IN THE MATTER OF	*	**BEFORE THE**
UPMC WESTERN MARYLAND	*	**MARYLAND HEALTH**
Docket No.: 19-01-CP024	*	**CARE COMMISSION**

*** ***

STAFF REPORT AND RECOMMENDATION

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

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

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

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

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

elective (non-primary) PCI services, for a given number of years specified by the Commission that cannot exceed five years. At the end of the period, the hospital must renew its authorization to provide PCI services by demonstrating that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance.

B. Applicant

UPMC Western Maryland

The University of Pennsylvania Medical Center (UPMC) Western Maryland,[1] previously known as Western Maryland Health System, is a 191-bed general hospital located in Cumberland (Allegany County). UPMC Western Maryland has a cardiac surgery program onsite.

Health Planning Region

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

C. Staff Recommendation

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

II. PRODEDURAL HISTORY

UPMC Western Maryland filed a Certificate of Ongoing Performance application on June 20, 2019. MHCC staff reviewed the application and requested additional information on May 22, 2020, October 14, 2020, December 10, 2020, January 7, 2021, April 16, 2021, and April 26, 2021. MHCC received additional information on June 22, 2020, November 2, 2020, January 8, 2021, April 6, 2021, April 29, 2021, and May 27, 2021.

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

[1] The legal name of Western Maryland Health System changed on February 3, 2020 to UPMC Western Maryland, the effective date of the written integration and affiliation agreement signed with UPMC.

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

UPMC Western Maryland responded that it participates in the ACC-NCDR CathPCI and Chest Pain registries. UPMC Western Maryland stated that the hospital meets the MHCC mandated requirement for data collection and submits the requested summary reports each quarter. Additionally, UPMC Western Maryland submitted a statement from Michele R. Martz, President, UPMC Western Maryland, affirming that the hospital is committed to quality care by supporting the collection and submission of data. Ms. Martz also noted that UPMC Western Maryland participates in the Door to Balloon Quality Alliance and the American Heart Association Mission Lifeline.

Staff Analysis and Conclusion

UPMC Western Maryland 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 the submission of 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 then-Western Maryland Health System's data reported during the audit period.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland has three cardiac catheterization laboratories (CCLs). UPMC Western Maryland stated that there has never been an interruption in its ability to provide 24/7 coverage for primary PCI services. UPMC Western Maryland also submitted maintenance logs from 2015 through early 2020 for the three CCLs.

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 CCL, as shown in Table 1.

Table 1: Number of Separate Instances of Downtime Reported by UPMC Western Maryland by CCL, CY 2015 – CY2019

Calendar Year	CCL 1	CCL 2	CCL 3	Simultaneous Downtime*
2015	4	3	10	No
2016	2	2	7	No
2017	2	5	6	No
2018	3	5	2	No
2019	8	8	4	No

Source: UPMC Western Maryland application Q2, updated Q2, June 2020
*Simultaneous downtime refers to downtime reported that overlaps for all three rooms on the same date.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland provided a signed statement from Ms. Martz affirming that UPMC Western Maryland is committed 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 cases. Ms. Martz also stated that UPMC Western Maryland shall track door-to-balloon (DTB) times for transfer cases and evaluate areas for improvement. Additionally, UPMC Western Maryland provided the DTB time for each applicable PCI case from January 2015 through December 2019.

UPMC Western Maryland noted that the hospital receives transfers from Potomac Valley Hospital in West Virginia. This hospital has an established STEMI protocol for patients, and UPMC Western Maryland is geographically the closest hospital providing primary PCI services. The current protocol for Potomac Valley Hospital requires that all STEMI patients receive thrombolytic therapy prior to transfer. UPMC Western Maryland's Director of Cardiology collaborates with the Potomac Valley Hospital Emergency Department Director to coordinate the protocol for STEMI patients. UPMC Western Maryland provided information about DTB times for all transfer cases for 2011 through May 2019.

UPMC Western Maryland also explained some of the steps that it has taken to improve transport times. A STEMI protocol, as detailed above, has been in place since 2011. The emergency medical service (EMS) and the Maryland State Police, which operates a medevac helicopter, coordinate for the air lifting of STEMI patients from the area of southern Garrett County, which has resulted in excellent DTB times. To assure follow-up on transferred STEMI patients, the Cardiac Data Analyst or another designee calls the referring facility's Emergency Department director to discuss each patient being transferred. In addition, the referring facility is asked to evaluate the process and make suggestions for improvements.

Staff Analysis and Conclusion

MHCC staff determined that UPMC Western Maryland tracks transfer times and evaluates areas for improvement on an ongoing basis. MHCC staff compiled DTB data submitted by UPMC Western Maryland by quarter in Table 2.

Table 2: UPMC Western Maryland Reported Compliance with DTB Benchmark by Quarter January 2015- December 2019

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	19	17	89.5%
CY2015 Q2	7	7	100.0%
CY2015 Q3	8	8	100.0%
CY2015 Q4	9	9	100.0%
CY2016 Q1	14	14	100.0%
CY2016 Q2	16	15	93.8%
CY2016 Q3	7	7	100.0%
CY2016 Q4	14	14	100.0%
CY2017 Q1	17	17	100.0%
CY2017 Q2	10	10	100.0%
CY2017 Q3	13	13	100.0%
CY2017 Q4	15	14	93.3%
CY2018 Q1	13	13	100.0%
CY2018 Q2	23	23	100.0%
CY2018 Q3	11	10	90.9%
CY2018 Q4	14	13	92.9%
CY2019 Q1	11	11	100.0%
CY2019 Q2	11	11	100.0%
CY2019 Q3	17	17	100.0%
CY2019 Q4	15	15	100.0%

Source: UPMC Western Maryland Application, Q4 (updated November 2020).

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer ST-elevation myocardial infarction (STEMI) cases, as shown in Table 3, on the following page. MHCC staff concluded that UPMC Western Maryland met the DTB benchmark 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, UPMC Western Maryland complied with this standard, with between 91.5% and 96.4% of PCI cases meeting the DTB time standard over rolling eight-quarter periods, as shown in Table 3.

MHCC staff concludes that UPMC Western Maryland complies with this standard.

Table 3: UPMC Western Maryland 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
2015q1	20	18	90.0%			
2015q2	7	7	100.0%			
2015q3	9	9	100.0%			
2015q4	7	6	85.7%			
2016q1	16	16	100.0%			
2016q2	16	15	93.8%			
2016q3	7	6	85.7%			
2016q4	14	14	100.0%	96	91	94.8%
2017q1	19	17	89.5%	95	90	94.7%
2017q2	10	9	90.0%	98	92	93.9%
2017q3	15	13	86.7%	104	96	92.3%
2017q4	12	13	108.3%	109	103	94.5%
2018q1	13	10	76.9%	106	97	91.5%
2018q2	24	24	100.0%	114	106	93.0%
2018q3	12	11	91.7%	119	111	93.3%
2018q4	12	11	91.7%	117	108	92.3%
2019q1	12	12	100.0%	110	103	93.6%
2019q2	10	10	100.0%	110	104	94.5%
2019q3	17	17	100.0%	112	108	96.4%
2019q4	12	12	100.0%	112	107	95.5%

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

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

As shown in Table 4A, below, UPMC Western Maryland reported the number of physicians, nurses, and technicians who were available to provide cardiac catheterization services to acute myocardial infarction patients.

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

Staff Category	Number/FTEs**	Cross Training (S/C/M)*
Physician	N = 3	
Nurse	6.1	1.8 FTE = S, C, M 4.3 FTE = C, M
Technician	7.3	S, M

Source: UPMC Western Maryland Application, Q6a, updated Q6a, November 2020.
*Scrub (S), circulate (C), monitor (M).
**UPMC Western Maryland also reported 0.9 flex nurse FTEs, one relief nurse, and 1.7 flex technician FTEs.

Staff Analysis and Conclusion

MHCC staff compared the staff levels noted by UPMC Western Maryland to information reported by three other existing PCI program applications for Certificates of Ongoing Performance. MHCC staff observed that UPMC Western Maryland has a greater number of full-time equivalent (FTE) nurses than Adventist HealthCare (AHC) Shady Grove but fewer FTE nurses than University of Maryland (UM) Prince George's Hospital Center and University of Maryland Medical Center. UPMC Western Maryland reported more technician FTEs than University of Maryland Prince George's Hospital Center, and AHC Shady Grove, both of which performed a lower volume of PCI cases than UPMC Western Maryland but fewer technical FTEs than University of Maryland Medical Center, which performed a higher volume of PCI cases than UPMC Western Maryland, as shown in Table 4B.

Table 4B: CCL Staffing for UPMC Western Maryland and Other Select PCI Programs

Program	2018 Total PCI Volume*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
UPMC Western Maryland	348	N = 3	6.1	7.3
University of Maryland Medical Center	515	N = 8	11.0	7.5
UM Prince George's Hospital Center	247	N = 5	10.0	6.0
AHC Shady Grove	269	N = 5	6.0	5.0

Sources: UPMC Western Maryland 2019 PCI Certificate of Ongoing Performance application, University of Maryland Medical Center 2019 PCI Certificate of Ongoing Performance application, UM Prince George's Hospital Center 2019 PCI Certificate of Ongoing Performance application, AHC Shady Grove 2019 PCI Certificate of Ongoing Performance application.
*Volumes for either fiscal or calendar year.

MHCC staff observed that the number of interventionalists decreased during the review period. UPMC Western Maryland responded that this number had decreased from five interventionalists at the beginning of the review period to one as of November 2020. UPMC Western Maryland explained that the case volume could not support five interventionalists, and when two interventionalists retired in 2016, replacements were not sought. One interventionalist is no longer able to perform PCI at the facility due to a lapse in board certification in interventional cardiology. Another interventionalist had an unexpected family matter that required a move out of state; therefore, UPMC Western Maryland procured locums coverage, and a rotation of locum interventionalists are alternating weeks until a new full-time interventionalist starts in late summer 2021, upon completion of his fellowship. Despite these challenges, UPMC Western Maryland stated that an interventional cardiologist has remained on-call at all times.

MHCC staff concludes that there is adequate nursing and technical staff to provide services. UPMC Western Maryland 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.

UPMC Western Maryland provided a signed letter of commitment from Ms. Martz acknowledging that UPMC Western Maryland is committed to providing primary PCI services as soon as possible to those who need it.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of commitment provided and concludes that UPMC Western Maryland 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.

UPMC Western Maryland provided a description of the staff involved with these functions. UPMC Western Maryland reported that the hospital retains one Cardiac Data Analyst who oversees the registries and assesses compliance. This data analyst, a registered nurse, also serves as a liaison with emergency department management, EMS, and physicians for issues related to the interventional care of patients. The Cardiac Data Analyst attends the National ACC-NCDR conference and participates in the development of initiatives and guidelines to ensure that program standards are met and forward looking.

Staff Analysis and Conclusion

MHCC staff concludes that UPMC Western Maryland meets 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.

Christopher Bryce Haas, D.O., was named the Medical Director of Cardiology at UPMC Western Maryland in August 2012. UPMC Western Maryland states that Dr. Haas is responsible for defining and implementing credentialing criteria for the CCL and for overall primary PCI program management, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges. Dr. Haas works directly with Timothy Abrell, R.N., B.S.N., Director of Perioperative Services/Interventional Imaging, and they are jointly responsible for equipment and personnel. UPMC Western Maryland also submitted a copy of a curriculum vitae for Dr. Hass and Mr. Abrell.

Staff Analysis and Conclusion

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland provided a list of its CCL education and activities for calendar year 2014 through 2019. These activities included annual competencies and continuing education offered on-site. UPMC Western Maryland also provided a list of the Cardiovascular Unit annual competencies and continuing education offered on-site for calendar year 2015 through 2019 and a list of all continuing education opportunities system-wide from calendar year 2017 through 2020. UPMC Western Maryland stated that continuing education opportunities are available for staff through the HealthStream portal, and the hospital reimburses up to eight hours of continuing education annually per employee. Staff also has access to educational opportunities through virtual and web-based media.

UPMC Western Maryland stated that the hospital follows the Maryland Board of Physicians' requirements that physicians need 50 Continuing Medical Education credits (CMEs) every two years; physicians attest to this requirement every two years on a license renewal application. UPMC Western Maryland keeps records of any physician who attends a UPMC Western Maryland sponsored CME program and ensures that board-certified physicians are achieving the Maintenance of Certification credits for board certification. Additionally, other certifications, such as cardiopulmonary resuscitation and advanced cardiovascular life support, are required for certain types of providers.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. There were several years where documentation of continuing educational activities for CCL staff was limited. However, in these years, there were continuing education activities for Cardiovascular Unit staff and other activities held for staff at the hospital more broadly.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland has a cardiac surgery program on-site.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to UPMC Western Maryland.

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.

UPMC Western Maryland has a cardiac surgery program on-site. However, UPMC Western Maryland also submitted a copy of a service agreement between UPMC Western Maryland and Butler Medical Transport, LLC.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to UPMC Western Maryland.

Quality

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

UPMC Western Maryland provided a list of all meetings that included case presentations from January 2015 through January 2021. UPMC Western Maryland explained that the quarterly peer review committee reviews any external review reports and adverse outcomes case reviews. UPMC Western Maryland provided meeting agendas and attendance records for peer review meetings held between January 2015 and December 2019. The program reported that it has only a few interventionalists on staff, and the external review of cases has been overwhelmingly positive. In addition to the peer review committee, UPMC Western Maryland explained that its Cardiac Cath/PCI and Echo Quality Assurance (QA) Committees review statistical reports. Historically, these committees have rarely reviewed cases.

Staff Analysis and Conclusion

The documentation submitted by UPMC Western Maryland included attendance lists and dates for four peer review committee meetings in 2015, three meetings in 2016, two meetings in 2017, three meetings in 2018, and two meetings in 2019. Attendance records indicate that physicians, nurses, and technicians who are involved with the care of PCI patients attend these meetings.

UPMC Western Maryland also provided a log of all meetings where interventional case review occurred between January 2015 and January 2021. This log of meeting dates shows that a total of three meetings with case review were held in 2015, three in 2016, one in 2017, two in 2019, four in 2020, and one in 2021. UPMC Western Maryland reported that interventional case reviews primarily took place at peer review meetings. The hospital also reported that interventional

case review occurred at one Cath/PCI meeting in 2017, one Cath/PCI meeting in 2020, and two Cath/PCI & Echo QA meetings in 2020.

While the Cardiac Cath/PCI and Echo QA Committees may review cases infrequently, the hospital is willing to commit to performing interventional case review at meetings at least every other month in the future, documenting that case review occurred, and tracking the attendees at each meeting. UPMC Western Maryland states that this practice was implemented starting in October 2020.

Staff recommends that the Commission find that UM PGHC complies with this standard and recommends a condition be added to the Certificate of Ongoing Performance requiring semiannual submission to MHCC staff of documentation of attendance, including attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients, and that meetings are held at least every other month.

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.

UPMC Western Maryland provided meeting agendas, attendance records, and minutes for monthly DTB committee meetings from January 2015 through December 2019. UPMC Western Maryland also stated that, in addition to DTB committee meetings, summary information is emailed to each DTB committee member shortly after every STEMI case. The hospital reports that this process has led to corrective actions being implemented more quickly.

Staff Analysis and Conclusion

The documentation submitted by UPMC Western Maryland included attendance records and meeting minutes for: eight DTB committee meetings in 2015; seven meetings in 2016; nine meetings in 2017; seven meetings in 2018; and six meetings in 2019. UPMC Western Maryland provided reasons for meeting cancellations including staff vacation or illness, a conflicting meeting, conflicting clinical duties (i.e., STEMI patient care, backlog in cardiac clinic), and staff out of town on hospital business. MHCC staff inquired whether any process changes had been implemented to ensure that multiple care area group meetings will be held monthly. The applicant responded that meetings will be scheduled monthly, and if a meeting must be postponed, it will be rescheduled within the same month. Since that response, the program implemented this change and reports that meetings have been held monthly from October 2020 through April 2021.

MHCC staff recommends that the Commission find that UPMC Western Maryland meets this standard and that a condition be added to the Certificate of Ongoing Performance that requires the hospital to make semiannual submissions to MHCC staff documenting meeting dates and attendance for each meeting.

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.

UPMC Western Maryland submitted copies of the external review reports for PCI cases performed between January 2015 and December 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 are shown in Table 5. Although only 5% of cases are required to be reviewed externally, UPMC Western Maryland obtained external review of between 8.0% and 10.7% of cases each year, as shown in Table 5.

Table 5: UPMC Western Maryland External Review, January 2015- June 2019

Time Period	Reported PCI Case Volume^	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2015	277	23	8.3%	Semi-annually	Yes
CY 2016	233	25	10.7%	Semi-annually	Yes
CY 2017	277	25	9.0%	Semi-annually	Yes
CY 2018	287	23	8.0%	Semi-annually	Yes
CY 2019	265	22	8.3%	Semi-annually	Yes

Source: MHCC staff analysis of Cardiac Community Core Lab (CCCL) reports, q28, updated q28, response to COMAR 10.24.17.07D(8)(a), June 2020 & November 2020.
^PCI case volume reported, less primary PCI case volume reported
* Beginning in the second half of 2015, each semiannual review included at least three cases per physician or all cases if the interventionalist performed fewer than three cases during the review period. One interventionalist had cases from 2017 to 2019 reviewed later because they were not initially included in the regular semiannual review.

Beginning in the second half of 2015, a minimum number of three cases per interventionalist must be reviewed for each semiannual review or all cases if fewer than three cases were performed, as specified in COMAR 10.24.17. For the period between January 2015 and December 2019, MHCC staff verified that, if fewer than three cases had been performed by an interventionalist, then all cases were externally reviewed for non-locum interventionalists, as required, with few exceptions. In the January to June 2015 external review report, four clinicians had fewer than three cases reviewed, despite performing greater than three elective PCI cases. UPMC Western Maryland explained that this was because the external review agency had misinterpreted the regulations and that this error was corrected in subsequent reports.

For one locum interventionalist, cases were not reviewed semi-annually. UPMC Western Maryland reported that between January and June 2017, one locum interventionalist had only one case reviewed when the interventionalist had performed two elective PCI cases in that period. Additionally, no cases were initially reviewed from 2018 or 2019 for this provider. MHCC staff requested that UPMC Western Maryland complete the required external review of cases, and the hospital complied with this request and provided the results of these reviews.

UPMC Western Maryland 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 external reviews, UPMC Western Maryland explained that, beginning in 2012, all PCI cases performed at the facility were reviewed by Dr. Haas, except his own cases which were reviewed by Dr. Curran. While Dr. Haas was on medical leave of absence in 2015 and 2018, Dr. Curran reviewed all PCI cases and Dr. Haas reviewed all of Dr. Curran's cases that occurred during his leave of absence upon returning to work. This process took place up until Dr. Curran's departure in the summer of 2020.

UPMC Western Maryland provided a copy of the hospital's policy titled "Treatment and Evaluation of Coronary Lesions." UPMC Western Maryland also reported that any cases that were determined not to meet the appropriateness criteria by the internal reviewer were sent for external review. UPMC Western Maryland provided a list of all cases sent for external review following internal review between January 2015 and December 2020. UPMC Western Maryland stated that, beginning with cases performed in July 2020, it plans to randomly review 10% of each operator's cases internally.

UPMC Western Maryland also stated that cases are reviewed internally at peer review committee meetings and infrequently at Cardiac Cath/PCI and Echo QA Committee meetings. The results of external review reports are discussed at the peer review meeting, and cases with negative comments are presented for internal review that includes an evaluation of angiographic images, test results, and the patient's medical records. For cases with death or complications, UPMC Western Maryland reported that the cases are externally reviewed, but external review for those reasons has been a rare occurrence. Interesting cases may also be presented for educational purposes as part of internal case review.

Staff Analysis and Conclusion

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number of cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of cases to be reviewed to satisfy the requirements for review of individual interventionalists. The bulletin states that a semi-annual review of at least three cases or 10% of cases, whichever is greater, per interventionalist, as part of an external review meets the standard for the review of individual interventionalists, and the requirements in COMAR 10.24.17.07D(5)(c) are equivalent to those in COMAR 10.24.17.07C(4)(d).[2]

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

The requirement for external review changed with the adoption of an updated Cardiac Surgery Chapter in October 2015; for the period January to June 2015, a hospital was not required to include at least three cases per physician in its external review. The external reviews conducted by Cardiac Community Core Lab (CCCL) meet the requirements of 10.24.17.07D(5)(d) because CCCL has been approved by MHCC as a reviewer that meets the requirements for an external review organization. The review of cases by CCCL includes a review of angiographic images, medical test results, and patients' medical records. In addition to the external case review, UPMC Western Maryland reported that it conducted internal review of all PCI cases performed between January 2015 and June 2020. Additional cases were also reviewed during peer review, Cath/PCI, and Echo QA committee meetings.

MHCC staff concludes that UPMC Western Maryland 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).[3]

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.

UPMC Western Maryland submitted a letter from Ms. Martz, 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 interventionalist review consistent with COMAR 10.24.17.07C(4)(c). The letter also states that providers are evaluated every eight months during the ongoing professional practice process, that they undergo an annual evaluation, and are reviewed for reappointment every two years. Consideration for reappointment includes peer evaluation and a review of ongoing professional practice materials.

Staff Analysis and Conclusion

MHCC staff concludes that UPMC Western Maryland 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 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***

[3] Staff recommends that the next revision to COMAR 10.24.17 clarify the requirements for review of individual interventionalist.

confidential.

UPMC Western Maryland submitted meeting minutes from its DTB committee meetings, peer review committee meetings, and cardiac Cath/PCI and Echo QA meetings from January 2015 to April 2019. Additionally, UPMC Western Maryland provided a description of actions taken to improve the hospital's response upon the arrival of a STEMI patient. For example, there is a one-call activation process. UPMC Western Maryland states that it is the first rural community in the state to implement field activation of the CCL team regardless of the EMS provider's ability to transmit the 12-lead electrocardiogram to the emergency department due to "dead zones" in the rural area.

Staff Analysis and Conclusion

MHCC staff reviewed the meeting minutes and description of quality assurance practices provided and concludes that UPMC Western Maryland 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

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

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

Reporting Period	STEMI				Non-STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2019q4-2020q3	6.23	[1.30, 17.38]	6.37	Yes	0.89	[0.02, 4.92]	1.06	Yes
2019q3-2020q2	6.93	[1.45, 19.34]	6.06	Yes	NR	[0.00, 3.54]	1.00	Yes
2019q2-2020q1	6.48	[1.35, 18.14]	5.99	Yes	NR	[0.00, 3.43]	0.95	Yes
2019q1-2019q4	8.86	[2.45, 21.62]	6.01	Yes	NR	[0.00, 3.64]	0.95	Yes
2018q4-2019q3	6.82	[1.42, 19.03]	6.06	Yes	NR	[0.00, 2.90]	0.98	Yes
2018q3-2019q2	2.71	[0.07, 14.34]	6.38	Yes	NR	[0.00, 2.97]	1.00	Yes
2018q2-2019q1	10.90	[3.01, 26.68]	6.13	Yes	0.66	[0.02, 3.66]	0.99	Yes
2018q1-2018q4	5.01	[0.61, 17.48]	6.00	Yes	0.82	[0.10, 2.92]	1.00	Yes
2017q4-2018q3	6.81	[1.88, 16.79]	6.54	Yes	0.90	[0.11, 3.23]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	4.56	[1.26, 11.10]	6.91	Yes	0.44	[0.01, 2.40]	1.03	Yes
2017q1-2017q4	5.65	[2.12, 11.60]	6.86	Yes	0.50	[0.01, 2.79]	0.99	Yes
2016q4-2017q3	5.33	[1.77, 11.74]	6.75	Yes	0.51	[0.01, 2.82]	0.98	Yes
2016q3-2017q2	5.39	[1.49, 13.04]	6.64	Yes	0.52	[0.01, 2.88]	0.95	Yes
2016q2-2017q3	5.27	[1.46, 12.88]	6.77	Yes	1.95	[0.24, 6.97]	0.97	Yes
2016q1-2017q4	3.88	[0.47, 13.50]	6.82	Yes	0.83	[0.02, 4.57]	0.95	Yes
2015q4-2016q3	2.89	[0.07, 15.52]	6.71	Yes	0.74	[0.02, 4.07]	0.95	Yes
2015q3-2016q2	4.48	[0.55, 15.53]	6.66	Yes	0.66	[0.02, 3.64]	0.93	Yes
2015q2-2016q1	3.63	[0.09, 19.34]	6.45	Yes	0.43	[0.01, 2.38]	0.90	Yes
2015q1-2015q4	4.11	[0.50, 14.13]	6.26	Yes	0.83	[0.10, 2.97]	0.90	Yes

*Source: MHCC staff's compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and September 2020.

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

Staff Analysis and Conclusion

This standard is not applicable for most of the review periods included in UPMC Western Maryland'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 UPMC Western Maryland's performance relative to the current standard over the period between January 2015 and September 2020.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different from the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for UPMC Western Maryland for all 12-month reporting periods between January 2015 and September 2020, when an adjusted mortality rate was reported. MHCC staff concludes that UPMC Western Maryland would have met this standard, if it had been applicable for the period of January 2015 through December 2018. The hospital meets the benchmark for both STEMI and non-STEMI cases for the periods ending December 2019, March 2020, June 2020, and September 2020 the reporting periods to which the current standard applies.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland has a cardiac surgery program on-site. UPMC Western Maryland also provided PCI case volume at UPMC Western Maryland, by quarter for Q1 2015 through Q1 2019, for Drs. Curran, Singh, and Haas.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to UPMC Western Maryland, which has on-site cardiac surgery.

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.

UPMC Western Maryland has a cardiac surgery program on-site.

Staff Analysis and Conclusion

MHCC staff concludes that this standard also does not apply to UPMC Western Maryland.

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.

UPMC Western Maryland has a cardiac surgery program on-site.

Staff Analysis and Conclusion

This standard does not apply to UPMC Western Maryland.

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.

UPMC Western Maryland submitted a statement from Dr. Haas, dated January 4, 2021, acknowledging that all interventional cardiologists currently practicing at UPMC Western Maryland, including locum providers, are board certified in interventional cardiology. In June 2019, MHCC staff learned that an interventional cardiologist allowed his board certification to lapse. UPMC Western Maryland proposed a corrective plan stating that the provider would be allowed to sit for the recertification exam in October 2019 and requested that the interventionalist be permitted to continue providing PCI services until that time because of the provider's history of performing high-quality services and the limited number of providers in the service area. In July 2019, MHCC staff accepted UPMC Western Maryland's proposed corrective plan for this provider and agreed that it was acceptable for the interventionalist to continue providing PCI services. The

provider failed the board exam in fall of 2019 and has not performed PCI at UPMC Western Maryland since November 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and recommends that the Commission find that UPMC Western Maryland 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.

UPMC Western Maryland submitted signed and dated attestations from Drs. Singh, Haas, Curran, and Howell 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. The hospital also provided evidence of continuing medical education credits for locum providers who provided PCI services between June 2019 and December 2020. Specifically, UPMC Western Maryland submitted signed and dated attestations for Drs. Azouz and Wilkinson. The hospital also submitted certificates for completion of continuing education activities for Drs. Howell, Jessup, and Shamshad.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that UPMC Western Maryland meets this standard.

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

UPMC Western Maryland submitted a signed and dated statement from Dr. Haas acknowledging that each physician who performed primary PCI services between January 2015 and June 2019 participated in an on-call schedule and that all physicians performing primary PCI services at the time of application, Drs. Haas, Curran, Singh, and Howell, were participating in an on-call schedule. UPMC Western Maryland also submitted a copy of its on-call schedule for June 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for June 2019 and observed that Drs. Haas, Curran, Singh, and Howell were all scheduled to be on-call at different times during the month.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland provided PCI volume information by calendar year for 2015 through 2019, as shown in Table 7. This information shows that UPMC Western Maryland performed between 287 and 349 cases annually.

Table 7: UPMC Western Maryland
Total PCI Volume, CY 2015- CY 2019

Calendar Year	Total PCI Volume
2015	320
2016	287
2017	332
2018	349
2019	319

Source: UPMC Western Maryland application, question 28, and updated question 28

Staff Analysis and Conclusion

MHCC staff reviewed the PCI volume information submitted by UPMC Western Maryland and determined at least 200 PCI procedures were completed in each calendar year, from 2015 through 2019.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland provided the number of primary PCI cases by calendar year between 2015 and 2019, as shown in Table 8.

Table 8: UPMC Western Maryland
Primary PCI Volume, CY 2015- CY 2019

Calendar Year	Primary PCI Volume
2015	43
2016	54
2017	55
2018	61
2019	54

Source: UPMC Western Maryland updated application, response to COMAR 10.24.17.07D(8)(a).

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI volume information submitted by UPMC Western Maryland, which ranged from 43 to 61 cases in each calendar year. UPMC Western Maryland exceeded the threshold of 36 cases annually referenced in the standard.

MHCC staff determined that this standard does not apply to UPMC Western Maryland.

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

UPMC Western Maryland provided the number of primary PCI cases at UPMC Western Maryland by interventionalist for 2015 through 2019, by calendar year. The hospital provided primary case volumes through December 2020 for Drs. Singh, Haas, and Curran. UPMC Western Maryland reported that between 2015 and 2019, the interventionalists had an equal share in the call coverage arrangement but there were variations in the number of STEMIs performed from year to year. Additionally, in January 2020, UPMC Western Maryland reported that all current locum providers reported to Dr. Haas that they had performed at least 11 primary PCI procedures in the last calendar year.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI volume information submitted by UPMC Western Maryland, and observed that between January 2015 and December 2019, there were instances where interventionalists did not perform 11 or more primary PCI cases at UPMC Western Maryland annually. In 2015, three out of four interventionalists did not meet the target. In 2016, one out of three interventionalists did not meet the target. In 2017, two out of four interventionalists did not meet the target. In 2018 and 2019, one out of four interventionalists did not meet the target. Of note, in 2017, 2018, and 2019, one provider who did not perform 11 or more primary PCI cases was a locum tenens provider. Generally, when interventionalists fell short of the 11 cases, they were close to the target volume, ranging between 8 and 10 cases. MHCC staff also analyzed data from the NCDR CathPCI data submitted by UPMC Western Maryland to verify the accuracy of the information provided by UPMC.

This standard references a target volume. STEMI procedures are emergent in nature. While there were some years when individual providers fell short of the target volume for primary PCI cases, Drs. Singh, Haas, and Curran all averaged more than 11 STEMI procedures per year.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland responded that, during the review period, no patients received elective PCI services inappropriately.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports from January 2015 through December 2019 and determined that there were no cases between January 2015 and December 2019 that were determined to be "rarely appropriate" with respect to ACC/AHA appropriateness criteria. Additionally, external review reports raised very few concerns about clinical appropriateness or angiographic appropriateness.

MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland reported that, in 2017, one patient received thrombolytic therapy that subsequently failed and, in 2019, two patients received thrombolytic therapy that subsequently failed. UPMC Western Maryland also responded that between January 2015 and March 2019, there were no primary PCI procedures deemed inappropriate by an internal review.

Staff Analysis and Conclusion

MHCC staff determined thrombolytic therapy subsequently failed in just 2% of primary PCI cases in 2017 and 4% of primary PCI cases in 2019.

MHCC staff determines that UPMC Western Maryland complies with the standard.

RECOMMENDATION

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

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

2. UPMC Western Maryland shall hold monthly multiple care area group meetings and, as required in COMAR 10.24.17.07D(5)(b), and shall submit to Commission staff attendance lists for each of these meetings held between January and June by August 1 of each year and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2022. After this date, the Executive Director may release UPMC Western Maryland from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.