 2025 because of the need to complete a focused review. The focused review was required because the hospital's adjusted mortality rate for STEMI[4] patients was statistically significantly worse than the national average in the 12-month reporting period ending 2023 Q3.[5] Subsequently, there were three more consecutive reporting periods when the hospital performed statistically significantly worse than the national average for mortality of STEMI patients. The focused review of UCMC's PCI program was completed on March 13, 2025.[6]

On May 14, 2025, MHCC staff notified the hospital that its Certificate of Ongoing Performance had been extended again, for approximately six months. On June 11, 2025, MHCC staff requested additional information from UCMC due to the amount of time that had passed since the hospital submitted its application. MHCC sent additional requests for information on August 20, 2025, August 22, 2025, and August 29, 2025. Staff received responses on July 18, 2025, August 21, 2025, August 22, 2025, August 26, 2025, August 27, 2025, and September 3, 2025.

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 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

[4] As defined in COMAR 20.24.17.11, an ST-segment elevation myocardial infarction (STEMI) means a heart attack in which there is cardiac muscle damage resulting from an acute interruption of blood supply to a part of the heart that can be demonstrated by a change of ST-segment elevation on an electrocardiogram.

[5] COMAR 10.24.17.07D(6)(c) requires that a focused review be conducted when a hospital's risk adjusted mortality rate for STEMI cases exceeds the established benchmark beyond the acceptable margin of error.

[6] There were other focused reviews of PCI programs that were identified prior to the one for UCMC and that delayed the review of cases for UCMC.

necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

UCMC stated that no deficiencies in data collection or reporting have been identified. Data for all STEMI and non-STEMI patients are entered into the American Heart Association Get with the Guidelines-coronary artery disease (AHA GWTG-CAD) database and data for all STEMI, non-STEMI, and other PCI patients are recorded in the American College of Cardiology's National Cardiac Data Registry (ACC-NCDR) CathPCI registry of catheterization cases. UCMC shares data from the ACC-NCDR CathPCI registry with MHCC as requested.

Staff Analysis and Conclusion

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

UCMC provided a table of downtime between January 1, 2019 and July 2, 2025, along with the reasons for the downtimes. Room 1 is the cardiac catheterization laboratory (CCL), the primary space for PCI procedures, and Room 2 is the interventional angiography laboratory, the secondary (back-up) space for PCI procedures. This information is shown below in Table 1.

Table 1: UCMC CCL Downtime by Room, Duration of Downtime, and Reason

Room	Start Date	End Date	Duration (hours)	Reason / Explanation
2	4/7/19	4/7/19	2.00	Replaced TCCS and smart box
2	4/26/19	4/29/19	76.18	IT issue, not sending images to AW server
2	5/22/19	5/22/19	14.92	Cannot turn system on, UPS problem
1	6/26/19	6/26/19	5.00	Preventive Maintenance
2	7/10/19	7/10/19	2.73	Opened and re-seated all connections
1	7/12/19	7/12/19	2.97	C-Arm repair
2	7/27/19	7/27/19	5.00	Preventive Maintenance
1	8/1/19	8/1/19	3.63	Hardware issue
2	8/12/19	8/12/19	0.78	Replaced the TSSC cable
1	9/9/19	9/9/19	2.00	Replaced pan controller wire harness
1	10/3/19	10/3/19	2.50	Repaired the x-ray tube water lines
2	10/31/19	10/31/19	2.27	Angio cable repair
1	11/25/19	11/25/19	2.38	Hardware Replacement
1	11/30/19	11/30/19	4.50	Preventive maintenance
2	12/13/19	12/13/19	1.18	Table Evaluation – not moving side to side
2	12/23/19	12/23/19	0.75	Table repair – not moving side to side
2	1/13/20	1/13/20	1.00	Replaced batteries in cabinet UPS
2	1/16/20	1/16/20	2.17	Replace the table panning board
2	1/17/20	1/17/20	6.32	Hardware replacement, repair.

Table 1: UCMC CCL Downtime by Room, Duration of Downtime, and Reason

Room	Start Date	End Date	Duration (hours)	Reason / Explanation
2	1/25/20	1/25/20	3.00	Preventive maintenance
2	2/20/20	2/20/20	0.50	Horizontal grid lines during fluoro - repair
2	4/28/20	4/28/20	2.00	Adjusted boom tension
2	4/30/20	4/30/20	5.00	Adjusted bearing, cleaned
2	5/13/20	5/13/20	1.00	Repair X-ray
1	5/18/20	5/18/20	2.50	Preventive Maintenance
1	5/21/20	5/21/20	2.00	Replaced the smart box
2	7/7/20	7/8/20	25.98	Replaced both drives in the DL, database setup.
2	7/8/20	7/8/20	1.50	Preventive Maintenance
2	7/8/20	7/8/20	2.00	Preventive Maintenance
2	7/10/20	7/10/20	1.00	System reboot and DICOM info check
2	7/13/20	7/13/20	5.62	Software and hardware maintenance
2	7/15/20	7/16/20	24.03	Hard drives failed, replaced
2	8/13/20	8/13/20	4.48	Repair by GE
2	8/18/20	8/18/20	3.00	“Last query failed” – will not pull list - Repair
2	9/3/20	9/3/20	0.50	Preventive Maintenance
2	9/18/20	9/18/20	0.25	Replace footswitch
1	11/8/20	11/8/20	5.00	Preventive maintenance
1	11/8/20	11/8/20	2.00	Hardware replacement
1	11/8/20	11/8/20	1.00	Hardware replacement
1	11/16/20	11/17/20	38.50	Tube replacement
2	1/17/21	1/17/21	4.50	Preventive Maintenance
2	2/5/21	2/5/21	2.75	Swap out and test large control modules
2	2/16/21	2/16/21	1.50	Replaced the smartbox on the slave connector
2	3/15/21	3/15/21	1.00	Fixed broken rail
2	3/19/21	3/19/21	0.50	Fixed broken rail
1	4/23/21	4/23/21	1.00	Hardware replacement
2	5/4/21	5/6/21	56.25	Angio lab will not shoot x-rays bad Fiber optics
1	5/15/21	5/15/21	4.00	Preventive maintenance
2	5/28/21	5/28/21	0.50	AW server issue
2	7/23/21	7/23/21	2.50	Preventive Maintenance
2	7/29/21	7/29/21	0.93	Replaced collimator controller
1	8/12/21	8/14/21	48.17	Replaced coolant hose
1	9/16/21	9/17/21	30.38	DIPB, FIBP Board replacement
1	11/13/21	11/13/21	3.00	Preventive maintenance
1	12/3/21	12/3/21	3.50	Replaced cable covers
2	1/29/22	1/29/22	2.50	Preventive Maintenance
2	1/29/22	1/29/22	2.50	Preventive Maintenance
2	2/15/22	2/15/22	0.75	Filled the detector chiller with coolant
1	5/21/22	5/21/22	3.75	Preventive Maintenance
2	5/23/22	5/23/22	0.50	Replaced fluids in detector chiller with coolant
2	7/23/22	7/23/22	3.00	Preventive Maintenance
2	10/10/22	10/12/22	50.07	Hardware / software repair / maintenance
2	10/19/22	10/23/22	90.09	Not sending to PACS
2	10/21/22	10/21/22	0.88	Chiller overheating/ HVAC was turned off
1	11/19/22	11/19/22	3.50	Preventive maintenance
2	1/21/23	1/23/23	44.57	Tube replacement
2	1/23/23	1/23/23	1.43	Preventive Maintenance
2	1/24/23	1/24/23	6.78	Preventive Maintenance
1	4/25/23	4/25/23	0.75	Replacing footswitch

Table 1: UCMC CCL Downtime by Room, Duration of Downtime, and Reason

Room	Start Date	End Date	Duration (hours)	Reason / Explanation
1	5/20/23	5/20/23	3.50	Preventive maintenance
2	7/18/23	7/18/23	2.02	Angio System not rebooting
2	7/29/23	7/29/23	4.50	Preventive Maintenance
2	8/30/23	8/30/23	1.50	Controller replacement
1	11/28/23	11/28/23	3.50	Semi-Annual Planned Maintenance
1	3/1/24	3/1/24	1.00	Corrective Maintenance
1	3/4/24	3/4/24	0.50	Corrective Maintenance
1	5/31/24	5/31/24	1.00	Corrective Maintenance
1	5/31/24	5/31/24	3.50	Semi-Annual Planned Maintenance
1	10/25/24	10/25/24	0.10	Corrective Maintenance
1	11/16/24	11/16/24	5.75	Semi-Annual Planned Maintenance
1	1/6/25	1/8/25	56.57	Corrective Maintenance
1	5/1/25	5/1/25	0.03	Corrective Maintenance
1	5/21/25	5/21/25	1.55	Corrective Maintenance
1	5/29/25	5/29/25	4.01	Planned Maintenance
1	6/23/25	6/23/25	0.09	Corrective Maintenance
1	7/1/25	7/2/25	16.46	Corrective Maintenance

Source: UCMC application, pages 4-7 and UCMC information submitted on July 18, 2025.

UCMC stated that it was not necessary to notify the Maryland Institute for Emergency Medical Services Systems (MIEMSS) of downtimes because the STEMI program and cardiac catheterization services were continuously available. MIEMSS must only be informed if the hospital cannot treat STEMI patients. UCMC reported that data it submitted for downtimes included the downtimes for the CCL. There were several dates that indicated extended downtimes (over 24 hours) for the CCL. During these times, the other room was used for cardiac catheterizations. There were seven episodes of extended downtime for Room 2, as shown in Table 1, and in those instances, cardiac catheterizations were performed in Room 1.

Staff Analysis and Conclusion

MHCC staff reviewed the hospital's reported CCL closures during the period from April 2019 to December 2024 and determined that there was never a time that both CCLs were out of commission simultaneously. Primary PCI services were available 24 hours per day, seven days per week, as required. Staff concludes that UCMC meets 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.

UCMC provided a signed statement from Elizabeth Wise, FACHE, President and Chief Executive Officer (CEO), stating that door-to-balloon (DTB) times, exclusive of transfer patients, will not exceed 90 minutes from patient arrival at the hospital to revascularization for at least 75 percent of appropriate PCI patients. The hospital CEO also stated that the program will continue to track DTB times for all STEMI patients coming directly to the facility as well as transfer cases and that UCMC performs an extensive review of each individual case to identify and evaluate opportunities for improvement. UCMC provided quarterly counts of non-transfer patients who

received primary PCI and the number who had a DTB time of less than 90 minutes, as shown in Table 2a below.

Table 2a: UCMC Reported Compliance with DTB Benchmark for Non-Transfer Primary PCI Cases by Quarter, January 2020 – June 2024

Quarter	Total Non-Transfer Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases with DTB <=90 Minutes
2020 Q1	41	35	85.37%
2020 Q2	32	28	87.50%
2020 Q3	16	14	87.50%
2020 Q4	20	16	80.00%
2021 Q1	24	20	83.33%
2021 Q2	30	25	83.33%
2021 Q3	21	17	80.95%
2021 Q4	20	17	85.00%
2022 Q1	22	17	77.27%
2022 Q2	30	25	83.33%
2022 Q3	23	21	91.30%
2022 Q4	15	14	93.33%
2023 Q1	15	12	80.00%
2023 Q2	23	19	82.61%
2023 Q3	20	19	95.00%
2023 Q4	19	18	94.74%
2024 Q1	21	19	90.48%
2024 Q2	19	18	94.74%

Source: UCMC application page 8 and UCMC information submitted on July 18, 2025.

UCMC also stated that the hospital receives PCI transfer cases and provided quarterly information on its DTB times for transfer patients for the period of January 2020 through June 2024, as shown in Table 2b. The hospital also provided the reasons for delays of transfer patients. In several cases there were transportation delays. Some delays were due to the need to stabilize a patient or other patient factors beyond the hospital's control. The benchmark for DTB times for transfer of primary PCI patients is 120 minutes, as established by the American Heart Association and American College of Cardiology guidelines.[7]

UCMC explained that its strategies for improving transfer times for PCI patients include having representatives from the ambulance providers also participate in the multiple care area group meeting to review the STEMI case process. Another strategy the hospital implemented is the designation of an ED team member to review all STEMI transfer cases, participate in the weekly meetings, and provide feedback, support and education to both the ED team and EMS providers. Finally, Aberdeen Medical Center, the only facility that transfers STEMI PCI patients to UCMC, now has a specialized critical care ambulance available for the transfer of STEMI PCI patients.

[7] O'Gara PT, Kushner FG, Ascheim DD, et al. 2013. ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2013; 29(127):e362–425. https://www.ahajournals.org/doi/10.1161/cir.0b013e3182742cf6 Accessed September 7, 2025.

Table 2b: UCMC Reported Compliance with DTB Benchmark for Transfer Primary PCI Cases by Quarter, January 2020 – June 2024

Quarter	Total Transfer Primary PCI Volume	Cases with DTB <= 120 minutes	Percent of Cases with DTB <=120 Minutes
2020 Q1	3	2	66.67%
2020 Q2	3	2	66.67%
2020 Q3	6	5	83.33%
2020 Q4	7	4	57.14%
2021 Q1	3	1	33.33%
2021 Q2	3	2	66.67%
2021 Q3	10	5	50.00%
2021 Q4	4	2	50.00%
2022 Q1	1	1	100.00%
2022 Q2	6	5	83.33%
2022 Q3	3	2	66.67%
2022 Q4	3	0	0.00%
2023 Q1	5	5	100.00%
2023 Q2	6	6	100.00%
2023 Q3	5	5	100.00%
2023 Q4	3	3	100.00%
2024 Q1	5	5	100.00%
2024 Q2	4	4	100.00%

Source: UCMC application page 10 and UCMC information submitted on July 18, 2025.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer PCI cases and concluded that UCMC met the DTB standard in 14 of the 20 quarters from January 2020 through December 2024. 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 nonsystem reason for delay, and MHCC uses a DTB metric that includes all cases. MHCC staff also considers the hospital's performance on the DTB standard over longer periods that include multiple quarters. Over rolling eight-quarter periods, UCMC had a DTB of 90 minutes or less for over 75% of primary PCI cases in all periods shown in Table 3, with between 77.3% and 81.4% of PCI cases meeting this standard.

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

	Quarter			Rolling 8 Quarters		
Time Period	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes
2020 Q1	41	35	85.4%			
2020 Q2	32	28	87.5%			
2020 Q3	21	14	66.7%			
2020 Q4	22	16	72.7%			
2021 Q1	24	20	83.3%			
2021 Q2	30	25	83.3%			
2021 Q3	21	17	81.0%			
2021 Q4	23	17	73.9%	214	172	80.4%
2022 Q1	23	18	78.3%	196	155	79.1%
2022 Q2	30	25	83.3%	194	152	78.4%
2022 Q3	21	20	95.2%	194	158	81.4%
2022 Q4	21	14	66.7%	193	156	80.8%
2023 Q1	21	14	66.7%	190	150	78.9%
2023 Q2	25	18	72.0%	185	143	77.3%
2023 Q3	23	18	78.3%	187	144	77.0%
2023 Q4	18	15	83.3%	182	142	78.0%
2024 Q1	19	16	84.2%	178	140	78.7%
2024 Q2	14	12	85.7%	162	127	78.4%
2024 Q3	13	12	92.3%	154	119	77.3%
2024 Q4	17	14	82.4%	150	119	79.3%

Source: MHCC analysis of ACC-NCDR CathPCI data, January 1, 2020 – Dec. 31, 2024.

UCMC provided information on the reasons why the DTB standard of 90 minutes or less was not met in quarters when the standard was met in less than 75% of cases. UCMC provided detailed explanations for individual cases, as requested. Some patients did not initially present as STEMI and had other testing prior to PCI, based on symptoms. In CY 2020, four patients missed the DTB standard by less than 10 minutes due to prolonged time for an interventionalist to arrive. In CY 2021, there were three patients who missed the DTB standard by seven minutes or less due to prolonged time for an interventionalist to arrive. Some patients had cardiac arrest and required other treatment first. In some cases, obtaining patient consent or consent from a caregiver delayed treatment. In one case, the delay was due to another patient already in the CCL for PCI.

Eight patients missed the DTB standard due to prolonged time for an interventionalist to arrive during either CY 2020 or CY 2021, and MHCC staff requested additional information on the reasons interventionalists were often delayed in arriving. UCMC, years after these instances, speculated that traffic may have been an issue based on the route physicians would be driving and a multi-year construction project that affected traffic on that route. There was one quarter when, on four separate occasions, it took an interventionalist nearly an hour to arrive. Since 2021, late arrival of an interventionalist has not been reported as a reason for delays in quarters when UCMC missed the DTB standard.

With respect to transfer cases, staff analyzed the hospital's performance relative to a DTB benchmark of 120 minutes, as shown below in Table 4. The benchmark of 120 minutes is consistent with the American Heart Association and American College of Cardiology guidelines.[8]

Table 4: UCMC Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 120 Minutes, by Time Period

Time Period	Total Transfer PCI Volume	Cases With DTB<=120 Minutes	Percent of Cases with DTB <=120 Minutes
2020 Q1	3	1	33.3%
2020 Q2	3	2	66.7%
2020 Q3	4	4	100.0%
2020 Q4	7	4	57.1%
2021 Q1	2	1	50.0%
2021 Q2	3	2	66.7%
2021 Q3	9	4	44.4%
2021 Q4	4	2	50.0%
2022 Q1	1	0	0.0%
2022 Q2	6	4	66.7%
2022 Q3	2	1	50.0%
2022 Q4	4	0	0.0%
2023 Q1	1	1	100.0%
2023 Q2	4	2	50.0%
2023 Q3	4	4	100.0%
2023 Q4	2	1	50.0%
2024 Q1	4	2	50.0%
2024 Q2	2	1	50.0%
2024 Q3	9	4	44.4%
2024 Q4	4	2	50.0%

Source: MHCC analysis of ACC-NCDR CathPCI data, January 1, 2020 – Dec. 31, 2024.

MHCC staff's analysis of the ACC-NCDR CathPCI data shows that in 12 of the 20 quarters between January 2020 and December 2024, 50% or less of the transfer PCI cases achieved a DTB of 120 minutes or less in each quarter. A hospital is expected to strive to achieve a DTB time in primary PCI transfer cases of 120 minutes or less, however, many factors outside of a hospital's control affect the DTB times in transfer cases. For this reason, there is not a requirement that a certain percentage of cases achieve the benchmark of 120 minutes or less each quarter. Instead, a hospital is required to track the DTB times for transfer cases and evaluate areas for improvement.

In addition to tracking DTB times for transfer cases, UCMC provided information on the reasons for delays in DTB times for transfer patients and strategies it utilized for improving transfer times for PCI patients. The strategies UCMC identified for improving transport time included collaborating with AMR ambulance service, local Emergency Medical Services (EMS), and ExpressCare to optimize pick-up and transport times.

MHCC staff recommends that the Commission find that UCMC complies with the DTB standard for non-transfer cases because the hospital is meeting the standard for rolling eight-quarter periods between January 2020 and December 2024 and the reasons for missing the DTB standard in the past three years were primarily for non-system reasons for delay, such as difficult vascular access and a delay obtaining patient consent.

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.

UCMC provided the number of physicians, nurses, and technicians staffing the CCLs. This information is shown in Table 5a.

Table 5a: UCMC Reported
CCL Physician, Nursing, and Technician Staff

Role	Number / FTEs	Cross Training (S/C/M)*
Physician	4	
Nurse (FTE)	14 (0.9 FTEs)	13 - C/M 1 – C/M/S
Technician (FTE)	7 (0.9 FTEs)	7 – M/S

Source: UCMC January 2024 PCI Certificate of Ongoing Performance application, page 8
*(S) scrub, (C) circulate, (M) monitor.

Staff Analysis and Conclusion

MHCC staff compared the reported staffing levels at UCMC to the staffing levels for programs at three other hospitals with similar PCI case volumes. Table 5b provides comparative information on the PCI volume and staffing levels for UCMC, Johns Hopkins Hospital (JHH), Ascension St. Agnes (St. Agnes), and Suburban Hospital (Suburban). UCMC employs the same number of interventionalists as St. Agnes, and one less than Suburban. However, a comparison of the number of interventionalists at different hospitals is not particularly meaningful because some interventionalists may perform PCI at multiple hospitals, and there is not a strong correlation between the number of interventionalists needed and PCI volume. UCMC uses a similar number of technicians as compared to Suburban and St. Agnes and about half the number of technicians used at JHH. With regard to nurses, UCMC uses significantly more nurses, 14, compared to 8 at Suburban and 8.3 at St. Agnes and 6.5 at JHH.

Table 5b: CCL Staffing, UCMC and Selected Other PCI Programs

Program	Total PCI Case Volume in 2024	Interventionalists	Nurse FTEs	Technician FTEs
UCMC	412	4	14.0	6.5
Suburban	389	5	8.0	7.5
JHH	327	8	6.5	9.5 + 2 PRN
St. Agnes	276	4	8.3	5.0

Sources: UCMC January 2024 PCI Certificate of Ongoing Performance application and St. Agnes' PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2024; St. Agnes' January 2024 application for renewal of its Certificate of Ongoing Performance for Primary and Elective PCI Services and St. Agnes' PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2024; Suburban's June 2025 PCI Certificate of Ongoing Performance application and Suburban's PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2024; JHH's 2019 PCI Certificate of Ongoing Performance application with supplemental updates to Question 6a in 2023 and JHH's PCI volume from ACC-NCDR CathPCI registry report for period ending December 31, 2024.

Based on the above analysis of the number of staff reported at other hospitals with comparable PCI volumes to UCMC, MHCC staff concludes that there are adequate nursing and technical staff to provide services 24 hours per day, seven days per week. There was an issue with late arrivals of interventionalists affecting DTB times in CY 2020 and CY 2021, but that issue appears to have been resolved based on the hospital's compliance with the DTB standard in the three following years and the reported reasons for delays in quarters when the DTB standard was missed. MHCC staff concludes that UCMC complies with this standard.

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

UCMC provided a signed letter, dated October 31, 2023, from Elizabeth Wise, FACHE, President and Chief Executive Officer, committing UCMC to providing primary PCI services in accord with the requirements established by the Commission. Elizabeth Wise, FACHE stated that the hospital administration remains 100% committed to the PCI program as a key component of its heart and vascular service line and the critical level of care this program provides to the community.

Staff Analysis and Conclusion

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

UCMC stated, on page 13 of its application, that the hospital employs a 1.0 FTE STEMI coordinator who collects and enters data into the AHA GWTG-CAG database and a full-time PCI registry coordinator who collects and enters data into the CathPCI database. These coordinators also report on quarterly outcomes and review all cases at weekly STEMI review meetings and monthly STEMI Process Action Team meetings. A Quality Management Specialist (1.0 FTE), shared with other specialties, is primarily responsible for facilitating ongoing professional practice evaluation and for-cause focused professional practice evaluation activities for medical staff, facilitating peer review activities, abstracting data, and preparing reports for the National Hospital Quality Measures. The Quality Management Specialist is responsible for obtaining a list of all PCI procedures and sending this to the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ), an external review organization. This individual maintains and reports the results to leadership and monitors all PCI cases and other cardiac catheterizations performed at the facility and reports data to administration/leadership on a regular basis.

Staff Analysis and Conclusion

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

quality assurance activities to address DTB times for PCI patients and other concerns. MHCC staff concludes that UCMC 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.

UCMC stated that Michael N. Drossner, M.D., was appointed as the CCL Medical Director in 2008, and he continues to serve in that role. UCMC provided a copy of Dr. Drossner's job description.

Staff Analysis and Conclusion

MHCC staff reviewed the job description provided. The responsibilities include defining and implementing credentialing criteria, and reviewing, standardizing, and approving processes, procedures, and order sets related to the delivery of care and services in the CCL. Other responsibilities include assuring appropriate internal and external peer review, providing medical oversight to the monthly STEMI/Elective Angioplasty Process Action Team meetings, and maintaining ongoing communication with the manager of the CCL, the angiography laboratory, and the Director of the Heart and Vascular Institute to ensure quality and effectiveness. Based on the job description provided, MHCC concludes that UCMC complies with this standard.

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

UCMC requires that registered nurses complete at least 20 continuing education hours and that technicians complete at least five continuing education hours per year. These requirements are tracked by the Education Department in "UMMS U," the education program utilized by the University of Maryland Medical System. All classes and educational activities are recorded in UMMS U and can be reviewed by the manager to ensure that nurses and other staff meet all education requirements. UCMC also states that, on occasion, CCL staff receive education in the form of continuing education units or contact hours from vendor partners. These activities are also recorded in the UMMS U system. In addition, nurses and technicians participate in annual competency reviews that are closely tracked by the Education Department. All team members at UCMC have mandatory corporate training requirements. A list of these classes was submitted to MHCC for review. UCMC provided a list of the continuing educational programs and activities that staff in the CCL and intensive care unit participated in between 2019 and 2023, and the hospital reported that there were no changes to the educational programs as of June 2025.

Staff Analysis and Conclusion

MHCC staff reviewed the continuing medical education programming for staff that includes appropriate topics such as Advanced Cardiovascular Life Support (ACLS), Basic Life Support (BLS), Acute Kidney Injury After Cardiac Catheterization, Basic Arrhythmia, Intra-

Aortic Balloon Pump (IABP) and many other topics pertaining to emergency care, and specifically caridiac emergency, medicine. The hospital has a method for tracking the completion of the required educational activities. MHCC staff concludes that UCMC complies with this standard.

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

The applicant submitted a copy of its agreement, originally effective on February 15, 2011, with the University of Maryland Medical Center (UMMC), a tertiary care center, to unconditionally accept the transfer of patients who have undergone cardiac catheterizations or primary angioplasty services at UCMC for any required additional care, including emergent or elective cardiac surgery or PCI, and to provide timely transmission of required follow-up data on transferred patients.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and verified with UCMC that the agreement remains in effect. The agreement includes an automatic renewal provision that renews for one-year periods unless terminated. MHCC staff concludes that UCMC meets 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.

UCMC submitted a signed agreement dated May 5, 2023, between UCMC and Maryland Express Care, a division of the University of Maryland Medical System, for cardiac support emergency services. The agreement guarantees the arrival of an air or ground ambulance within 30 minutes of a request for the transport of a primary PCI patient to a tertiary care center.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement submitted by UCMC and concludes that the hospital meets the standard.

<u>Quality</u>

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

UCMC provided a list of the dates for the interventional case review meetings from January 2019 through June 2025, as well as attendee names, credentials, and titles.

Staff Analysis and Conclusion

MHCC reviewed dates and attendance records for interventional case review meetings and noted that an insufficient number of meetings were held, with sometimes long gaps between meetings. There were four meetings held in CY 2019; seven meetings in CY 2020; four in CY 2021; four in CY 2022; one in CY 2023; 12 in CY 2024; and six from January to June 2025. Initally, staff noted that typically one interventionalist attends UCMC's case review meetings that include nurses and technicians, primarily due to logistical challenges. Most of the interventionalists are based at St. Agnes Hospital, far from UCMC, and only one is available per day.

There were only four meetings held in 2019 because of a leadership change in the CCL. In 2021, there were only four meetings because of the COVID-19 pandemic increasing patient admissions and lab volume, and the hospital administration asked that meetings be reduced.

UCMC explained that the long gaps between meetings in multiple years stemmed from the transition to the Epic electronic medical record system requiring extensive staff training. Additionally, staff shortages due to departures and family medical leave, difficulty in recruiting, and turnover in leadership in 2022 exacerbated the irregularity of meetings.

When MHCC staff asked UCMC to provide information on more recent case review meetings in 2024 and 2025, UCMC provided information that documented additional meetings with case review, involving multiple interventional cardiologists, other physicians involved in the care of PCI patients, and other CCL staff. The UCMC interventionalists regularly participate in those meetings, which occur between one and four times a month. These meetings allow for both virtual and in-person participation by staff for both St. Agnes Hospital and UCMC. These meetings, along with both the frequency and greater attendance by interventionalists, leads MHCC staff to conclude that the hospital is sufficiently meeting the standard for case review meetings that include interventionalists, technicians, and nurses.

MHCC staff recommends that the Commission find that UCMC complies with this standard with the following condition on the Certificate of Ongoing Performance:

> UCMC shall submit to Commission staff, by January 31, 2026, the attendance lists for the interventional case review meetings that are held between July 1, 2025 and December 31, 2025, and submit attendance lists for interventional case review meetings held between January 1, 2026 and June 30, 2026, by July 31, 2026. UCMC shall continue to report this information every six months until the Executive Director releases UCMC from the reporting requirement.

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

UCMC submitted dates, attendee names, credentials, and titles for the multiple care area group between March 2019 and June 2025. UCMC also submitted minutes for these multiple care area group meetings.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for meetings between January 2019 through June 2025. UCMC held 10 meetings in CY 2019; eight meetings in CY 2020; 12 meetings in CY 2021; 11 meetings in 2022; 12 meetings in CY 2023; 12 meetings in CY 2024; and six meetings between January and June 2025. UCMC explained that two meetings were canceled in 2020 due to COVID-19, and a meeting scheduled in May 2022 was cancelled because of a meeting with representatives for the Joint Commission that day. MHCC staff also reviewed the titles of attendees and determined that leaders in each care area, as well as other relevant organizations (e.g., Harford County Emergency Medical Services, UMMS Transport, MIEMSS, Medicare Ambulance, QHIM) attended the meetings. MHCC staff recommends that the Commission find that UCMC satisfies this standard based on close adherence to holding the number of meetings required with the exception of 2020.

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.

UCMC provided MHCC with external review reports for the period January 2019 through June 2024. The external reviews were completed by MACPAQ, an MHCC-approved external review organization.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. UCMC submitted reports for external reviews that were conducted semiannually in 2019, 2020, 2021, 2022, 2023, and from January to June of 2024. As shown below in Table 6, the percentage of cases reviewed per year was greater than 5%, as required. MHCC staff reviewed the MACPAQ reports and determined that during the period January 2019 through June 2024, the semiannual MACPAQ reviews included at least three cases per physician. MHCC staff concludes that UCMC complies with this standard.

Table 6: UCMC External Review, CY 2019 – June 2024

Review Period	Elective PCI Case Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Meets Standard
CY 2019	351	27	7.7%	Yes
CY 2020	283	25	8.8%	Yes
CY 2021	293	25	8.5%	Yes
CY 2022	331	25	7.6%	Yes
CY 2023	302	26	8.6%	Yes
2024 (Jan-Jun)	143	13	9.1%	Yes

Source: MHCC Analysis, UCMC Application Q13, and MACPAQ Reports

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

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

(ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than three cases during the relevant period, as provided in Regulation .08; or

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

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

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

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

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

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

10.24.17.07C(4)(e) and .07D(5)(d) The 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 review reports from MACPAQ discussed above, UCMC provided information regarding its internal review processes and records of the number of cases reviewed per physician, per year. UCMC stated that internal peer review is performed on an ongoing continuous basis throughout the year. The UCMC Quality Management Department screens every cardiac catheterization case based on pre-determined indicators, such as complications. If a concern is found, the case is reviewed through the internal peer review process. Peer review of cases occurs monthly. The interventional cardiologists individually review each other's cases using an UMMS on-line report structure and form. The Interventional Cardiology Peer Review Committee meets twice per year to review and score select cases and any outstanding cases that have not been reviewed/scored at the time of the meeting.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by UCMC and analyzed the ACC-NCDR CathPCI data to determine the number of elective PCI cases performed by each interventionalist. Staff calculated the number of cases required to be reviewed for each interventionalist, per calendar year, and compared the results of the analysis to the number of PCI cases reviewed internally and externally, per physician, according to the hospital. MHCC staff observed that all physicians had ten percent, or ten cases reviewed, whichever was greater, for all reporting periods from January 2019 through June 2024.

The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because it includes a review of angiographic images, medical test results, and patients' medical records. In addition to external review of individual interventionalists, UCMC's internal review process includes reviews of PCI cases for individual interventionalists. Based on staff's review of the number of cases the hospital reported were reviewed internally and through MACPAQ for each interventionalist, UCMC exceeded the requirement that at least 10% of PCI cases be reviewed for each individual interventionalist.

MHCC staff concludes that UCMC complies with this standard.

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

UCMC submitted an affidavit from Elizabeth Wise, FACHE, dated November 29, 2023, 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 semi-annual interventionalist reviews.

Staff Analysis and Conclusions

MHCC staff reviewed the statement provided and concludes that UCMC complies with this standard.

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

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

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

UCMC provided copies of semi-annual external review reports from January 2019 through June 2024 and submitted meeting minutes for two peer review committee meetings and several of the multiple care area meetings to discuss STEMI patients (January 2019 through June 2025). UCMC also provided information about the hospital's quality management team and a robust list of quality improvement efforts. In multiple areas, UCMC provided a target metric that the hospital decided to establish as a goal and data on how the hospital performed in achieving that goal. For example, in the following areas of care for STEMI patients, UCMC documented its performance on several goals: ECG within 10 minutes of arrival; DTB of 90 minutes or less; aspirin at discharge; beta blocker at discharge; angiotensin-converting enzyme inhibitors or angiotensin receptor blocks at discharge; cardiac rehabilitation referral from inpatient setting; and high-intensity statin at discharge. In each of these areas, UCMC documented achieving its goal of 75% or greater. The hospital also provided goals for non-STEMI cases and efforts to improve transfer times, as discussed previously in this report.

Staff Analysis and Conclusion

Based on the meeting minutes and list of quality assurance activities provided, MHCC staff concludes that UCMC complies with this standard.

Patient Outcome Measures

10.24.17.07C(5)

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

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

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

(i)The primary benchmark is the national median in-hospital risk-adjusted mortality rate for non-STEMI PCI cases, calculated from the CathPCI Registry data; and

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

10.24.17.07D(6)

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

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

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

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

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

UCMC's adjusted mortality rates for STEMI and non-STEMI PCI patients, by rolling 12-month reporting period, for reporting periods ending between 2019 Q3 and 2025 Q1, are shown in Table 7.

Table 7: UCMC Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Periods and Performance on MHCC Standards for PCI Programs								
	STEMI				NON-STEMI			
Reporting Period	Hospital AMR	95% CI	National AMR	Meets MHCC Standard	Hospital AMR	95% CI	National AMR	Meets MHCC Standard
2018q4-2019q3	6.01	[1.97, 13.65]	6.06	Yes	1.05	[0.29, 2.66]	0.98	Yes
2019q1-2019q4	7.02	[2.86, 14.00]	6.01	Yes	0.56	[0.07, 2.01]	0.95	Yes
2019q2-2020q1	7.44	[3.26, 14.20]	5.99	Yes	0.33	[0.01, 1.84]	0.95	Yes
2019q3-2020q2	8.72	[4.25, 15.53]	6.06	Yes	0.36	[0.01, 1.98]	1.00	Yes
2019q4-2020q3	7.55	[3.31, 14.40]	6.37	Yes	0.29	[0.01, 1.62]	1.06	Yes
2020q1-2020q4	7.63	[3.11, 15.25]	6.89	Yes	0.29	[0.01, 1.59]	1.13	Yes
2020q2-2021q1	9.04	[3.69, 18.02]	7.55	Yes	0.00	[0.00, 1.11]	1.21	Yes
2020q3-2021q2	6.08	[1.67, 15.12]	7.51	Yes	0.31	[0.01, 1.70]	1.18	Yes
2020q4-2021q3	0.00	[1.55, 4.99]	2.18	Yes	0.43	[0.01, 2.37]	2.23	Yes
2021q1-2021q4	1.27	[0.03, 6.92]	2.17	Yes	1.46	[0.18, 5.23]	2.23	Yes
2021q2-2022q1	4.14	[0.86, 11.77]	2.19	Yes	2.11	[0.44, 6.10]	2.25	Yes
2021q3-2022q2	4.15	[0.86, 11.80]	2.18	Yes	2.23	[0.46, 6.46]	2.26	Yes
2021q4-2022q3	4.75	[0.99, 13.48]	2.11	Yes	3.12	[0.85, 7.88]	2.20	Yes
2022q1-2022q4	5.28	[1.10, 14.95]	2.00	Yes	1.60	[0.33, 4.64]	2.14	Yes
2022q2-2023q1	3.37	[0.41, 11.83]	1.89	Yes	2.14	[0.58, 5.41]	2.05	Yes
2022q3-2023q2	4.49	[0.93, 12.69]	1.89	Yes	1.72	[0.36, 4.97]	2.02	Yes
2022q4-2023q3	6.62	[2.18, 14.91]	1.91	**No**	1.94	[0.53, 4.90]	2.02	Yes
2023q1-2023q4	6.22	[2.05, 14.02]	1.88	**No**	2.99	[1.21, 6.07]	1.99	Yes
2023q2-2024q1	4.13	[0.86, 11.72]	0.79	**No**	2.55	[1.11, 4.95]	2.00	Yes
2023q3-2024q2	4.48	[0.93, 12.69]	0.78	**No**	2.56	[1.18, 4.80]	1.99	Yes
2023q4-2024q3	3.03	[0.37, 10.63]	0.75	Yes	2.62	[1.21, 4.90]	1.97	Yes
2024q1-2024q4	3.57	[0.43, 12.52]	0.74	Yes	2.13	[0.79, 4.58]	1.95	Yes
2024q2-2025q1	3.11	[0.38, 10.90]	0.73	Yes	1.47	[0.30, 4.26]	1.94	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports form the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between October 2018 through March 2025.

Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the National AMR or indicates statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI or non-STEMI cases, as applicable.

Staff Analysis and Conclusion

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for both STEMI and non-STEMI cases. The hospital's risk-adjusted mortality rate for non-STEMI cases was not statistically significantly different than the national benchmark in any reporting period between January 2020 and December of 2024. For STEMI cases, the hospital's risk-adjusted mortality rate was statistically significantly worse than the national benchmark in four reporting periods, from the reporting period ending 2023 Q3 through 2024 Q2. This triggered a focused review.

The focused review evaluated the quality of care provided to STEMI patients at UCMC and whether the hospital responded appropriately to issues identified. MHCC staff contracted with an organization to provide an independent review by a board certified interventionalist. A total of six cases were reviewed.

The focused review report was provided to UCMC on March 13, 2025. The hospital responded on March 14, 2025, and did not dispute the overall findings of the reviewer. For a more complete and detailed description of the conclusions of the focused review, refer to Appendix 1. This information is confidential and protected by MHCC's status as a medical review committee.

Based on the hospital's acceptable performance on the mortality metric for STEMI cases for the three most recent reporting periods, the hospital's acceptable performance on the mortality metric for non-STEMI cases, and staff's review of the conclusions of the focused review, MHCC staff recommends that the Commission find that UCMC complies with this standard.

Physician Resources

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

UCMC submitted the total number of primary and elective PCI cases that were performed at UCMC for four interventionalists (Drs. Drossner, Voss, Albornoz, and Plack) as well as the total number of cases performed by these physicians at other hospitals by quarter from 2019 through 2024. Each physician signed and dated an affidavit affirming under penalties of perjury that the information provided is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed the reported PCI volume for the interventionalists at UCMC, and the ACC-NCDR CathPCI data submitted by the hospital. Staff determined that current interventionalists performed, on average, at least 50 PCI procedures on a rolling eight-quarter basis between January 2019 and December 2024. MHCC staff concludes that UCMC complies with this standard.

10.24.17.07D(7)(b) Each physician who performs primary PCI at a hospital that provides

primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24-month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to the Commission. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to UCMC. While the hospital does not have on-site cardiac surgery, each physician performing primary PCI performed 50 PCI procedures annually when averaged 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.

UCMC submitted information on the volume of primary and elective PCI cases at UCMC and other hospitals, by physician and quarter, for January 2019 through September 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the reported physician volumes for the interventionalists who performed primary PCI services at UCMC from January 2019 through September 2023 and determined that each interventionalist performed at least 50 PCI procedures annually on average, even in years when the standard was waived. In addition, MHCC staff analyzed the ACC-NCDR CathPCI data for January 2019 through December 2024 to confirm each interventionalist performed at least 50 PCI procedures annually on average. The requirement to perform at least 50 PCI procedures annually average over a 24-month period was waived for 2020 and 2021, due to the COVID-19 pandemic. However, even during those two years, all interventionalists met the standard. MHCC staff determined that UCMC complies with this standard.

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.

UCMC submitted a signed statement, dated December 14, 2023, from Dr. Drossner acknowledging that all physicians performing primary PCI services at UCMC (i.e., Drs. Drossner, Plack, Voss, and Albornoz) are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the letter provided and concludes that UCMC complies with this standard.

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

UCMC submitted signed and dated attestations from Drs. Drossner, Plack, Albornoz, and Voss as documentation that each of these physicians has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC staff reviewed the statements provided and concludes that UCMC complies with this standard.

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

UCMC submitted a signed statement from Dr. Drossner, acknowledging that each physician who has performed primary PCI services since January 2019 has participated in the on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. UCMC also submitted a copy of its on-call schedules for September through December 2023 and for June 2025.

Staff Analysis and Conclusion

Staff examined the on-call schedules provided by UCMC and observed that Drs. Drossner, Voss, Albornoz, and Plack were all scheduled to be on call at different times during the month. Based on the statement provided and the on-call schedules submitted MHCC staff concludes that UCMC complies with this standard.

<u>Volume</u>

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

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

UCMC provided a table identifying the number of primary PCI, elective PCI, and total PCI cases for 2019 through 2024. This information is shown in Table 8.

Table 8: UCMC PCI Case Volume

Calendar Year	Primary PCI Cases	Elective PCI Cases	Total PCI Cases
2019	123	356	479
2020	143	293	436
2021	119	296	415
2022	113	337	450
2023	113	306	419
2024	112	302	414

Source: Primary and elective case totals are from UCMC application page 36 and information submitted July 18, 2025. Total numbers of PCI cases are from MHCC staff adding the number of primary and elective PCI cases together.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI case volume information submitted by UCMC. This data shows that the hospital consistently exceeds the target volume of 200 PCI cases annually. MHCC staff also calculated the volume of PCI cases, using the ACC-NCDR CathPCI data for the period from CY 2019 to CY 2024. This analysis indicates that UCMC performed between 404 and 468 PCI cases each year between CY 2019 and CY 2024. MHCC staff concludes that UCMC complies with this standard.

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

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the volume of primary PCI cases performed at UCMC from CY 2019 through CY 2024. As shown in Table 9, the primary PCI volume ranged from 112 to 149 cases each year, annually. Because UCMC exceeded the 36-case threshold, no focused review is required.

Table 9: UCMC's Primary PCI Volume

Calendar Year	Primary PCI Volume
2019	122
2020	149
2021	121
2022	123
2023	112
2024	124

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2019 – CY 2024.

10.24.17.07D(8)(b) The target volume for each physician who performs primary PCI is 11 or more primary PCI cases annually.

UCMC provided the number of primary PCI cases by interventionalist and quarter from January 2019 to December 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the data submitted by UCMC and, by analyzing the ACC-NCDR CathPCI data, verified that at least 11 primary PCI procedures were completed by each interventionalist in each year between CY 2019 and CY 2024. MHCC staff concludes that UCMC 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.

UCMC submitted external review reports from MACPAQ for the period from January 2019 to June 2024. The hospital also submitted information regarding its review of the cases or response for cases that MACPAQ identified as "rarely appropriate" according to two of the three review criteria utilized by MACPAQ. The information submitted included peer review forms documenting the hospital's internal peer review of those cases. The hospital also explained that interventionalists who performed the cases were provided the feedback from MACPAQ's review and the interventionalists provided a written response to the Medical Director explaining their thought processes. The cases were all discussed again at a peer review meeting, and some recommendations were discussed with the interventionalists.

Staff Analysis and Conclusion

MHCC staff reviewed the MACPAQ reports and the results of internal peer review submitted by UCMC. In one case, while MACPAQ found the case to be "rarely appropriate" for elective PCI, the reviewers acknowledged the possibility of a particular documentation error, which, if true, would justify the performance of the elective PCI. UCMC's internal review concluded that there was a documentation error, and therefore, it was appropriate to perform elective PCI on the patient. In a second case, an internal review was performed because the patient died less than 30 days after elective PCI. UCMC's review found that the standard of care was met in all regards, there were no documentation issues with the case, and that the death was not preventable. In a third case, in response to the MACPAQ report, UCMC's internal peer review team reviewed the case and concluded that there was ample documented evidence to perform the PCI.

Based on MHCC staff's review of the MACPAQ reports and the hospital's description of its response to the three cases identified by MACPAQ as rarely appropriate by two criterion, MHCC staff concludes that UCMC complies with the standard.

10.24.17.07D(9) A hospital shall commit to only providing primary PCI services only 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 the primary PCI system was not initially available received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.

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

UCMC stated that it does not use thrombolytics in its PCI program, therefore no patient received thrombolytic therapy that subsequently failed.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for the period from CY 2020 through CY 2024 and observed that zero PCI patients received thrombolytic therapy at UCMC. Staff also notes that the ACC-NCDR CathPCI reports indicate that no PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate. Based on MHCC's analysis of the ACC-NCDR CathPCI data and review of the ACC-NCDR CathPCI reports, MHCC staff concludes that UCMC complies with the standard.

RECOMMENDATION

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

> UCMC shall submit to Commission staff, by January 31, 2026, the attendance lists for the interventional case review meetings that are held between July 1, 2025 and December 31, 2025, and submit attendance lists for interventional case review meetings held between January 1, 2026 and June 30, 2026, by July 31, 2026. UCMC shall continue to report this information every six months until the Executive Director releases UCMC from the reporting requirement.