IN THE MATTER OF	*	**BEFORE THE**
MEDSTAR UNION	*	**MARYLAND**
MEMORIAL HOSPITAL	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 19-24-CP018	*	

*** ***

STAFF REPORT AND RECOMMENDATION

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

September 17, 2020

I. INTRODUCTION

A. Background

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

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

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

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

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

elective PCI services, for a period of time specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must demonstrate that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide PCI services.

B. Applicant

MedStar Union Memorial Hospital

MedStar Union Memorial Hospital (Union Memorial) is a 131-bed general hospital located in Baltimore City. Union Memorial has a cardiac surgery program on site.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. Union Memorial is in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties and Baltimore City. Fourteen hospitals in this health planning region provide PCI services. Currently, one program only provides primary PCI services. All of the other programs provide both primary and elective PCI services. Five of the fourteen hospitals also provide cardiac surgery services, and one additional hospital in this region has a Certificate of Need to establish a cardiac surgery program.

C. Staff Recommendation

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

II. PRODEDURAL HISTORY

Union Memorial filed a Certificate of Ongoing Performance application on March 22, 2019. MHCC staff reviewed the application and requested additional information on April 21, 2020, August 5, 2020, and September 2, 2020. MHCC received additional information on May 7, 2020, August 17, 2020, and September 9, 2020.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

<u>Data Collection</u>

10.24.17.07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI

programs.

Union Memorial responded that the hospital is not aware of any deficiencies in data collection or reporting. Union Memorial stated that it has a team of cardiac, critical care registered nurses who are responsible for collecting, entering, and reporting data. The team attends the ACC-NCDR data mangers conference annually, and the team leader for the ACC-NCDR data collection attends monthly cardiac interventional performance improvement and ST-elevation myocardial Infarction (STEMI) meetings. Union Memorial also employs a data analyst who reports performance improvement activities across the cardiac service line and who uploads data to the required professional associations, the State of Maryland, and the Centers for Medicare and Medicaid Services.

Staff Analysis and Conclusion

Union Memorial has complied with the submission of the ACC-NCDR CathPCI data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of NCDR data to validate that hospitals submitted accurate and complete information to the ACC-NCDR data registry. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of Union Memorial's data reported during the audit period.

MHCC staff concludes that Union Memorial 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.

Union Memorial has a cardiac catheterization laboratory (CCL) that includes three dedicated rooms. There are also four other rooms available for interventional procedures and a cardiac hybrid operating room. Union Memorial stated that there has never been an interruption in the ability to provide 24/7 coverage for primary PCI services. Union Memorial also submitted maintenance logs from 2015 through 2019 by room for three CCL rooms.

Staff Analysis and Conclusion

MHCC staff reviewed the maintenance logs submitted and noted that there were no times when all rooms were down simultaneously in calendar year 2015 through calendar year 2019. MHCC staff provided the number of instances of downtime reported for each room, as shown in Table 1.

Table 1: Number of Separate Downtimes Reported by Union Memorial for the CCL by Room, CY 2015- CY 2019

Calendar Year	Room 1	Room 2	Room 3	Simultaneous Downtimes Reported*
2015	0	52	19	No
2016	1	21	1	No
2017	43	5	29	No
2018	1	44	0	No
2019	7	20	11	No

Source: Union Memorial Application, updated Q2 response.

*Downtimes were considered simultaneous if maintenance was reported in all rooms on any given day at the same time.

MHCC staff concludes that Union Memorial complies with this standard.

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

Union Memorial provided a signed statement from Bradley S. Chambers, President, affirming that Union Memorial commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital for at least 75% of cases. The statement also affirms that Union Memorial commits to tracking and improving door-to-balloon (DTB) times for transfer cases. Union Memorial provided quarterly median DTB times from January 2015 through December 2019 for non-transfer cases, as shown in Table 2a. Union Memorial reported that, in CY 2019 Q2, there were two patients for whom the DTB was not met. For each of the two cases, when the DTB benchmark was not met in this quarter the hospital described the situations resulting in delay in the follow-up.

Table 2a: Union Memorial Reported Compliance With DTB Times by Quarter for Non-Transfer Cases, January 2015- December 2019

Quarter	Total Primary PCI Volume	Cases With DTB <= 90 Minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	10	9	90%
CY2015 Q2	11	11	100%
CY2015 Q3	15	15	100%
CY2015 Q4	15	15	100%
CY2016 Q1	4	4	100%
CY2016 Q2	7	7	100%
CY2016 Q3	6	5	83%
CY2016 Q4	8	7	88%
CY2017 Q1	13	12	92%
CY2017 Q2	12	12	100%
CY2017 Q3	6	6	100%
CY2017 Q4	7	7	100%
CY2018 Q1	16	16	100%
CY2018 Q2	9	9	100%
CY2018 Q3	7	7	100%
CY2018 Q4	10	10	100%
CY2019 Q1	11	11	100%
CY2019 Q2	7	5	**71%**
CY2019 Q3	4	4	100%
CY2019 Q4	15	15	100%

Source: Union Memorial Application, Q4, updated response April 21, 2020.

Union Memorial provided information on its performance on DTB times for transfer cases, as show in Table 2b. Union Memorial also explained the steps taken to improve transfer times for patients who require primary PCI. The emergency department and contracted ambulance company attend monthly multidisciplinary meetings. Additionally, the ambulance company provides the committee with comprehensive reports and meets with emergency department leadership to create individual work plans for each facility. These action plans include giving a bolus of medication, discontinuing drips, or avoiding all unnecessary testing once STEMI is confirmed by ECG. Union Memorial also reports that the decision to take nursing staff from the emergency department instead of waiting for the ambulance company has improved transfer times. Union Memorial stated that times are monitored and reviewed monthly and there are quarterly STEMI meetings that include the interventional team, cardiac care leadership, and MedStar emergency department leadership.

Table 2b: Union Memorial Reported DTB Performance by Quarter for Transfer Cases, January 2015- June 2019

Quarter	Total Primary PCI Volume	Cases With DTB <= 120 Minutes	Percent of Cases With DTB <=120 Minutes
CY2015 Q1	5	5	100%
CY2015 Q2	11	8	73%
CY2015 Q3	12	11	92%
CY2015 Q4	7	6	86%
CY2016 Q1	6	5	83%
CY2016 Q2	5	4	80%
CY2016 Q3	7	3	**43%**
CY2016 Q4	13	12	92%
CY2017 Q1	4	4	100%
CY2017 Q2	8	7	88%
CY2017 Q3	10	10	100%
CY2017 Q4	9	8	89%
CY2018 Q1	3	2	**67%**
CY2018 Q2	12	11	92%
CY2018 Q3	10	9	90%
CY2018 Q4	9	7	78%
CY2019 Q1	9	7	78%
CY2019 Q2	9	8	89%

Source: Union Memorial Application, Q4, updated response, April 21, 2020.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases, as shown in Table 3, below. MHCC staff found that Union Memorial met the DTB benchmark in all but one quarter; in the quarter ending 2016 Q1, 66.7 % of cases met the DTB benchmark.

MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, whereas MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, Union Memorial complied with this standard, with between 86.6% and 92.6% of PCI cases meeting the door-to-balloon time standard over rolling eight-quarter periods, as shown in Table 3.

MHCC staff concludes that Union Memorial complies with this standard.

Table 3: Union Memorial 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
2015q1	9	8	88.9%			
2015q2	12	12	100.0%			
2015q3	16	14	87.5%			
2015q4	16	15	93.8%			
2016q1	6	4	**66.7%**			
2016q2	9	7	77.8%			
2016q3	6	5	83.3%			
2016q4	9	7	77.8%	83	72	86.7%
2017q1	11	10	909%	85	74	87.1%
2017q2	12	12	100.0%	85	74	87.1%
2017q3	6	6	100.0%	75	66	88.0%
2017q4	8	7	87.5%	67	58	86.6%
2018q1	18	16	88.9%	79	70	88.6%
2018q2	8	8	100%	78	71	91.0%
2018q3	7	6	88.9%	79	72	91. 1%
2018q4	8	6	88.9%	78	71	91.0%

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2015- CY 2019.
Note: Calculations for each quarter are based on the procedure date.

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

As shown in Table 4a, Union Memorial provided the number of physicians, nurses, and technicians able to provide cardiac catheterization services to acute myocardial infarction patients, in the week prior to the due date of the application.

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

	Number/FTEs	Cross Training (S/C/M)*
Physician	N = 4	Interventional Cardiologist
Nurse	10.9	9.9 = C,M; 1.0 = S,C,M
Technician	10.5	S,M

Source: Union Memorial Application, Q6a.
*Scrub (S), circulate (C), monitor (M)

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by Union Memorial to information reported by three other existing programs in their Certificate of Ongoing Performance applications. As shown in Table 4b, below, Union Memorial's 2018 PCI volume was greater than the volume reported by the University of Maryland (UM) Saint Joseph Medical Center, Peninsula Regional Medical Center, and Meritus Medical Center. Union Memorial reported that the PCI program had four interventionalists, which was less than the number reported by Peninsula Regional Medical Center, but greater than the number reported by UM Saint Joseph Medical Center and Meritus Medical Center. The number of full-time equivalent (FTE) nurses reported by Union Memorial was similar to the FTEs reported by UM Saint Joseph Medical Center, greater than the FTEs reported by Meritus Medical Center, and less than the FTEs reported by Peninsula Regional Medical Center. Finally, the number of Union Memorial's reported technician FTEs was either comparable or greater than those reported by all three programs.

Table 4b: Union Memorial and Other PCI Programs CCL Staff

Program & Year Reported	2018 PCI Volume*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
Union Memorial 2019	1027	N = 4	10.9	10.5
Meritus Medical Center 2019	852	N = 6	8.5	5.0
UM Saint Joseph Medical Center	741	N = 2	10.3	4.0
Peninsula Regional Medical Center	695	N = 10	13.5	10.7

Sources: Union Memorial 2019 PCI Certificate of Ongoing Performance Application, Meritus 2019 PCI Certificate of Ongoing Performance Application, UM Saint Joseph Medical Center 2019 PCI Certificate of Ongoing Performance Application, Peninsula Regional Medical Center 2019 PCI Certificate of Ongoing Performance Application.
*Volumes for either fiscal or calendar year

MHCC staff concludes that Union Memorial has adequate nursing and technical staff to provide PCI services.

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

Union Memorial provided a signed letter of commitment from Bradly S. Chambers, President, acknowledging that Union Memorial will provide primary PCI services in accord with the requirements established by the Commission, and MedStar Health administration and the Board of Directors will support the PCI program.

Staff Analysis and Conclusion

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

Union Memorial provided a description of the staff involved with these functions. Union Memorial employs a group of cardiac, critical care-trained, registered nurses to collect, enter, and report data for the cardiovascular service. There is one FTE dedicated specifically to the ACC-NCDR registries. Union Memorial uses a third party vendor, Armus, to allow for immediate access to the data for performance improvement in real time and employs a data analyst.

Staff Analysis and Conclusion

MHCC staff concludes that Union Memorial is compliant with this standard.

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

John C. Wang, M.D. is the medical director for Union Memorial's interventional cardiology services. Dr. Wang was appointed as the medical director in July of 2005. Union Memorial also provided a description of the responsibilities of the medical director of the CCL and a curriculum vitae for Dr. Wang. The responsibilities of the medical director include: supporting administrative needs (e.g. recruitment and retention of staff, program development and marketing); development, implementation, and monitoring of quality indicators; ensuring compliance with regulatory guidelines; and oversight of the invasive cardiology curriculum for residence teaching conferences.

Staff Analysis and Conclusion

MHCC staff concludes that Union Memorial complies with this standard.

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

Union Memorial stated that all registered nurses are required to complete 15 continuing education units (CEUs) per year. Technologists must follow the American Registry of Radiologic Technologists and the State of Maryland requirement of 24 continuing education credits every two years. Finally, interventionalists abide by the State of Maryland requirements for licensure which requires 50 CME credits in a two-year period. MedStar Health utilizes a web-based continuing education portal called CloudCME. This portal allows staff to access and track all MedStar Health conferences and learning opportunities, and it allows the manager of the unit to monitor CEUs for the nurses. The technologists and physicians are monitored via their licensing board.

Union Memorial stated that all MedStar employees have mandatory e-learning modules that must be completed annually, and all MedStar nurses have specific nursing modules that must be completed. The specialty units, including the CCL, have individualized clinical conferences or e-learning that staff are required to complete on an annual basis, beyond the hospital or nursing standards. Staff compliance is monitored electronically and reviewed annually. Union Memorial also provided a list of staff education activities from 2015 through May 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that Union Memorial is compliant with this standard.

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

Union Memorial states that this standard is not applicable because it is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Union Memorial.

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

Union Memorial notes that this standard is not applicable because it is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery .

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Union Memorial.

<u>Quality</u>

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

Union Memorial reviews cases at the monthly performance improvement meeting and submitted attendance records for 2015 through May 2019. In addition, case reviews are scheduled for every Tuesday. While all associates are encouraged to attend, there is no formal sign in sheet for case review meetings.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for the interventional case review meetings. Union Memorial has meetings monthly, except for occasional cancellations of meetings. Attendance information was submitted for twelve meetings in 2015, eleven in 2016, eleven in 2017, and nine in 2018. Meeting cancellations did not cause meeting frequency to drop below every other month at any time during the review period.

MHCC staff concludes that Union Memorial complies with this standard.

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

Union Memorial reviews and distributes via email information regarding each primary PCI case to the team of staff involved, within one business day of occurrence. Any delays are immediately identified and an explanation is required from the team, including an appropriate action plan, if appropriate. All cases are discussed at quarterly STEMI meetings and include other Baltimore MedStar hospitals with PCI programs. In addition, Union Memorial reports that there is a monthly service-line meeting that includes review of all transfer cases for the prior month. Union Memorial submitted attendance records for 2014 through May 2019 for the STEMI meetings and 2014 through December 2019 cardiology monthly service-line meetings.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for STEMI and cardiology monthly service-line meetings. STEMI meeting attendance records show that four meetings were held each year during the review period. Attendance records show CCL, coronary care unit, and emergency department leadership attendance. Cardiology service-line meeting attendance records showed that twelve meetings were held in 2015, eleven were held in 2016, twelve were held in 2017, eleven were held in 2018, and nine were held in 2019. Attendance records show participation from the CCL, human resources, and cardiac rehabilitation staff, among others. MHCC staff determined that the quarterly STEMI meetings and monthly cardiology service-line meetings, with few cancellations, ensured that twelve or more multiple care area group meetings were held each year during the review period.

MHCC staff concludes that Union Memorial 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.

Union Memorial submitted copies of external review reports for January 2015 through June 2019.

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 in shown in Table 5. Although only 5% of cases are required to be reviewed, as shown in Table 5, between 5.5% and 17.9% of cases were reviewed each year. Beginning in the second half of 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17.

Table 5: Union Memorial External Reviews, September 2014- June 2019

Time Period	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard*
9/2014 to 2015 Q4	390	70	17.9%	Semiannual	Yes
CY 2016	986	55	5.6%	Semiannual	Yes
CY 2017	1015	56	5.5%	Semiannual	Yes
CY 2018	869	55	6.3%	Semiannual	Yes
2019 Q1Q2	572	33	5.8%	Semiannual	Yes

Source: MHCC staff analysis of MACPAQ reports.
* Each semiannual review during the calendar year included three cases per physician or all cases if interventionalist performed fewer than three cases during the review period, as applicable.

For the period between January 2015 and June 2019, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that at least five percent of elective PCI cases were reviewed. Staff verified that if fewer than three cases were performed by an interventionalist, then all cases were reviewed by the external reviewer, MACPAQ, as required.

Union Memorial complies with this standard.

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

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

(ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than 3 cases during the relevant period, as provided in Regulation .08; or

(iii) A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual

requirement in Subparagraphs .07C(4)(d)(i).

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

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

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

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

10.24.17.07D(5)(d) The performance review of an interventionalist referenced in Paragraph .07D(5)(c) shall:

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

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

In addition to the external reviews described above, Union Memorial reviews cases at its monthly performance improvement meeting and additional case reviews are done every Tuesday morning. Union Memorial described the internal review practices of the program, noting that 15 cases are selected randomly for review each month. The individual responsible for the random selection of cases also monitors the number of reviews per physician and pulls additional cases for that interventionalist, if necessary, so that the greater of 10 or 10% of cases are reviewed per interventionalist. Union Memorial also states that internal reviews include angiographic images, medical test results, and patient medical records are reviewed for Appropriateness Use Criteria including indication, interpretation, and recommended treatment.

Staff Analysis and Conclusion

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

At least six cases per interventionalist were reviewed per year, as applicable, and additional cases were reviewed via internal review, except for 2015. Through the additional internal review of cases, at least 10% of cases per interventionalist were reviewed annually, as required. The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization. The review of cases by MACPAQ and internal review by Union Memorial include a review of angiographic images, medical test results, and patients' medical records.

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

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

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

Staff Analysis and Conclusion

MHCC staff concludes that Union Memorial complies with this standard.

10.24.17.07D (5)(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases

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

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

and external review cases.

(i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.

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

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

Union Memorial stated that the hospital is always looking to improve DTB times and has made improvements over the years. For example, in January 2015, the process was changed so that the emergency department would make the initial call to Heartline and that Heartline's initial call will be to the hospital's STEMI team to initiate a 30-minute staff response. In April 2015, a question was added to the Heartline scripting so that STEMIs would be identified at the very beginning of the conversation.

In addition, Union Memorial reported that the hospital reviews Acute Kidney Injury (AKI)[3], frequently and submitted documentation of performance improvement activities related to these issues. Specifically, Union Memorial submitted an AKI action plan that was updated in August 2017.

Union Memorial submitted meeting minutes for MedStar North Quarterly STEMI Review meetings between January 2019 and January 2020 and Cardiology Service Line Meetings between January 2015 and December 2018. Union Memorial also submitted performance improvement indicators and trends by year for 2015 through 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the meeting minutes and description of quality assurance practices provided and determined that Union Memorial demonstrates ongoing improvement efforts.

MHCC staff concludes that Union Memorial complies with this standard.

Patient Outcome Measures

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

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

[3] Acute kidney injury is one of the potential complications of the contrast used for imaging of the arteries of PCI patients.

(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

Union Memorial submitted adjusted mortality by rolling 12-month reporting period for 2015 Q1 through 2019 Q2 when available, as shown in Table 6. These data are not available for any hospitals participating in the ACC-NCDR CathPCI data registry for the rolling 12-month period of 2017 Q3 through 2018 Q2.

Table 6: Union Memorial Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI				Non-STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2019q1-2019q4	6.82	[2.26, 15.11]	6.01	Yes	0.65	[0.30, 1.22]	0.95	Yes
2018q4-2019q3	4.98	[1.38, 12.14]	6.06	Yes	0.50	[0.16, 1.15]	0.98	Yes
2018q3-2019q2	8.94	[3.68, 17.43]	6.38	Yes	0.55	[0.07, 1.98]	1.00	Yes
2018q2-2019q1	8.89	[3.66, 17.40]	6.13	Yes	0.46	[0.15, 1.06]	0.99	Yes
2018q1-2018q4	7.93	[3.90, 13.83]	6.00	Yes	0.70	[0.28, 1.44]	1.00	Yes
2017q4-2018q3	8.26	[3.86, 14.95]	6.54	Yes	0.69	[0.28, 1.42]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry							
2017q2-2018q1	6.20	[2.04, 13.91]	6.91	Yes	0.50	[0.14, 1.28]	1.03	Yes
2017q1-2017q4	3.39	[0.41, 11.87]	6.86	Yes	0.26	[0.03, 0.93]	0.99	Yes
2016q4-2017q3	4.98	[1.37, 12.30]	6.75	Yes	0.27	[0.03, 0.96]	0.98	Yes
2016q3-2017q2	7.58	[2.82, 15.86]	6.64	Yes	0.62	[0.20, 1.44]	0.95	Yes
2016q2-2017q3	8.60	[3.79, 6.20]	6.77	Yes	0.76	[0.28, 1.64]	0.97	Yes
2016q1-2017q4	7.38	[3.26, 13.87]	6.82	Yes	0.63	[0.21, 1.47]	0.95	Yes
2015q4-2016q3	7.11	[2.66, 14.82]	6.71	Yes	0.61	[0.20, 1.41]	0.95	Yes
2015q3-2016q2	5.76	[2.53, 10.91]	6.66	Yes	0.67	[0.22, 1.55]	0.93	Yes
2015q2-2016q1	6.31	[2.94, 11.54]	6.45	Yes	0.75	[0.31, 1.46]	0.90	Yes
2015q1-2015q4	6.71	[3.12, 12.28]	6.26	Yes	1.20	[0.64, 2.04]	0.90	Yes

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

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

Staff Analysis and Conclusion

This standard is not applicable for most of the review periods because the current standard did not become effective until January 14, 2019. A similar, earlier standard referenced a statewide average as the benchmark, but MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. MHCC staff has provided information on Union Memorial's performance between January 2015 and December 2019, as shown in Table 6.

MHCC staff reviewed the adjusted mortality rates by rolling 12-month period 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 because the national benchmark fell within the 95% confidence interval for Union Memorial for all 12-month reporting periods ending between January 2015 and December 2019, when an adjusted mortality rate was reported. MHCC staff concludes that Union Memorial would have met this standard, if the standard had been applicable for the period reviewed between January 2015 and September 2019. The hospital meets the benchmark for both STEMI and non-STEMI cases for the period ending December 2019, the first and only reporting period to which the current standard applies.

MHCC staff concludes that Union Memorial complies with this standard.

Physician Resources

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

Union Memorial states that, because it is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery, this standard is not applicable. Union Memorial submitted volume logs for Drs. Wang, Siddiqi, Kahliyada, Peichert, Prewitt, Sura, Insel, Saeed from 2014 Q3 to 2018 Q4.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Union Memorial.

10.24.17.07D(7)(b)Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24 month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Union Memorial points out that because it is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery, this standard is not applicable.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Union Memorial.

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.

Union Memorial states that because it is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery, this standard does not apply.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Union Memorial.

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

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

Union Memorial submitted a signed and dated statement from Dr. Wang, Director of the CCL, acknowledging that the physicians performing PCI at Union Memorial are qualified under the regulations required by MHCC. Drs. Wang, Saeed, Siddiqi, and Kaliyadan are board certified in interventional cardiology and Dr. Peichert is exempt from this requirement.

Staff Analysis and Conclusion

MHCC staff reviewed the letter and additional information submitted. MHCC staff concludes that Union Memorial meets these standards based on the letter provided.

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

Union Memorial submitted signed and dated attestations from Drs. Wang, Siddiqi, Peichert, Saeed, and Kaliyadan stating each has completed a minimum of 30 hours of continuing medical education credits in interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC staff reviewed the statements provided and concludes that Union Memorial meets this standard.

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

Union Memorial submitted a signed statement from the Medical Director of the Cardiac Interventional Service, Dr. Wang, acknowledging that each physician who has performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians who are currently performing primary PCI services are participating in the on-call schedule. Union Memorial also submitted a copy of the on-call schedule for June 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for June 2019 and observed that Drs. Wang, Siddiqi, Peichert, Saeed, and Kaliyadan were all scheduled to be on-call at different times during the month.

MHCC staff concludes that Union Memorial meets this standard.

Volume

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

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

Union Memorial provided the total number of PCI cases for fiscal years 2015 through 2018.

Table 7: Union Memorial Total PCI Case Volume, FY 2015- FY 2018

Fiscal Year	Total PCI
2015	1,019
2016	1,126
2017	1,064
2018	1,027

Source: Union Memorial application, question 28.

Staff Analysis and Conclusion

MHCC staff reviewed the table submitted by Union Memorial. Staff also analyzed the ACC-NCDR CathPCI data for CY 2015 through CY 2018 and determined that the PCI volume reported by Union Memorial is consistent with this analysis.

MHCC staff determines that Union Memorial 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.

Union Memorial responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2019. This analysis shows primary PCI volume ranged from 70 to 200 cases each calendar year, and it confirms that Union Memorial Hospital exceeded the threshold of 49 cases annually referenced in the standard.

MHCC staff determined that this standard does not apply to Union Memorial.

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

Union Memorial provided the number of primary PCI cases by interventionalist from 2014 Q3 through 2018 Q4.

Staff Analysis and Conclusion

MHCC staff reviewed the tables submitted by Union Memorial. According to the tables, between 2014 Q3 and 2018 Q4, at least 11 primary PCI procedures were completed per year, for practicing interventionalists at the time of application (i.e., Drs. Saeed, Peichert, Kaliyadan, Siddiqi, and Wang). MHCC staff also analyzed the ACC-NCDR Cath PCI registry data. This analysis shows that one physician who is not currently on the roster for the hospital performed fewer than 11 primary PCI procedures in CY 2017 and CY 2018, and in 2019 one physician on the current roster performed fewer than 11 primary PCI procedures.

Because the standard references a target, and the physician who performed fewer than 11 primary PCI cases in 2019 far exceeded the target in prior years, MHCC staff concludes that Union Memorial meets this standard.

<u>Patient Selection</u>

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

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

(b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, are not suitable for elective PCI.

Union Memorial stated that no patients identified by internal or external reviews have received elective PCI services inappropriately. Union Memorial also submitted its internal review by John C. Wang, M.D., its CCL director who performed an analysis and review of all cases determined to be "rarely appropriate" under any criteria by external review.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from 2015 through June 2019 and determined that there were no cases between January 2017 and June 2019 that were determined to be "rarely appropriate" with respect to clinical criteria, angiographic criteria, and ACC/AHA appropriateness criteria. Seven cases were determined to be "rarely appropriate" with respect to one criteria. Dr. Wang's internal review of these cases determined that PCI was an acceptable treatment approach in all cases.

MHCC staff concludes that Union Memorial complies with this standard.

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

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

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

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

(d) Patients who experienced a return of spontaneous circulation following cardiac arrest

and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believes that transfer to a tertiary institution may be harmful to the patient.

Union Memorial stated there were no patients identified by internal or external review who had received primary PCI services inappropriately during the review period. Additionally, no patients received thrombolytic therapy because the primary PCI system was not available.

Staff Analysis and Conclusion

MHCC staff determines that Union Memorial complies with the standard.

RECOMMENDATION

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