IN THE MATTER OF	*	**BEFORE THE**
UNIVERSITY OF MARYLAND	*	**MARYLAND**
SHORE MEDICAL CENTER-EASTON	*	**HEALTHCARE**
	*	**COMMISSION**
Docket No.: 20-20-CP034	*	

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STAFF REPORT AND RECOMMENDATION

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

November 18, 2021

I. INTRODUCTION

A. Background

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

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

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

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter (Cardiac Surgery Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Surgery Chapter was subsequently revised in November 2015 and again in January 2019. The main change in these revisions to the Cardiac Surgery Chapter that affects PCI programs has been a change to the benchmark used to evaluate hospitals' risk-adjusted mortality rates. Commission staff was unable to obtain benchmark information for risk-adjusted mortality rates consistent with the regulations adopted in November 2015 that reflected the recommendations of the CAG. As a result, the standard 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 specified period of time that cannot exceed five years. At the end of the specified 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

University of Maryland Shore Medical Center at Easton

University of Maryland Shore Medical Center at Easton (UM SMC-E) is a 126-bed general hospital located in Easton (Talbot County) that is part of the University of Maryland Medical System. UM SMC-E does not have a cardiac surgery program on site.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. UM SMC-E is located 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. One program has only provided primary PCI services since its inception; all of the other programs provide both primary and elective PCI services. Six of the fourteen hospitals also provide cardiac surgery services.

Staff Recommendation

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

II. PRODEDURAL HISTORY

UM SMC-E filed a Certificate of Ongoing Performance application on August 26, 2020. MHCC staff reviewed the application and requested additional information on April 27, 2021, May 6, 2021, September 10, 2021, and October 27, 2021. MHCC received additional information on June 25, 2021, August 12, 2021, October 15, 2021, and November 5, 2021.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

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

UM SMC-E responded that there are currently no deficiencies in data collection or reporting that have been identified by MHCC staff.

Staff Analysis and Conclusion

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

MHCC staff concludes that UM SMC-E 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 SMC-E reported that the hospital's cardiac catheterization laboratory (CCL) has not experienced any downtime that has resulted in the inability to provide primary PCI services in accordance with accepted guidelines. Preventative maintenance of UM SMC-E's two procedure rooms is scheduled in advance to always ensure that one of the hospital's two procedure rooms is immediately available. UM SMC-E reported that there was no overlapping downtime, as shown in Table 1.

Table 1: UM SMC-E Reported Frequency of Downtime by CCL and Time Period, April 2017- December 2020

Time Period	Number of Downtime Occurrences		Overlapping Downtime
	CCL ROOM 1	CCL ROOM 2	
CY 2017	12	7	No
CY 2018	8	5	No
CY 2019	11	11	No
CY 2020	7	7	No

Source: UM SMC-E Application Q2, UM SMC-E updated Q2 response.

Staff Analysis and Conclusion

MHCC staff concludes that UM SMC-E complies with the 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.

UM SMC-E provided a signed statement from Kenneth D. Kozel, President and CEO stating that UM SMC-E commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases at a minimum of 75% of the time, and UM SMC-E commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement.

UM SMC-E performed the hospital's first elective PCI case on March 31, 2017. Since the start of the hospital's PCI program, UM SMC-E reported that each primary PCI case performed at the hospital is reviewed by members of the multi-disciplinary Cardiac Services Steering Committee each month as a standing agenda item. UM SMC-E developed a tracking tool to facilitate monthly review of door-to-balloon (DTB) and door-to-door-to-balloon (D2D2B) times. Outliers are reviewed to determine contributing factors for delays in transfer.

UM SMC-E identified three common issues that have contributed to DTB times over 120 minutes for PCI cases: delays in transport, transport distance, and delays in patients receiving EKGs. To address delay in transport, UM SMC-E worked with local 911 EMS agencies to establish a protocol for transporting patients in need of urgent transport to the hospital's CCL. Patients requiring transport from the Chestertown ED typically are transported via helicopter to UMMS facilities located across the Bay. When air transport is unavailable, patients are transported via ground transportation. In an effort to address EKG delays, UM SMC-E re-evaluated the criteria for an urgent EKG and updated the hospital's EKG policy. ED team members were then educated on the hospital's updated EKG policy. UM SMC-E reports that opportunities for improvement, if discovered, result in recommendations from the Cardiac Services Steering Committee in order to address those factors that are controllable.

Additionally, UM SMC-E provided quarterly DTB times for the period from April 2017 through December 2020, as shown in Table 2.

Table 2a: UM SMC-E Reported Compliance with DTB Benchmark by Quarter for Non-Transfer Cases, April 2017- December 2020

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2017 Q2	2	1	**50.0%**
CY2017 Q3	7	3	**42.9%**
CY2017 Q4	5	2	**40,0%**
CY2018 Q1	12	10	83.0%
CY2018 Q2	21	21	100.0%
CY2018 Q3	20	18	90.0%
CY2018 Q4	13	12	92.3%
CY2019 Q1	15	15	100.0%
CY2019 Q2	18	17	94.4%
CY2019 Q3	20	17	85.0%
CY2019 Q4	13	12	92.3%
CY2020 Q1	15	13	86.7%
CY2020 Q2	8	6	75.0%
CY2020 Q3	10	8	80.0%
CY 2020 Q4	5	5	100.0%

Source: UM SMC-E application and updated response for Q4.

Table 2b: UM SMC-E Reported DTB Performance by Quarter for Transfer Cases, April 2017- December 2020

Quarter	Total Primary PCI Volume	Cases With DTB <= 120 Minutes	Percent of Cases With DTB <=120 Minutes
CY2017 Q2	2	0	**0%**
CY2017 Q3	1	1	100.0%
CY2017 Q4	0	0	N/A
CY2018 Q1	2	1	**50.0%**
CY2018 Q2	4	4	100.0%
CY2018 Q3	2	1	**50.0%**
CY2018 Q4	5	3	**60.0%**
CY2019 Q1	2	2	100.0%
CY2019 Q2	2	1	**50.0%**
CY2019 Q3	4	2	**50.0%**
CY2019 Q4	3	2	**66.7%**
CY2020 Q1	5	3	**60.0%**
CY2020 Q2	5	2	**40.0%**
CY2020 Q3	6	3	**50.0%**
CY2020 Q4	5	2	**40.0%**

Source: UM SMC-E application, updated response for Q4.
Note: N/A means not applicable

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer ST-elevation myocardial infarction (STEMI) cases, as shown in Table 3. MHCC staff found that UM SMC-E met the DTB benchmark for non-transfer cases in all quarters. MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases in reviewing compliance with this standard. 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, UM SMC-E complied with this standard, with between 88.1% and 100% of PCI cases meeting the DTB time standard as shown in Table 3.

MHCC staff concludes that UM SMC-E complies with this standard.

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

Quarter				Rolling 8-Quarters		
Time Period	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes
2018q1	1	1	100%	1	1	100.0%
2018q2	18	17	94.4%	19	18	94.7%
2018q3	19	17	89.5%	38	35	92.1%
2018q4	13	12	92.3%	51	47	92.2%
2019q1	13	12	92.3%	64	59	92.2%
2019q2	17	13	76.5%	81	72	88.9%
2019q3	17	16	94.1%	98	88	89.8%
2019q4	13	13	100%	111	101	91.0%
2020q1	1	1	100%	112	102	91.1%
2020q2	10	8	80%	122	110	90.2%
2020q3	8	5	62.5%	130	115	88.5%
2020q4	5	4	80%	135	119	88.1%

Source: MHCC analysis of ACC-NCDR CathPCI data April 2017- CY 2020.
Note: Calculations for each quarter are based on the procedure date.
*No primary PCI cases based on MHCC analysis for 2017 q2, q3 and q4

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 below in Table 4A, UM SMC-E reported the number of physicians, nurses, and technicians who were available to provide cardiac catheterization services to acute myocardial infarction patients as of April 27, 2021.

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

Staff Category	Number/FTEs**	Cross Training (S/C/M)*
Physician	N= 3	--
Nurse	8.0	S/C/M
Technician	4.0	S/M/C

Source: UM SMC-E Application, Q6a, updated Q6a and Q6b.
*Scrub (S), circulate (C), monitor (M)
**At the time of application, there were 8 total FTE nurses and 4 total FTE technician positions. UM SMC-E was fully staffed at the time of application. As a result of the pandemic, UM SMC-E is actively recruiting for several open nursing positions with the help of a nursing agency.
***At the time of application, there were additional part-time staff: 3 per diem nurses and 2 per diem technicians.

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by UM SMC-E to information reported in three other hospitals' applications for Certificates of Ongoing Performance for PCI services.

MHCC staff observed that UM SMC-E has fewer full-time equivalent (FTE) interventionalists than Johns Hopkins Bayview Medical Center (JHBMC), University of Maryland Prince George's Hospital Center (UM PGHC), and Shady Grove Medical Center (SGMC). UM SMC-E reported more nurse FTEs than JHBMC and SGMC, but fewer than UM PGHC (8 FTEs and 10 FTEs respectively). UM SMC-E reported fewer technician FTEs than JHBMC, which performed a similar volume of PCI cases as UM SMC-E, as well as fewer technician FTEs than UM PGHC and SGMC, shown in Table 4B.

Table 4B: CCL Staffing for UM SMC-E and Other Select PCI Programs

Program	2018 Total PCI Volume*	Number of Interventionalists	Nurse FTEs	Technician FTEs
UM SMC-E	202	3	8	4.0
Johns Hopkins Bayview Medical Center	200	10	6	5.8
UM Prince George's Hospital Center	247	5	10	6.0
SGMC	269	5	6	5.0

Sources: SGMC 2019 PCI Certificate of Ongoing Performance Application, Johns Hopkins Bayview Medical Center 2019 PCI Certificate of Ongoing Performance Application, UM Prince George's Hospital Center 2019 PCI Certificate of Ongoing Performance Application, UM SMC-E 2019 PCI Certificate of Ongoing Performance Application.
*Volumes for either fiscal or calendar year

MHCC staff concludes that there is adequate nursing and technical staff to provide services; UM SMC-E complies with this standard.

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

UM SMC-E provided a signed letter of commitment from Mr. Kozel, acknowledging that UM SMC-E will provide primary PCI services in accordance with the requirements established by the Commission.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of commitment provided and concludes that UM SMC-E 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 SMC-E provided a description of the staff involved with these functions. At the time of application, UM SMC-E reported there were no dedicated FTE(s) responsible for data management, reporting and coordination with institutional quality improvement efforts. UM SMC-E provided additional information that the following operational team members assist with data management, reporting and coordination as daily operations and procedural volumes allow: Shelby Yinger, RN, RCIS, Tina Blalock, RN, Clinical Nurse Coordinator, Steve Pringle, RN, Cardiac Cath Manager (currently vacant), Gary Jones, Director, Heart and Vascular Center, Dr. Jeff Etherton, Medical Director Interventional Cardiology, and QCentrix contracted services. In May

2021, UM SMC-E informed MHCC staff that that Joshua Cherrix had replaced Gary Jones as the new director for the Heart and Vascular Center.

Staff Analysis and Conclusion

MHCC staff concludes that UM SMC-E 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.

On June 27, 2016, Dr. Jeff Etherton was appointed as Medical Director for Interventional Cardiology/Cardiac Cath Lab. UM SMC-E provided a detailed description of the responsibilities of Dr. Etherton that include reviewing the performance of staff, developing and implementing performance improvement plans, annually reviewing policies and procedures, assuring compliance with regulations and accreditation standards, and ensuring coverage for all hours of operation.

Staff Analysis and Conclusion

MHCC staff concludes that UM SMC-E 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 SMC-E provided a list of the continuing educational programs and activities in which staff in the CCL, Critical Care Unit, and Emergency Department participated between March 2017 and December 2019. UM SMC-E stated that staff participate in continuing education trainings and services throughout the year as needed or required. These educational activities may include independent assigned learning, staff meetings, clinical inquiry meetings, best practice meetings, and PCI performance meetings. UM SMC-E requires annual mandatory compliance training for all staff which is assessed, monitored and tracked through a learning management system. The mandatory training modules include, but are not limited to annual safety, fire safety, emergency management, and infection control updates. UM SMC-E reported that all annual mandatory compliance trainings, educational certificates and rosters received by staff are filed within the department the staff is assigned to work and are included in the staff's annual performance evaluation.

Staff Analysis and Conclusion

MHCC staff concludes that UM SMC-E 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 PCI, for hospitals performing primary PCI without on-site cardiac surgery.

Mr. Kozel signed a transfer agreement with Dana Farrakhan, Senior Vice President of University of Maryland Medical Center. The agreement ensures an ALS equipped ambulance will arrive within 30 minutes of a request for patient transfer to University of Maryland Medical Center, a tertiary facility with cardiac surgery services. UM SMC-E reported that the originally submitted transfer agreement, effective October 13, 2015, remains the current binding transfer agreement between UM SMC-E and University of Maryland Medical Center.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that UM SMC-E meets this standard.

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

UM SMC-E reported the hospital has a Memorandum of Understanding (MOU) with Maryland ExpressCare, a division of UMMS, that provides around the clock emergency transportation services for patients requiring care at any of the system's tertiary care hospitals. The agreement provides that, for emergent transport requests, Maryland ExpressCare will provide emergency air transport within 30 minutes, twenty-four hours a day, except when prohibited by weather. If a Maryland ExpressCare air ambulance is not available to fly, the Maryland ExpressCare Transfer Center at the University of Maryland Medical Center will notify another air ambulance vendor or the UM SMC-E contractual ground transportation vendor.

Maryland Express Care has an agreement with Best Care Ambulance, Inc., a licensed advanced cardiac life support emergency medical service private contractor. The agreement provides that, for emergent transport requests, Best Care Ambulance is required to arrive at the sending facility for pick-up within 30 minutes of a request.

Staff Analysis and Conclusion

MHCC staff reviewed the transport agreements submitted by UM SMC-E. The agreement with Maryland ExpressCare states that the transport company will arrive at UM SMC-E no more than thirty minutes after the receipt of a request for transfer of a PCI patient. This agreement also includes contingency plans that include notifying another air ambulance vendor or the UM SMC-E contractual ground transportation vendor.

MHCC staff concludes that UM SMC-E complies with this standard.

Quality

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

UM SMC-E reported interventional case review meetings were established in April of 2017 and occurred weekly for the first year, and then at least monthly thereafter. Although attendance records were kept, UM SMC-E reported that all documentation of these meetings from April 2017 to December 2018 was lost due to multiple leadership changes and office relocations. UM SMC-E completed an exhaustive search of the facility for this documentation without success. Jeffrey Etherton, Medical Director at UM SMC-E provided MHCC staff with a signed attestation that the interventional case review meetings were held since April 2017, were led by interventional cardiologists, and included mandatory attendance by physicians, nurses, and technicians who care for primary PCI patients. UM SMC-E reported that the cases reviewed in these meetings were not limited to STEMI patients.

UM SMC-E provided sign in sheets for its interventional case review meetings held between January 2019 and February 2021, with limited exceptions. Meetings were held monthly, with several months including multiple meetings. UM SMC-E reported that three meetings were canceled in 2018, and three meetings were canceled in 2019. The reasons included holidays and scheduling conflicts.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for the interventional case review meetings. The documentation shows that physicians, nurses, and technicians regularly attend these meetings. The documentation submitted by UM SMC-E included attendance records for 19 meetings in 2019, 11 meetings in 2020, and two meetings during the first two months of 2021. Although the hospital canceled a few scheduled meetings in 2018 and 2019, UM SMC-E still exceeded the minimum number of case review meetings required in 2018 and 2019.

MHCC staff recommends that the Commission find UM SMC-E 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.

UM SMC-E reported that its multiple care area group known as the Cardiac Services Steering Committee (CSSC) includes members from the emergency department, nursing, Emergency Medical Services, and CCL leadership. The CSSC was originally focused on evaluating the patient experience and clinical outcomes of PCI patients and was established years

prior to the establishment of PCI services. Initially CSSC meetings were held every other month; however, since 2018 the meetings have been held monthly.

All committee members are required to attend monthly. UM SMC-E reported that CCL staff join the meetings monthly for the case review portion. The CSSC is responsible for monitoring and evaluating the care and activities that relate to cardiac patients through the full continuum of care. UM SMC-E provided a list of meeting dates and attendees for the CSSC meetings held between October 2015 and February 2021. If a meeting was cancelled due to scheduling conflicts or holidays, UM SMC-E reported that relevant information was sent to participants electronically.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for the CSSC multiple care area meetings. The documentation submitted by UM SMC-E included meeting minutes for meetings held from October 2015 through February 2021, with limited exceptions. Only meetings held after establishment of the PCI program in April 2017 are relevant to staff's evaluation of compliance. Six meetings were held in 2017, two less than required. Nine meetings were held in 2018, 2019, and 2020, which is three less meetings than required. In the first two months of 2021, two meetings were held. UM SMC-E reported a total of nine meeting cancellations during the review period. The reasons for cancellations included holidays and scheduling conflicts.

MHCC staff recommends that the Commission find that UM SMC-E 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 SMC-E submitted copies of the external review reports for PCI cases performed between April 2017 and June 2020. UM SMC-E explained that due to the timing of establishing a contract with an external reviewer, the first report covers April to December 2017.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 5. As shown in Table 5, although only 5% of cases are required to be reviewed externally, between 5.4% and 12.2% of cases were reviewed semi-annually.

Table 5: UM SMC-E External Review, July 2017- June 2020

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
04/17-12/17	74	6	8.0%	Semi-annually	Yes
01/18-06/18	111	6	5.4%	Semi-annually	Yes
07/18-12/18	64	6	9.0%	Semi-annually	Yes
01/19-06/19	76	6	8.0%	Semi-annually	Yes
07/19-12/19	89	10	11.2%	Semi-annually	Yes
01/20-06/20	74	9	12.2%	Semi-annually	Yes

Source: MHCC staff analysis of MACPAQ reports.
* Each semiannual review after October 2015 is required to include at least three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

The regulations in place prior to October 2015 did not require a minimum number of cases per interventionalist. After October 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. For the period between January 2018 and June 2020, MHCC staff verified that, if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by MACPAQ, as required.

UM SMC-E 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 completed by Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ) described above, UM SMC-E stated that internal review consists of a review of a minimum of four cases per year for each interventionalist. UM SMC-E reported that cases for internal review are not randomly selected; cases are selected based on several factors including severity, unique findings, level of difficulty, outcomes, and appropriateness of STEMI activation. All PCI cases performed (primary and elective) are reviewed on a weekly basis, and the information reviewed includes angiographic images, medical test results, and patients' medical records.

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, as applicable. The external reviews conducted by Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ) meet the requirements of 10.24.17.07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records.

MHCC staff concludes that UM SMC-E 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.

UM SMC-E submitted an affidavit from Mr. Kozel, 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, internal reviews of at least 10% 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 UM SMC-E complies with this standard.

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

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

[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.

(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 SMC-E reported that the Medical Quality Review Committee is required to review each external quality review report provided by MACPAQ. This review serves to identify any quality improvement opportunities and establish a timeline for completion.

The Medical Quality Review Committee meetings are held monthly to review practice patterns and establish process improvement goals to ensure optimal patient outcomes. All cases with a DTB over the standard in the ACC/AHA guidelines are reviewed, as well as PCI cases with complications tracked in the hospital's incident reporting system. All PCI cases are reviewed individually to ensure quality care and process improvement. UM SMC-E reported development of a tracking tool to facilitate monthly review of D2B and D2D2B times.

UM SMC-E reported that it has worked with local 911 EMS agencies to establish a protocol for transporting STEMI patients in need of urgent transport in order to reduce transport delays. When air transport is unavailable, patients are transported via ground to UM SMC-E. The hospital has also established a single dedicated hot line to communicate and facilitate transfer of the walk-in patients with STEMI at UM Shore Medical Center at Chestertown, UM Shore Emergency Center at Queenstown, and UM Shore Medical Center at Dorchester.

UM SMC-E also reported educating staff in the ED on how to reduce the time from arrival at the hospital to arrival in the CCL, as an effort to address EKG delays. UM SMC-E re-evaluated the criteria for an urgent EKG and updated the hospital's EKG policy. UM SMC-E achieved measurable improvement in the median time of arrival at the facility to device time from 2019 to 2020. UM SMC-E reported that it is currently engaged in a process improvement project to further improve on this metric.

Staff Analysis and Conclusion

MHCC staff reviewed UM SMC-E's description of quality assurance practices and concludes that UM SMC-E 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

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

Table 6: University of Maryland Shore Medical Center at Easton'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% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2020q4-2021q1	9.07	[2.52, 21.78]	7.55	Yes	0.94	[0.11, 3.33]	1.21	Yes
2020q3-2020q4	6.34	[1.76, 15.34]	6.89	Yes	0.62	[0.02, 3.41]	1.13	Yes
2019q4-2020q3	8.14	[2.70, 17.97]	6.37	Yes	0.54	[0.01, 2.98]	0.95	Yes
2019q3-2020q2	6.98	[2.62, 14.33]	6.06	Yes	NR	[0.00, 3.22]	0.95	Yes
2019q2-2020q1	6.90	[2.59, 14.27]	5.99	Yes	NR	[0.00, 3.55]	0.95	Yes
2019q1-2019q4	7.44	[2.46, 16.51]	6.01	Yes	NR	[0.00, 3.35]	0.95	Yes
2018q4-2019q3	7.06	[2.65, 14.59]	6.32	Yes	NR	[0.00, 5.85]	0.99	Yes
2018q3-2019q2	10.79	[3.56, 23.98]	6.38	Yes	NR	[0.00, 6.90]	1.00	Yes
2018q2-2019q1	10.8	[4.04, 22.38]	6.13	Yes	0.57	[0.01, 3.13]	0.99	Yes
2018q1-2018q4	11.37	[4.68, 22.18]	6.00	Yes	1.24	[0.15, 4.38]	1.00	Yes
2017q4-2018q3	12.09	[4.02, 26.52]	6.54	Yes	1.21	[0.15, 4.27]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	6.49	[3.75, 13.35]	6.91	Yes	0.98	[0.52, 2.42]	1.03	Yes
2017q1-2017q4	6.35	[3.62, 12.80]	6.86	Yes	0.96	[0.48, 2.32]	0.99	Yes
2016q4-2017q3	6.29	[3.60, 12.73]	6.75	Yes	0.94	[0.50, 2.23]	0.98	Yes
2016q3-2017q2	NR	[3.71, 12.25]	6.64	Yes	NR	[0.50, 2.13]	0.95	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports form the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and March 2021.

Notes: NR means a value was not reported. When a hospital has zero deaths, then no value is reported for a hospital's adjusted mortality rate. A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark for ST Elevated Myocardial Infarction (STEMI) or non-STEMI cases, as applicable.

A hospital does not meet MHCC's standard when it performs statistically significantly worse than the national benchmark for STEMI or non-STEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEMI and non-STEMI cases for each reporting period.

Staff Analysis and Conclusion

This standard is not applicable for most of the review periods included in UM SMC-E's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar, earlier standard referenced a statewide average as the benchmark. However, MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. MHCC staff has provided information in Table 6 that shows UM SMC-E's performance relative to the current standard over the period between April 2017 and March 2021.

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 because the national benchmark fell within the 95% confidence interval for UM SMC-E for all 12-month reporting periods between April 2017 and March 2021, when an adjusted mortality rate was reported. MHCC staff concludes that UM SMC-E would have met this standard if it had been applicable for the entire review period. The hospital meets the benchmark for both STEMI and non-STEMI cases for the periods ending December 2019, March 2020, June 2020, September 2020 and March 2021.

MHCC staff concludes that UM SMC-E 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.

UM SMC-E submitted information on the volume of primary and elective PCI cases at UM SMC-E and other hospitals, by physician and quarter, for the period for January 2018 through December 2020 for Drs. Etherton, Sardi, and Pena-Sing. The hospital also provided information for Dr. Etherton's volume of primary and elective PCI cases for 2017 and the total number of elective PCI cases for Dr. Sardi in 2017. Each physician signed and dated an affidavit affirming under penalty of perjury that the information provided is true and correct to the best of the physician's knowledge.

Three additional physicians were granted Locum Tenens privileges at UM SMC-E in order to assist in providing continual coverage for PCI services as needed: Dr. Kelly Miller, MD, Interventional Cardiologist from University of Maryland Baltimore/Washington Medical Center (UM BWMC), Dr. Shumile Zaidi, MD, Interventional Cardiologist from University of Maryland St. Joseph's Medical Center (UM SJMC), and Dr. Greg Treuth, MD, Interventional Cardiologist from Peninsula Regional Medical Center (now known as Tidal Health) Dr. Zaidi only performed primary PCI at UM SMC-E in 2018. Drs. Miller and Trueth performed primary PCI cases in both 2018 and 2019. UM SMC-E reported that these physicians were not needed in 2020.

Staff Analysis and Conclusion

MHCC staff reviewed the reported physician volumes for the interventionalists who performed primary PCI services at UM SMC-E in 2017, 2018, 2019, and 2020 and determined that each interventionalist performed at least 50 PCI procedures annually on average over the 24-month periods of January 2017 through December 2018 and January 2019 through December 2020. In addition, MHCC staff analyzed the ACC-NCDR CathPCI data to confirm that Drs. Miller, Treuth, and Zaidi complied with this standard.

MHCC staff concludes that UM SMC-E complies with this standard.

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

UM SMC-E responded that this regulation is not applicable, as each interventional cardiologist performed more than the required 50 PCI procedures averaged over a 24-month period.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to UM SMC-E because each physician performing primary PCI procedures at UM SMC-E performed 50 PCI procedures annually on average over a 24-month period.

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

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

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

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

UM SMC-E responded that this regulation is not applicable, as each interventional cardiologist performed more than the required 50 PCI procedures averaged over a 24-month period. PCI services began on March 31, 2017, with two full-time interventionalists, Drs.

Etherton and Sardi. Dr. Greg Treuth provided call coverage during 2017. None of the interventional cardiologists took a leave of absence during this period.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to UM SMC-E.

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.

UM SMC-E submitted a signed and dated statement from Dr. Etherton, Medical Director for the CCL, acknowledging that all physicians performing primary PCI services at UM SMC-E are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that UM SRH 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 SMC-E submitted signed and dated attestations from Drs. Etherton, Sardi, and Pena-Sing 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. UM SMC-E attempted to contact Drs. Miller, Zaidi and Treuth to obtain signatures acknowledging their continuing medical education credit status but were unable to obtain the signed documentation.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and verified that Drs. Miller, Treuth, and Zaidi previously all attested to completing the minimum 30 hours of continuing medical education credits in interventional cardiology as part of the applications for a Certificate of Ongoing Performance at the three respective hospitals where each primarily practices.

MHCC staff concludes that UM SMC-E meets this standard.

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

UM SMC-E submitted a signed statement from Dr. Etherton, acknowledging that each physician who performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. UM SMC-E also submitted a copy of its on-call schedule for May 2020.

Staff Analysis and Conclusion

Staff examined the on-call schedule for May 2020 and observed that Drs. Etherton, Sardi, and Pena-Sing were all scheduled to be on-call at different times during the month.

MHCC staff concludes that UM SMC-E 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.

UM SMC-E began providing primary and elective PCI services in March 2017. In the original application, UM SMC-E reported that STEMI patients were only transported by EMS providers to the hospital after February 28, 2018, when UM SMC-E CCL was designated as an approved Cardiac Intervention Center (CIC) by MIEMSS. After February 28, 2018, UM SMC-E's five county EMS paramedic agencies began to transfer pre-hospital STEMI patients to UM SMC-E as the closest approved CIC Center. Prior to that designation, those EMS agencies were required to transport to Anne Arundel Medical Center (AAMC) or TidalHealth Peninsula Regional Medical Center (PRMC). After obtaining CIC designation, UM SMC-E's primary PCI volume increased significantly.

UM SMC-E provided PCI volume information by fiscal year 2017 through 2020, as shown in Table 7. UM SMC-E did not begin PCI services until March 31, 2017. This information shows that UM SMC-E performed between 113 and 338 cases annually.

Table 7: UM SMC-E Total PCI Volume, FY 2017- FY 2020

Fiscal Year	Number of PCI Cases
2017	113
2018	202
2019	246
2020	338

Source: UM SMC-E application, question 28, and updated question 28 provided June 25, 2021.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI volume information submitted by UM SMC-E and analyzed the ACC-NCDR CathPCI data submitted for April 2017 through March 2018. For this first year of operation, UM SMC-E performed approximately 157 cases. However, as a newly established program, the hospital is given until the end of the second year to reach a volume of 200 cases. Staff determined at least 200 PCI procedures were completed per calendar year in 2018, 2019, and 2020.

MHCC staff finds that UM SMC-E 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.

UM SMC-E responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI case volume for CY 2017 through CY 2020, as shown in Table 8. UM SMC-E did not begin performing PCI services until March 31, 2017. This analysis shows primary PCI volume ranged from 66 to 98 cases each calendar year from 2018 and 2020, greater than the threshold referenced in the standard, 49 cases annually.

Table 8: UM SMC-E Primary PCI Volume
CY 2018- CY 2020

Calendar Year	Number of Primary PCI Cases
2018	98
2019	80
2020	66

Source: MHCC staff analysis of ACC-NCDR CathPCI data CY 2018- CY 2020

MHCC staff concludes that UM SMC-E complies with this standard.

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

UM SMC-E provided the number of primary PCI cases by interventionalist for the period of April 2017 through December 2020 by quarter. Between 2018 Q1 and 2020 Q4, at least 11 primary PCI procedures were completed per year, for practicing interventionalists at the time of application, with two exceptions. One physician retired in 2019 and completed only nine cases in 2019, and another physician also performed only nine cases in 2019.

Staff Analysis and Conclusion

MHCC staff notes that 11 primary PCI cases is a target rather than a strict standard. MHCC staff reviewed the information submitted by UM SMC-E for the period from January 2018 through December 2020. MHCC staff also analyzed the ACC-NCDR Cath PCI registry data. This analysis is consistent with the information provided by UM SMC-E that two physicians performed less than 11 primary PCI procedures for only one year of the review period.

MHCC staff concludes that UM SMC-E meets 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 SMC-E stated that all cases in CathPCI Registry PCI Appropriate Use Criteria (AUC) Metric reports from July 2017 through June 2020 were reviewed, and these cases meet Appropriate Use Criteria based on the ACCF/AHA/SCAI Guidelines. UM SMC-E also noted that external review did not identify any inappropriate PCI cases, and all cases were subsequently reviewed by the UM SMC-E Medical Quality Review Team, which concurred with the results of all MACPAQ reviews.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports for elective PCI cases performed through June 2020 and determined that no cases between April 2017 and June 2020 were deemed to be "rarely appropriate" with respect to one or more of the following: clinical criteria; angiographic criteria; and ACC/AHA appropriateness criteria.

MHCC staff concludes that UM SMC-E 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 Expert Guidelines.

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

(c)Patients for whom the primary PCI system was not initially available 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.

UM SMC-E stated that all cases in ACC-NCDR CathPCI Registry PCI Appropriate Use Criteria Metric reports from April 2017 through June 2020 were reviewed, and these cases meet Appropriate Use Criteria based on the ACCF/AHA/SCAI Guidelines. UM SMC-E also stated that external review did not identify any inappropriate PCI cases. When asked about the number of PCI patients who received thrombolytic therapy that subsequently failed during the review period, UM SMC-E reported that there were no documented patients who received thrombolytic therapy that subsequently failed.

Staff Analysis and Conclusion

MHCC staff concludes that UM SMC-E complies with the standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff recommends that the Commission find that UM SMC-E meets all of the 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 UM SMC-E to continue providing primary and elective percutaneous coronary intervention services for four years.