IN THE MATTER OF	*	**BEFORE THE**
UNIVERSITY OF MARYLAND	*	**MARYLAND**
ST. JOSEPH MEDICAL CENTER	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 24-03-CP057	*	

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STAFF REPORT AND RECOMMENDATION

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

March 20, 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 these hospitals from the requirement for co-location of primary PCI services with cardiac surgery. In the following decade, similar research evaluated the safety of providing elective PCI services at hospitals without on-site cardiac surgery.

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

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

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

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

B. Applicant

University of Maryland St. Joseph Medical Center

University of Maryland St. Joseph Medical Center (UM SJMC) is a 217-bed acute general hospital located in Towson, Maryland (Baltimore County). It is part of the University of Maryland Medical System and has a cardiac surgery program on-site.

The hospital's first Certificate of Ongoing Performance for primary and elective PCI services was approved on December 17, 2020, for four years. In December 2024, a six-month extension was granted by the Executive Director of the Commission, to allow MHCC staff time to complete a thorough review of UM SJMC's current application for a Certificate of Ongoing Performance. This is the hospital's first renewal of its Certificate of Ongoing Performance for primary and elective PCI services.

Health Planning Region

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

C. Staff Recommendation

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

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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).

II. PRODEDURAL HISTORY

UM SJMC filed its application for a Certificate of Ongoing Performance for primary and elective PCI services on June 6, 2024. MHCC staff requested additional information on December 3, 2024, January 17, 2025, and February 28, 2025. Additional information was provided by UM SJMC on December 30, 2024, February 11, 2025, and March 7, 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 ACC-NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

UM SJMC reported that data has been submitted on time to both the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI and MHCC, per the outlined submission schedules. No deficiencies have been identified, according to the hospital.

Staff Analysis and Conclusion

UM SJMC has complied with the data submission to the ACC-NCDR for CathPCI, with duplicate data submitted to MHCC in accordance with the established schedule. There are no reporting periods when the hospital's performance on mortality metrics or other key quality metrics is unavailable.

MHCC staff concludes that UM SJMC 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.

UM SJMC reported that no overlapping downtime occurred due to unforeseen circumstances or required equipment maintenance for the period from January 2020 through March 2024. The hospital has two cardiac catheterization laboratories (CCLs), one electrophysiology laboratory, one interventional radiology laboratory, and one hybrid operating room that may be used to perform PCI procedures. All of these locations have imaging equipment that can be utilized for primary PCI services. UM SJMC also submitted a summary of all work orders that were completed for the hospital's CCLs from January 1, 2020, through March 1, 2024. The number of annual downtime occurrences for each CCL are shown in Table 1 below.

Table 1. Number of Separate Instances of CCL Downtime Reported by UM SJMC, by Time Period, January 2020 – March 2024

Year	Lab 1	Lab 2	Overlapping Downtime*
CY 2020	3	11	No
CY 2021	9	10	No
CY 2022	11	9	No
CY 2023	8	11	No
January 1 to March 1 2024	2	5	No

Source: UM SJMC's supplemental information for its application for Certificate of Ongoing Performance 2024, received on December 30, 2024, and February 11, 2025.
*Overlapping downtime refers to instances when both CCLs are not in service.

Staff Analysis and Conclusion

MHCC staff reviewed the information that was provided by UM SJMC on CCL downtime for both labs and determined that because there was no overlapping downtime between the two CCLs, it is unlikely that both rooms were unavailable simultaneously. Additionally, during the review period the hospital had three other rooms available to use as backup; therefore, UM SJMC was able to ensure that primary PCI services were available 24 hours per day, seven days per week from calendar year (CY) 2020 through March 1, 2024.

MHCC staff concludes that UM SJMC complies with this standard.

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

UM SJMC provided a signed statement from Thomas B. Smyth, the hospital's President and Chief Executive Officer (CEO), attesting that the hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from the time when patients arrive at the hospital, for at least 75 percent of appropriate patients, excluding transfer cases. The hospital also agreed to track the door-to-balloon (DTB) times for transfer cases and evaluate areas for improvement, through review of all transfer cases by the Cardiac Interventional Center Quality Assurance Medical Review Committee (CIC QAMRC), which meets monthly. Additionally, UM SJMC provided the number and percentage of non-transfer primary PCI patients with a DTB time 90 minutes or less, for the period between January 2020 through March 2024, as shown in Table 2a. The hospital explained that cases with a non-system reason for delay were excluded from the dataset. During this period, the hospital reported that 83.3 to 100 percent of cases met this standard.

Table 2a. UM SJMC's Reported Door-to-Balloon Times for Non-Transfer Primary PCI Cases by Quarter, January 2020 – March 2024

Quarter Ending	Number of Non-Transfer Primary PCI Patients	Number of Non-Transfer Patients with DTB Time ≤ 90 Minutes	
		Number	Percentage
CY 2020 Q1	23	23	100.0%
CY 2020 Q2	11	11	100.0%
CY 2020 Q3	20	20	100.0%
CY 2020 Q4	13	13	100.0%
CY 2021 Q1	14	13	92.9%
CY 2021 Q2	28	28	100.0%
CY 2021 Q3	10	10	100.0%
CY 2021 Q4	14	14	100.0%
CY 2022 Q1	11	11	100.0%
CY 2022 Q2	20	20	100.0%
CY 2022 Q3	16	16	100.0%
CY 2022 Q4	21	19	90.5%
CY 2023 Q1	19	18	94.7%
CY 2023 Q2	12	10	83.3%
CY 2023 Q3	15	13	86.7%
CY 2023 Q4	10	10	100.0%
CY 2024 Q1	20	18	90.0%

Source: UM SJMC's application for Certificate of Ongoing Performance 2024, p.4.

UM SJMC stated that the hospital has a long-standing collaboration with Greater Baltimore Medical Center (GBMC), which is UM SJMC's primary transferring ST-segment elevation myocardial infarction (STEMI) referral center. GBMC's emergency department (ED) physician leadership and STEMI RNs are reported to consistently attend the monthly CIC QAMRC meetings, where each transfer STEMI case is reviewed in detail according to current ACC and American Heart Association (AHA) guidelines, which include a benchmark of 120 minutes for the DTB times for transfer cases. During this meeting, important time intervals are tracked and reviewed and opportunities for improvement are identified. A specific feedback form is also provided to GBMC for each transfer case.

Copies of its transfer process, ED feedback form provided to GBMC for each transfer patient, and the ED physician STEMI alert checklist were submitted with UM SJMC's application. The hospital also provided the number and percentage of primary PCI transfer patients with a DTB time of 120 minutes or less, for the period from January 2019 through March 2024, as shown in Table 2b. During this time, the hospital reports between 50 and 100 percent of primary PCI transfer cases met a DTB time of 120 minutes or less. UM SJMC indicated that cases with a non-system reason for the delay were removed from this dataset.

Table 2b. UM SJMC's Reported Door-to-Balloon Times for Primary PCI Transfer Cases by Quarter, January 2019 – March 2024

Quarter Ending	Number of Transfer Primary PCI Patients	Number of Transfer Patients with DTB Time ≤ 120 Minutes	
		Number	Percentage
CY 2019 Q1	1	1	100.0%
CY 2019 Q2	3	3	100.0%
CY 2019 Q3	5	4	80.0%
CY 2019 Q4	7	6	85.7%
CY 2020 Q1	4	3	75.0%
CY 2020 Q2	2	1	**50.0%**
CY 2020 Q3	5	4	80.0%
CY 2020 Q4	6	6	100.0%
CY 2021 Q1	5	5	100.0%
CY 2021 Q2	3	3	100.0%
CY 2021 Q3	5	5	100.0%
CY 2021 Q4	6	6	100.0%
CY 2022 Q1	6	6	100.0%
CY 2022 Q2	4	4	100.0%
CY 2022 Q3	6	5	83.3%
CY 2022 Q4	1	1	100.0%
CY 2023 Q1	3	3	100.0%
CY 2023 Q2	8	7	87.5%
CY 2023 Q3	6	5	83.3%
CY 2023 Q4	8	7	87.5%
CY 2024 Q1	10	10	100.0%

Source: UM SJMC's application for Certificate of Ongoing Performance 2024, p.5.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases for the period from CY 2020 to CY 2023, as shown in Table 3a. Staff found that UM SJMC met the DTB standard in all quarters, with between 81.3 and 100 percent of non-transfer primary PCI cases meeting the DTB standard of 90 minutes or less during the review period. 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 the delay, and MHCC includes all cases in reviewing compliance with this standard.

Table 3a. UM SJMC's Compliance with DTB Benchmark for Non-Transfer PCI Cases by Quarter, CY 2020 – CY 2023

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <= 90 Minutes
CY 2020 Q1	22	22	100.0%
CY 2020 Q2	15	15	100.0%
CY 2020 Q3	17	17	100.0%
CY 2020 Q4	13	13	100.0%
CY 2021 Q1	15	14	93.3%
CY 2021 Q2	27	26	96.3%
CY 2021 Q3	11	9	81.8%
CY 2021 Q4	15	14	93.3%
CY 2022 Q1	11	10	90.9%
CY 2022 Q2	21	20	95.2%
CY 2022 Q3	17	15	88.2%
CY 2022 Q4	23	19	82.6%
CY 2023 Q1	16	15	93.8%
CY 2023 Q2	12	10	83.3%
CY 2023 Q3	16	13	81.3%
CY 2023 Q4	12	10	83.3%

Source: MHCC staff analysis of the ACC-NCDR CathPCI data for CY 2020 – CY 2023.

MHCC staff also considers the hospital's performance over rolling eight-quarter periods, as shown in Table 3b. Between 81.8 and 96.4 percent of non-transfer primary PCI cases met the 90-minute DTB time standard, over rolling eight-quarter periods.

Table 3b. UM SJMC's Non-Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period

Quarter				Rolling Eight-Quarters		
Time Period	Total Non-Transfer Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <= 90 Minutes	Total Non-Transfer Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <=90 Minutes
CY 2018 Q1	20	20	100.0%			
CY 2018 Q2	15	14	93.3%			
CY 2018 Q3	17	17	100.0%			
CY 2018 Q4	25	24	96.0%			
CY 2019 Q1	17	17	100.0%			
CY 2019 Q2	18	16	88.9%			
CY 2019 Q3	11	10	90.9%			
CY 2019 Q4	18	16	88.9%			
CY 2020 Q1	22	22	100.0%	143	136	95.1%
CY 2020 Q2	15	15	100.0%	143	117	81.8%
CY 2020 Q3	17	17	100.0%	143	137	95.8%
CY 2020 Q4	13	13	100.0%	131	126	96.2%
CY 2021 Q1	15	14	93.3%	129	123	95.3%
CY 2021 Q2	27	26	96.3%	138	133	96.4%
CY 2021 Q3	11	9	81.8%	138	132	95.7%
CY 2021 Q4	15	14	93.3%	135	130	96.3%
CY 2022 Q1	11	10	90.9%	124	118	95.2%
CY 2022 Q2	21	20	95.2%	136	123	90.4%
CY 2022 Q3	17	15	88.2%	130	121	93.1%
CY 2022 Q4	23	19	82.6%	140	127	90.7%
CY 2023 Q1	16	15	93.8%	141	128	90.8%
CY 2023 Q2	12	10	83.3%	126	112	88.9%
CY 2023 Q3	16	13	81.3%	131	116	88.5%
CY 2023 Q4	12	10	83.3%	128	112	87.5%

Source: MHCC staff analysis of the ACC-NCDR CathPCI data for CY 2018 – CY 2023.
Note: Calculations for each quarter are based on the procedure date.

For the period from January 2019 through December 2023, MHCC staff also reviewed the ACC-NCDR CathPCI Registry data compared to the information reported by UM SJMC regarding the number and percentage of transfer PCI cases with a DTB time of 120 minutes or less. According to UM SJMC (Table 2b), in 20 of 21 quarters, over 75 percent of transfer PCI cases had a DTB time of 120 minutes or less, and the percentage of transfer cases achieving this DTB time ranged from 50 to 100 percent for each quarter. Conversely, MHCC staff's analysis of the ACC-NCDR CathPCI data, shown in Table 3c, indicates that only seven of 20 quarters met the goal of 75 percent of cases with a DTB time of 120 minutes or less.

Although hospitals strive to achieve DTB times in primary PCI transfer cases of 120 minutes or less, many factors impacting the DTB times for transfer patients are outside of the hospital's control. For this reason, there is no requirement for a certain percentage of cases to achieve a benchmark of 120 minutes or less each quarter. Instead, a hospital is required to track the DTB times for transfer cases and evaluate areas for improvement. UM SJMC reported that important time intervals are tracked for each transfer case and reviewed in detail in monthly CIC QAMRC meetings. Opportunities for improvement are identified by UM SJMC, and feedback is

provided to the hospital's main transfer facility, GBMC, for each transfer case.

Table 3c. UM SJMC's Compliance with DTB Benchmark for Transfer PCI Cases by Quarter, CY 2019 – CY 2023

Quarter	Total Primary PCI Volume	Cases with DTB <= 120 Minutes	Percent of Cases with DTB <= 120 Minutes
CY 2019 Q1	1	0	0.0%
CY 2019 Q2	4	4	100.0%
CY 2019 Q3	5	2	**40.0%**
CY 2019 Q4	7	6	85.7%
CY 2020 Q1	5	3	**60.0%**
CY 2020 Q2	3	0	**0.0%**
CY 2020 Q3	5	3	**60.0%**
CY 2020 Q4	6	4	**66.7%**
CY 2021 Q1	6	4	**66.7%**
CY 2021 Q2	4	1	**25.0%**
CY 2021 Q3	5	3	**60.0%**
CY 2021 Q4	6	5	83.3%
CY 2022 Q1	8	7	87.5%
CY 2022 Q2	5	4	80.0%
CY 2022 Q3	5	2	**40.0%**
CY 2022 Q4	2	1	**50.0%**
CY 2023 Q1	3	3	100.0%
CY 2023 Q2	8	7	87.5%
CY 2023 Q3	7	4	**57.1%**
CY 2023 Q4	8	5	**62.5%**

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

MHCC staff concludes that UM SJMC complies with this standard.

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

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

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

Staff Category	Number/FTEs	Cross Training (S/C/M*)
Physician	2 + 1 PRN	
Nurse	7.9 + 2 PRN	S/C/M
Technician	4.5 + 1 PRN	S/C/M

Source: UM SJMC's application for a Certificate of Ongoing Performance 2024, p. 9.
*Scrub (S), Circulate (C), Monitor (M)

Staff Analysis and Conclusion

MHCC staff compared the staffing levels described by UM SJMC to information reported by three other existing PCI programs. A comparison of volume and staffing levels for UM SJMC, Sinai Hospital of Baltimore (Sinai), Medstar Union Memorial Hospital (MUMH), and TidalHealth Peninsula Regional Medical Center (TH PRMC) is shown in Table 4b. Staff observed that UM SJMC had similar PCI case volumes to MUMH in 2023, but much higher PCI case volumes than TH PRMC and Sinai. UM SJMC reported a total of two full-time interventionalists and one additional interventionalist, as needed (PRN), which is less than the number reported by all three of the other programs. Compared to UM SJMC, MUMH has two additional interventionalists dedicated to its primary PCI program, while Sinai and TH PRMC had four and six more interventionalists than UM SJMC, respectively. MHCC staff's analysis of CathPCI data shows that, in practice, UM SJMC used additional interventionalists as needed in CY 2021 (4), CY 2022 (3), and CY 2023 (1), with these PRN physicians completing a much lower volume of PCI cases annually than the two full-time interventionalists.

The number of nurses and technicians who are available to provide PCI services to patients are similar at UM SJMC and MUMH. While the number of nurses available to serve primary PCI patients at UM SJMC is approximately 1.5 and 3.5 FTEs greater than at TH PRMC and Sinai, respectively, the number of technicians available at UM SJMC to serve primary PCI patients is approximately two FTEs fewer than at Sinai and TH PRMC.

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

Program	Total PCI Volume 2023	Number of Interventionalists or FTEs	Nurse FTEs	Technicians FTEs
UM SJMC	754	2 + 1 PRN	7.9 + 2 PRN	4.5 + 1 PRN
Sinai	438	7	6.4	7
MUMH	728	5	9.9	5.4
TH PRMC	509	9	8.18	7.93

Sources: UM SJMC's application for Certificate of Ongoing Performance 2024, p. 9; Sinai's application for a Certificate of Ongoing Performance 2024, p. 8; MUMH's application for a Certificate of Ongoing Performance 2024, p. 6; TH PRMC's application for a Certificate of Ongoing Performance 2024, p. 9; PCI volumes for each hospital are from ACC-NCDR CathPCI registry reports for period ending December 31, 2023

Based on the information provided, MHCC staff determined that the hospital has adequate physician, nursing, and technical staff available to provide PCI services. Staff concludes that UM SJMC 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.

UM SJMC provided a written letter dated May 30, 2024, signed by President and CEO of the hospital, Thomas B. Smyth, confirming that the hospital will provide primary PCI services in accordance with the requirements established by the MHCC and as outlined in the Cardiac Services Chapter.

Staff Analysis and Conclusion

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

UM SJMC stated that data management, reporting, and coordination with institutional quality improvement efforts for PCI services are appropriately managed under the leadership of the Director of Nursing, who also serves as the Executive Sponsor for the ACC-NCDR CathPCI Registry. Data abstraction is performed by experienced registered nurses (2.5 FTEs) who have expertise in cardiovascular disease. The hospital stated that these RNs are properly trained in the ACC-NCDR data collection process and are compliant with all requirements detailed in the contract agreements. Data abstraction and reporting are also completed in accordance with State and federal regulations and requirements.

Additionally, the hospital has an RN Registry Site Coordinator, who is responsible for monitoring all registry data entry and quality outcomes. This Site Coordinator works with the Nurse Manager of Cardiac and Vascular Services, the Executive Sponsor, and the Physician Medical Director, Dr. Shumile Zaidi, to assist with the interpretation and analysis of outcomes reports and communicating findings and related performance improvement activities to the executive leadership team.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that UM SJMC 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.

UM SJMC reported that the Chief of Cardiology and Medical Director of the CCL is Dr. Shumile Zaidi. He has been in this role since 2019. Interventional Cardiology Services are under the direction of the Chief of Medicine, Dr. Madhat Arnouk, and peer review activities are coordinated by Stacy Weiss, Critical Care RN, in collaboration with Dr. Arnouk and Dr. Zaidi. The hospital reported that the physician leadership team works together to ensure compliance with the medical staff bylaws. The hospital submitted descriptions of these bylaws along with job descriptions for both Drs. Arnouk and Zaidi. Job descriptions show that Dr. Zaidi is responsible for credentialing criteria, overall PCI program management, equipment, personnel, on-call schedules, quality and error management, and peer review conferences.

Staff Analysis and Conclusion

MHCC staff reviewed the description of job duties for the Medical Director of the CCL and Chief of Medicine that were provided by the hospital and concludes that UM SJMC 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.

UM SJMC provided a list of educational topics offered to both CCL, Coronary Care Unit (CCU), Cardiac Cath Prep/Recovery and Medical Surgical Intensive Care Unit (ICU) staff from CY 2020 to CY 2023. In addition to annual competencies, regular in-services were provided on equipment including intra-aortic balloon pump (IABP), Impella, Shockwave, intravascular ultrasound (IVUS), guidewires and catheters, coronary stents and balloons, medications, contrast management systems, and vascular closure devices. UM SJMC tracks trainings and competencies in Learning Management Software and on the EPIC scheduling board.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that UM SJMC 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.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to UM SJMC because the hospital has a cardiac surgery program on-site.

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.

Staff Analysis and Conclusion

Because UM SJMC has a cardiac surgery program on-site, MHCC staff determined that this standard does not apply to the hospital.

<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.

UM SJMC provided dates and attendees for PCI Case Review meetings held from CY 2020 through CY 2024. The hospital reported that all cases are reviewed by Dr. Zaidi and/or Dr. Ambinder with CCL staff in attendance. More recently, in addition to formal PCI review meetings, UM SJMC states that case reviews are also completed during each monthly CCL staff meeting.

The hospital also reported that it has deployed a Learning and Engagement System (LENS) in the CCL. This web-based dashboard has an educational section where physicians can post educational topics and questions for staff to view, making real-time communication, feedback, and updates possible.

Staff Analysis and Conclusion

UM SJMC submitted documentation that includes meeting dates and attendance records for five meetings in CY 2020, seven meetings in CY 2021, CY 2022, and CY 2023, and nine meetings in CY 2024. Review of meeting attendees shows that meetings are routinely attended by interventionalists, as well as other physicians, nurses, and technicians who care for primary PCI patients. MHCC staff concludes that UM SJMC complies with this standard.

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

UM SJMC provided meeting minutes, dates, and attendees of CIC QAMRC meetings held from the hospital's last COP application submission in June 2019 through CY 2024. The hospital explained that meetings were cancelled in December 2022 and August and December 2023 due to core staff and physician leadership's vacation schedules.

Staff Analysis and Conclusion

UM SJMC submitted documentation including meeting minutes, dates, and attendance records for six meetings in the last seven months of CY 2019, nine meetings in CY 2020, 12 in CY 2021, 11 in CY 2022, and 10 meetings in CY 2023 and CY 2024. Meeting attendees include leadership and physicians from the Heart Institute, ED, CCL, Cardiac Cath Prep and Recovery units, Observation unit, Medical/Surgical ICU, Clinical Excellence, and nursing supervision. Meeting attendees also include representatives from GBMC and Baltimore County Emergency Medical Services. While meetings did not take place monthly as required, the hospital provided reasons for meeting cancellations. MHCC staff recommends the Commission find that UM SJMC 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.

UM SJMC submitted copies of the external review reports for elective PCI cases performed between CY 2019 and CY 2023. The hospital contracts with the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ), an MHCC approved review organization, to complete these external reviews according to standards established by the Commission. These semi-annual reviews include analysis of angiographic images, medical test results, and a patient's medical record.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 5. Although only five percent of cases are required to be reviewed externally, between five and 7.7 percent of cases were reviewed each year.

Table 5. UM SJMC's External Review, CY 2019 – CY 2023

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2019	588	41	7.2%	Semi-annually	Yes
CY 2020	374	24	6.4%	Semi-annually	Yes
CY 2021	455	35	7.7%	Semi-annually	Yes
CY 2022	455	32	7.0%	Semi-annually	Yes
CY 2023	678	34	5.0%	Semi-annually	Yes

Source: MHCC staff analysis of MACPAQ external review reports, CY 2019 – CY 2023.

For the period between CY 2019 and CY 2023, MHCC staff verified that, if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by the MACPAQ.

MHCC staff concludes that UM SJMC complies with this standard.

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

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

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

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

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

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

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

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

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

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

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

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

UM SJMC reported that the hospital conducts an internal random review of the greater of 10, or 10 percent of PCI cases for all interventionalists who perform PCI at the hospital. This internal review is in addition to the external reviews conducted by MACPAQ semi-annually. Additionally, UM SJMC reported that specific PCI cases and events trigger an internal peer review. These include mortality cases, dissection/perforation cases, those who had a cerebrovascular accident after a PCI, those with vascular complications, those with emergency

CABG after PCI, and other PCI cases referred by physicians or staff. For these internal reviews, cases are randomized using an internet-based research randomizer and assigned a unique numerical identifier. The hospital also provided the number of PCI cases that were reviewed both internally and externally from July 2019 through December 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by UM SJMC and analyzed the ACC-NCDR CathPCI Registry data to determine the number of elective PCI cases performed by each interventionalist. Staff calculated the number of cases required to be reviewed for each interventionalist, per calendar year and compared the results of the analysis to the number of PCI cases reviewed internally and externally, per physician according to the hospital. MHCC staff observed that all physicians had ten percent, or ten cases reviewed, whichever was greater, for all reporting periods from July 2019 through CY 2023.

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

MHCC staff concludes that UM SJMC 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.

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

Staff Analysis and Conclusion

MHCC staff reviewed the affidavit and concludes that UM SJMC 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.

UM SJMC provided meeting minutes from the Interventional Cardiology Physician Peer Review Committee for meetings held from June 2019 through February 2024. The hospital provided minutes from CIC QAMCR meetings, which address quality issues that pertain to STEMI patients undergoing PCI. Additionally, the hospital states that no corrective actions were required as a result of internal or external reviews. A few examples of quality improvement activities related to patients receiving PCI are described below.

In Spring of 2022, UM SJMC reviewed their STEMI activation process as part of the hospital's commitment to continuing improvement. Following meetings with all stakeholders, a revised process was implemented in September 2022. This included using Tiger Connect for enhanced communication between ED staff and the CCL team, as well as implementation of standard procedures for all parties involved with STEMI activation. A process has also been established utilizing the Nursing Supervisor and the ED RNs in the event of any delays. This revised process has contributed to the hospital's success in achieving DTB times of 90 minutes or less for STEMI patients.

In July 2022, the hospital established a standard admission pathway for STEMI patients with the goal of enhancing patient care, reducing costs for both the patient and UM SJMC, increasing ICU bed availability, and reducing uncomplicated STEMI length of stays (LOS) as defined by the ACC-NCDR benchmark. The hospital reported seeing great success using this pathway. For example, UM SJMC reported that LOS for uncomplicated STEMI was 2.38 days in Q2 2022. Following implementation of this admission pathway, LOS decreased to 2.04 days in the following quarter (Q3 2022).

UM SJMC identified another opportunity for improvement in January 2023, when the CIC QAMCR recommended that a subcommittee meet to address the increasing number of patients that had a wait time of more than 10 minutes between arriving at the ED and the patient's first electrocardiogram (EKG), which is used to determine if a patient requires emergency PCI services. The subcommittee met on February 5, 2023, and performed a detailed review of all patients who did not meet the 10-minute goal. Factors contributing to delays included ED volumes and boarding of patients. The hospital subsequently completed a deeper review involving front line staff. The subcommittee made several recommendations as a result of this review. The hospital ordered new EKG machines and stationed them in the triage area, increased triage staffing during the ED's busiest times, and established standard procedures for RNs, registration staff, and triage staff.

Finally, UM SJMC provided education to staff regarding documentation and non-system reasons for delays. This measure continues to be monitored, and UM SJMC reported seeing success following implementation of the action plan, with 90 percent of cases in CY 2023 meeting the standard of 10 minutes or less between arrival at the ED and the patient's first EKG. This is an increase from only 69 percent of cases that met the standard in CY 2022.

Staff Analysis and Conclusion

MHCC staff reviewed the CIC QAMCR meeting minutes and other information provided by the hospital. UM SJMC has undertaken three quality assurance initiatives in the past three years focused on improving DTB times, the STEMI activation process, and time between patients' arrival in the ED and the first EKG. MHCC staff concludes that the hospital complies with this standard.

Patient Outcome Measures

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

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

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

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

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

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

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

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

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

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

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

Table 6. UM SJMC's 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% Confidence Interval	National AMR	Meets MHCC Standards	Hospital AMR	95% Confidence Interval	National AMR	Meets MHCC Standards
2023q3-2024q2	0.00	[0.00, 1.94]	0.78	Yes	0.90	[0.33, 1.95]	1.99	Yes
2023q2-2024q1	0.00	[0.00, 2.33]	0.79	Yes	0.77	[0.21, 1.96]	2.00	Yes
2023q1-2023q4	0.64	[0.02, 3.46]	1.88	Yes	0.66	[0.22, 1.54]	1.99	Yes
2022q4-2023q3	0.76	[0.02, 4.11]	1.91	Yes	0.61	[0.20, 1.41]	2.02	Yes
2022q3-2023q2	2.05	[0.43, 5.79]	1.89	Yes	0.49	[0.13, 1.24]	2.02	Yes
2022q2-2023q1	1.74	[0.36, 4.91]	1.89	Yes	0.60	[0.22, 1.30]	2.05	Yes
2022q1-2022q4	1.32	[0.16, 4.61]	2.00	Yes	1.01	[0.44, 1.98]	2.14	Yes
2021q4-2022q3	2.19	[0.46, 6.19]	2.11	Yes	1.39	[0.64, 2.61]	2.20	Yes
2021q3-2022q2	0.89	[0.02, 4.81]	2.18	Yes	2.08	[1.11, 3.51]	2.26	Yes
2021q2-2022q1	1.18	[0.03, 6.40]	2.19	Yes	2.62	[1.40, 4.43]	2.25	Yes
2021q1-2021q4	1.40	[0.04, 7.55]	2.17	Yes	2.41	[1.16, 4.40]	2.23	Yes
2020q4-2021q3	0.00	[0.00, 6.50]	2.18	Yes	1.85	[0.85, 3.48]	2.23	Yes
2020q3-2021q2	6.66	[2.19, 14.99]	7.51	Yes	1.44	[0.58, 2.95]	1.18	Yes
2020q2-2021q1	8.49	[2.34, 20.88]	7.55	Yes	1.11	[0.36, 2.58]	1.21	Yes
2020q1-2020q4	4.33	[0.53, 15.17]	6.89	Yes	1.41	[0.57, 2.88]	1.13	Yes
2019q4-2020q3	3.19	[0.39, 11.21]	6.37	Yes	1.50	[0.60, 3.06]	1.06	Yes
2019q3-2020q2	2.64	[0.32, 9.25]	6.06	Yes	1.01	[0.27, 2.56]	1.00	Yes
2019q2-2020q1	1.32	[0.03, 7.16]	5.99	Yes	1.29	[0.48, 2.79]	0.95	Yes

Source: MHCC staff compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data registry for PCI cases performed between April 2019 and June 2024.

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

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

Staff Analysis and Conclusion

As shown in Table 6, MHCC staff compiled the results from UM SJMC's quarterly reports from the ACC-NCDR CathPCI Registry for STEMI and non-STEMI PCI cases performed between January 2019 and June 2024. MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period for STEMI patients because the national benchmark fell within the 95 percent confidence interval for UM SJMC in all 12-month reporting periods between January 2019 and June 2024, when an adjusted mortality rate was reported. For non-STEMI patients, the hospital performed better than the national benchmark in the seven most recent reporting periods, beginning with the period ending 2022 Q4.

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

Physician Resources

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

Staff Analysis and Conclusion

Because UM SJMC has a cardiac surgery program on-site, MHCC staff determined that this standard is not applicable for the hospital.

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 is not applicable to UM SJMC, as the hospital has a cardiac surgery program on-site.

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

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

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

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

Staff Analysis and Conclusion

MHCC staff determined that this standard is not applicable to UM SJMC, as the hospital has cardiac surgery services on-site.

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.

UM SJMC submitted a signed and dated statement from CCL Medical Director, Dr. Shumile Ziadi, dated May 30, 2024, acknowledging that each physician performing primary PCI at the hospital is board-certified in interventional cardiology or exempt from this requirement. To be exempt from this requirement, the physician must have performed interventional procedures prior to 1998 and did not seek board certification before 2003, or the physician completed a fellowship in interventional cardiology less than three years ago.

Staff Analysis and Conclusion

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

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

UM SJMC submitted signed and dated attestations from Drs. Shumile Zaidi, Farrukh Jalisi, and Daniel Ambinder stating that each has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

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

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

call schedule.

UM SJMC submitted a letter dated May 30, 2024, signed by Dr. Shumile Zaidi, CCL Medical Director, acknowledging that each physician who performed primary PCI services from 2019 through the date of the letter has participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. The hospital also submitted the on-call schedules for April and May 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the letter from Dr. Zaidi and the on-call schedules for April and May 2024. Both full-time interventionalists who perform primary PCI at UM SJMC were included in the on-call schedules provided, but Dr. Jalisi was not observed to be on the schedule for May 2024. The hospital reported that he is included in the on-call schedule as needed, due to him being a PRN interventionalist.

MHCC staff concludes that the hospital complies with this standard.

Volume

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

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.

UM SJMC provided the total annual PCI case volume for each CY between 2020 and 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI case volume information submitted by UM SJMC. This data shows that the hospital consistently exceeds the target volume of 200 PCI cases annually. MHCC staff also calculated the volume of PCI cases, using the ACC-NCDR CathPCI Registry data for the period from CY 2020 to CY 2023. This analysis, shown in Table 7, indicates that UM SJMC performed between 447 and 706 PCI cases each year between CY 2020 and CY 2023.

Table 7. UM SJMC's
Total PCI Volume, CY 2020 – CY 2023

Year	Number of PCI Cases
CY 2020	447
CY 2021	529
CY 2022	516
CY 2023	706

Source: MHCC staff's analysis of ACC-NCDR CathPCI data registry (CY 2020 – CY 2023).

MHCC staff concludes that UM SJMC 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.

UM SJMC provided the number of primary PCI cases that were completed at the hospital from CY 2020 through CY 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the number of primary PCI cases completed at UM SJMC and analyzed the ACC-NCDR CathPCI Registry data to calculate the volume of primary PCI cases performed at UM SJMC from CY 2020 through CY 2023. As shown in Table 8, the primary PCI volume ranged from 91 to 115 cases each year.

Table 8. Primary PCI Volume at UM SJMC, CY 2020 – CY 2023

Year	Number of Primary PCI Cases
CY 2020	91
CY 2021	102
CY 2022	115
CY 2023	110

Source: MHCC staff's analysis of the ACC-NCDR CathPCI registry Data, CY 2020 – CY 2023.

Because UM SJMC exceeded the threshold of 49 primary PCI cases annually during the review period, no focused review is required.

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

UM SJMC provided the number of primary PCI cases completed, by location and interventionalist, for each quarter, from CY 2020 through CY 2023. The documentation submitted showed that each physician provided at least 11 primary PCI cases annually during the review period.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by UM SJMC and analyzed the ACC-NCDR CathPCI Registry data to verify the number of primary PCI cases performed by each interventional cardiologist between CY 2020 and CY 2023. MHCC staff determined that each interventionalist performed at least 11 primary PCI cases annually during the review period, therefore, UM SJMC is in compliance with this standard.

Patient Selection

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

UM SJMC reports that based on internal and external review of elective PCI cases, no

patients received elective PCI services inappropriately at the hospital.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from MACPAQ for CY 2019 through June 2022 and determined that no cases were identified as rarely appropriate across all angiographic, clinical, and AHA/ACC appropriate use criteria. One case completed between July and December 2021 was found to be rarely appropriate in terms of both clinical and AHA/ACC appropriate use criteria and one case performed between July and December 2023 was found to be rarely appropriate in terms of clinical criteria. However, MHCC staff notes that rarely appropriate does not mean inappropriate. Furthermore, UM SJMC stated that upon receipt of these external review reports, these cases were reviewed by physician leadership. Dr. Zaidi also met with the PCI operators to discuss the cases in question and MACPAQ findings.

MHCC staff concludes that UM SJMC complies with this standard.

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

(a) Patients described as appropriate for primary PCI in Expert Guidelines.

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

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

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

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

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR Cath PCI Registry data and noted that between CY 2019 and CY 2023, there were no patients who received thrombolytic therapy. In addition, the hospital's ACC-NCDR reports for the period reviewed indicate that no PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate.

MHCC staff concludes that UM SJMC complies with this standard.

RECOMMENDATION

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