IN THE MATTER OF	*	**BEFORE THE**
UNIVERSITY OF MARYLAND	*	**MARYLAND**
PRINCE GEORGE'S	*	**HEALTH CARE**
HOSPITAL CENTER	*	**COMMISSION**
	*	
Docket No.: 19-16-CP029	*	

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STAFF REPORT AND RECOMMENDATION

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

March 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 (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

University of Maryland Prince George's Hospital Center

The University of Maryland Prince George's Hospital Center (UM PGHC) is a 254-bed general hospital located in Cheverly (Prince George's County). UM PGHC is part of the University of Maryland Medical System and has a cardiac surgery program on site.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. UM PGHC is in the Metropolitan Washington health planning region, consisting of Calvert, Charles, Frederick, Montgomery, Prince George's and Saint Mary's Counties and the District of Columbia. Seven Maryland hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; each of the other programs provide both primary and elective PCI services. Three of the seven Maryland hospitals also provide cardiac surgery services.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

UM PGHC filed a Certificate of Ongoing Performance application on June 21, 2019, in accordance with the review schedule established by the Commission. MHCC staff reviewed the application and requested additional information on October 30, 2020, January 13, 2021, February 23, 2021, March 3, 2021, March 8, 2021, March 9, 2021 and March 10, 2021. Additional information was submitted on November 6, 2020, November 9, 2020, November 20, 2020, December 20, 2020, February 3, 2021, March 3, 2021, March 5, 2021, March 10, 2021, and March 11, 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 PGHC stated that the program participates in both the ACC National Cardiac Data Registry (NCDR) and the American Heart Association's Get with the Guidelines- Coronary Artery Disease (GWTG). The ACC-NCDR registry dashboard is reviewed by the hospital's Cardiac Catheterization Laboratory (CCL) Director and reported on quarterly at the Quality and Performance Improvement Meeting. UM PGHC also stated that outcome reports are also presented to interventional cardiologists, the chief medical officer, executive staff members, emergency department (ED) leadership, general medicine cardiologists, CCL staff, and transferring physicians, as applicable. The hospital uses Axis clinical software as a third-party vendor to manage clinical outcome data for quality improvement.

Staff Analysis and Conclusion

UM PGHC has complied with the submission of ACC-NCDR CathPCI data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of ACC-NCDR CathPCI data to validate that participating Maryland hospitals submitted accurate and complete information. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of UM PGHC's data for the audit period. During the review of UM PGHC's application, MHCC staff notes that one instance of an error in data reporting to the ACC-NCDR registry was reported. UM PGHC stated that one case was not entered into the ACC-NCDR registry in error but noted that this case was from early in the review period and the hospital does not have a reason to believe that a systemic issue contributed to the error.

MHCC staff concludes that UM PGHC 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 PGHC responded that all downtime is tracked and reported and that there has not been a time between January 2015 and the present when all rooms were out of service simultaneously. UM PGHC provided a report of downtime and maintenance from a vendor for the two CCL rooms between January 2015 and December 2018. UM PGHC also provided a manual log of CCL

downtime for June 2018 through December 2019; UM PGHC reported that there is no manual log of downtime available prior to 2018. MHCC staff's summary of this information is shown in Table 1. A third CCL room also opened on February 17, 2020.

Table 1: UM PGHC Downtime- Calendar Years 2015-2019

Room Number	Start Date	Duration of Downtime (hours: minutes)	Reason
Room 1	10/02/2015	1:57	System Booting Issue
Room 1	7/17/2015	104:45	System Booting Issue
Room 1	8/5/2015	1:14	System Booting Issue
Room 1	11/24/2015	26:02	Fluoroscopy Issue
Room 1	12/07/2015	26:00	Main Console System Monitor Issue
Room 1	01/12/2016	139:17	Main Console System Monitor Issue
Room 1	2/26/2016	88:39	Imaging Module Issue
Room 2	4/6/2016	24:53	Fluoroscopy Issue
Room 1	11/18/2016	88:44	C-Arm Issue
Room 1	11/29/2018	1:00	System Booting Issue
Room 2	8/6/2019	1:00	Fractional Flow Reserve Device Issue

Source: MHCC staff analysis of UM PGHC application and updated Q2 responses in February and March 2021.

Staff Analysis and Conclusion

MHCC staff reviewed the downtime documentation and determined that there were no overlapping downtimes for both CCL rooms between January 2015 and December 2019.

MHCC staff concludes that UM PGHC 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.

UM PGHC provided a signed statement from Nathaniel Richardson, Jr., President and CEO of UM PGHC, acknowledging that all physicians contracted for STEMI[1] call are required to follow protocols to maintain a door-to-balloon (DTB) time of 90 minutes or less. The statement also recognized UM PGHC's process to track DTB times for all cases, including transfer cases to assess opportunities for improvement.

As shown in Table 2A on the following page, UM PGHC provided quarterly information on the percentage of non-transfer STEMI patients who received primary PCI within 90 minutes for STEMI patients who were treated at UM PGHC between January 2015 and December 2019. In 2015 Q1, the percentage of cases with a DTB time less than or equal to 90 minutes was 71.4%. UM PGHC stated that a performance improvement plan was reviewed and discussed in the June 4, 2015 Chest Pain Center Multidisciplinary Committee Meeting. The hospital's plan included

[1] An ST-segment elevation myocardial infarction or STEMI is a type of heart attack that, in most cases, is best treated through performance of a primary PCI procedure.

improving processes related to troponin collection and results, obtaining an electrocardiograph (ECG) in 10 minutes, and time to first medical contact. UM PGHC reported that data submission was delayed due to transition from direct entry into the ACC-NCDR CathPCI database to the use of a third-party vendor in CY 2016 and a third-party vendor software upgrade in CY 2018. UM PGHC did not report data for CY 2016 Q2 and CY 2018 Q2, as shown in Table 2A. However, the hospital's performance and PCI volume in both of these quarters are currently viewable in the ACC-NCDR database and are reflected in MHCC staff's data analyses shown in Table 3.

As shown in Table 2B, UM PGHC provided information about DTB times for transfer cases between January 2015 and December 2019. UM PGHC briefly outlined steps that the hospital took to improve transfer times for patients who require primary PCI and were transferred from another hospital without PCI services. UM PGHC responded that the Activation Code STEMI from a referring hospital goes through a system, known as "One Call," that connects the referring facility with the interventional physician on-call. Once the interventionalist on-call has accepted the patient, One Call contacts the hospital page operator to activate the code STEMI team. Transportation by air via MedStar Air or STAT MedEvac are the preferred methods. UM PGHC also provided a copy of the hospital's contract with Procare, the ground ambulance service used as a back-up.

Table 2A: UM PGHC 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
CY 2015 Q1	14	10	**71.4%**
CY 2015 Q2	7	6	85.7%
CY 2015 Q3	11	10	90.9%
CY 2015 Q4	11	10	90.9%
CY 2016 Q1	16	14	87.5%
CY 2016 Q2	Not Reported	Not Reported	Not Reported
CY 2016 Q3	13	10	76.9%
CY 2016 Q4	19	16	84.2%
CY 2017 Q1	16	15	93.8%
CY 2017 Q2	10	9	90.0%
CY 2017 Q3	7	6	85.7%
CY 2017 Q4	11	10	90.9%
CY 2018 Q1	17	14	82.3%
CY 2018 Q2	Not Reported	Not Reported	Not Reported
CY 2018 Q3	21	19	90.5%
CY 2018 Q4	11	9	81.8%
CY 2019 Q1	11	10	90.9%
CY 2019 Q2	12	11	91.7%
CY 2019 Q3	5	4	80.0%
CY 2019 Q4	10	10	100.0%

Source: UM PGHC, Q4, updated Q4, November 2020.

Table 2B: UM PGHC Transfer DTB Times by Quarter January 2015- December 2019

Quarter	Total Transfer Primary PCI Volume	Transfer Cases with DTB ≤ 120 minutes	Percent of Cases With DTB ≤ 120 Minutes
CY 2015 Q1	9	3	33.3%
CY 2015 Q2	3	1	33.3%
CY 2015 Q3	6	1	16.7%
CY 2015 Q4	5	3	60.0%
CY 2016 Q1	4	1	25.0%
CY 2016 Q2	5	3	60.0%
CY 2016 Q3	5	2	40.0%
CY 2016 Q4	4	2	50.0%
CY 2017 Q1	3	0	0.0%
CY 2017 Q2	2	1	50.0%
CY 2017 Q3	2	0	0.0%
CY 2017 Q4	2	1	50.0%
CY 2018 Q1	3	1	33.3%
CY 2018 Q2	2	0	0.0%
CY 2018 Q3	4	2	50.0%
CY 2018 Q4	1	1	100.0%
CY 2019 Q1	3	1	33.3%
CY 2019 Q2	4	2	50.0%
CY 2019 Q3	5	3	60.0%
CY 2019 Q4	7	4	57.1%

Source: UM PGHC, Q4, updated Q4, November 2020.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data and noted that UM PGHC missed the DTB time standard in several quarters, as shown in Table 3. MHCC staff's analysis differs 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. 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.

UM PGHC's Chest Pain Coordinator and Data Analyst reviewed all cases with DTB time greater than 90 minutes in all quarters where MHCC analyses found that fewer than 75% of cases had a DTB of 90 minutes or less (i.e. CY 2015 Q1, CY 2016 Q2, CY 2017 Q3, CY 2017 Q4, CY 2018 Q4, CY 2019 Q1, and CY 2019 Q3). UM PGHC described four cases during these periods where the hospital's calculated DTB was different from MHCC staff's calculated DTB and one case where MHCC staff classified a case as a STEMI and UM PGHC stated that the case was a non-STEMI. UM PGHC provided additional information on the reasons for DTB delays. The most frequently reported reasons for DTB delays were Code in Progress, Emergency Care or Stabilization, Delay in EKG, and Physician Late Arrival.

As shown in Table 3, over rolling eight quarter periods, UM PGHC complied with the DTB standard in all periods, except for two periods in which UM PGHC fell very slightly short of the standard; in the rolling eight quarter periods ending in 2016 Q4 and 2017 Q4, 74.6% of cases met the DTB standard.

MHCC staff recommends that the Commission find that UM PGHC complies with this standard.

Table 3: PGHC 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	14	9	**64.3%**			
2015q2	8	6	75.0%			
2015q3	13	11	84.6%			
2015q4	11	9	81.8%			
2016q1	18	14	77.8%			
2016q2	22	15	**68.2%**			
2016q3	16	12	75.0%			
2016q4	24	18	75.0%	126	94	**74.6%**
2017q1	12	11	91.7%	124	96	77.4%
2017q2	11	9	81.8%	127	99	78.0%
2017q3	11	7	**63.6%**	125	95	76.0%
2017q4	16	11	**68.8%**	130	97	**74.6%**
2018q1	17	14	82.4%	129	97	75.2%
2018q2	14	12	85.7%	121	94	77.7%
2018q3	25	20	80.0%	130	102	78.5%
2018q4	11	7	**63.6%**	117	91	77.8%
2019q1	15	11	**73.3%**	120	91	75.8%
2019q2	12	10	83.3%	121	92	76.0%
2019q3	7	4	**57.1%**	117	89	76.1%
2019q4	13	11	84.6%	114	89	78.1%

Source: MHCC staff analysis of ACC-NCR CathPCI data, CY 2015- CY 2019.

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, UM PGHC provided the number of physicians, nurses, and technicians who were able to provide cardiac catheterization services to acute myocardial infarction patients as of November 2020. UM PGHC also explained that there was a recent

technician resignation and the shifts are currently being covered by a *pro re nata* (PRN) technician or registered nurse until the position can be filled.

Table 4A: UM PGHC Cardiac Catheterization Laboratory Staff

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	5	
Nurse	7.2 (FTE)^	C, M, S
Technician	5.0 (FTE)^	M, S

Source: UM PGHC Application, updated Q6a November 2020, February 2021.
*Scrub (S), circulate (C), monitor (M).
^UM PGHC also reported 1 PRN nurse and 1 PRN technician.

Staff Analysis and Conclusion

MHCC staff compared the reported staffing levels at UM PGHC to the staffing levels for programs at three other hospitals with similar case volumes. A comparison of volume and staffing levels for UM PGHC, Carroll Hospital Center, Johns Hopkins Bayview Medical Center, and Adventist HealthCare Shady Grove Medical Center is shown in Table 4B. Adventist HealthCare Shady Grove has a comparable level of PCI volume. UM PGHC reported 7.2 nurse FTEs and 5.0 technician FTEs compared to 6.0 nurse FTEs and 5.0 technician FTEs for Adventist HealthCare Shady Grove. The PCI volume for Johns Hopkins Bayview and Carroll are lower than the PCI volume for UM PGHC. However, the nurse volume is slightly higher at Carroll than UM PGHC, 11.0 and 7.2 FTEs, respectively. The nurse volume is slightly lower at Johns Hopkin Bayview at 6.0 FTEs but the technician volume is slightly higher at 5.8 FTEs.

Table 4B: UM PGHC and Other PCI Programs Cardiac Catheterization Laboratory Staff

Program & Year Reported	Total PCI Volume in Year Prior*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
UM PGHC 2019	247	N = 5	7.2	5.0
Carroll Hospital Center 2019	185	N = 6	11.0	5.0
Johns Hopkins Bayview Medical Center 2019	200	N = 10	6.0	5.8
Adventist HealthCare Shady Grove 2019	269	N = 5	6.0	5.0

Sources: CHC 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, Adventist Health Care Shady Grove 2019 PCI Certificate of Ongoing Performance Application.
*Note: The volume for each hospital is for either CY or FY 2018.

MHCC staff concludes that there is adequate nursing and technical staff to provide services and that UM PGHC 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 PGHC provided a signed letter of commitment from Mr. Richardson acknowledging that UM PGHC remains committed to providing primary PCI services in accord with the requirements established by the Maryland Health Care Commission.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of commitment provided and concludes that UM PGHC 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 PGHC reported that the hospital retains a CCL Database Coordinator (1.0 FTE) who reports to the Director of Cardiovascular Services and directs and coordinates all aspects of the NCDR functions including data collection, data submission, daily quality report issues outcomes report review and analysis, and contract management. The CCL Database Coordinator supervises and coordinates quality improvement efforts related to NCDR data collection and reporting and serves as the primary contact for these data. UM PGHC also retains a Chest Pain Coordinator (1.0 FTE) who manages and coordinates chest pain patient care during and post hospitalization. The Chest Pain Coordinator, among other responsibilities, conducts Committee Meetings to review quality measures and implement improvement plans for the organization, collects and analyzes on-going data regarding outcomes of the Chest Pain Program, and submits required data to the appropriate regulatory agencies, as requested.

Staff Analysis and Conclusion

MHCC staff concludes that UM PGHC complies with this standard.

10.24.17.07D(4)(f) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the 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.

Dr. Vivek Bahl was appointed as the Medical Director of the CCL at UM PGHC on August 1, 2019. Between January 2015 and August 2019, Dr. Rajendra Shetty served as the Director of the CCL. UM PGHC stated that Dr. Bahl is responsible for implementing credentialing criteria for the CCL and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges. UM PGHC also submitted a copy of the Medical Director's formal job description.

Staff Analysis and Conclusion

UM PGHC 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.

UM PGHC stated that CCL staff participate in a weekly educational session that lasts approximately 45 minutes to an hour. Additionally, staff must have at least two in-service trainings annually on all major equipment in the CCL. UM PGHC stated that staff are not required to complete a minimum number of continuing education units. However, annual internal mandatory education is tracked at the unit level and through Medelearn, an online education system.

UM PGHC submitted a list of the mandatory competencies and skills required for 2019. UM PGHC also provided a list of the weekly educational activities between June 2019 and January 2020. Unfortunately, the hospital was unable to obtain a list of the weekly educational sessions conducted for the rest of the review period due to leadership changes in the department. UM PGHC also stated that external education was suspended early in 2020 due to the COVID-19 pandemic. However, the education during the pandemic is focused on PPE, donning, and doffing. The Director of Education provided education on the Lucas 2 mechanical check compression device in September 2020 and the ICU educator conducted an educational fair on wound care and skin care products to reduce pressure ulcers in October 2020. UM PGHC detailed in the February 3, 2021 response that that month's continuing education would focus on groin management, pre-and post-procedure care, cardiac anatomy and physiology, STEMI management, and acute coronary syndrome.

UM PGHC is committed to providing regular continuing education to CCL and cardiac critical care unit staff. Additionally, the applicant explained that logging of continuing education activities is currently being transitioned to an online platform so that activities can be monitored over time and readily accessible in case of staff turnover.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff identified by UM PGHC and the mandatory competencies and skills checklist include appropriate topics. MHCC staff recommends that the Commission find that UM PGHC meets this requirement and recommends that a condition be added to the Certificate of Ongoing Performance requiring semiannual submission of the continuing medical education activities of staff for the CCL and CCU.

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.

UM PGHC provides cardiac surgery on site so this standard is not applicable to UM PGHC. UM PGHC stated that if transfer to another hospital is needed, the patients will go to the University of Maryland Medical Center.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to UM PGHC.

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.

Because UM PGHC provides cardiac surgery on site, this standard is not applicable. However, UM PGHC submitted an agreement with Procare, that provides STEMI/ACLS[2] response.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to UM PGHC.

<u>Quality</u>

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

UM PGHC provided the dates of interventional care review meetings between January 2015 and December 2019. UM PGHC explained that, historically, technicians have not attended case review meetings. UM PGHC explained that the gaps in interventional case review meetings are due to staff availability. Meetings were not held because some required attendees would have been unable to attend due to emergencies or scheduled time off.

As of November 2020, the hospital states that meetings will be held as required, at least every other month, and meetings will include all members of the CCL team (e.g. interventionalists, other physicians, nurses, and technicians caring for the primary PCI patient). UM PGHC states that the Quality Director or Quality Coordinator will attend the physician peer review meetings and multidisciplinary care review meetings and report any issues with adherence to State regulations to the Chief Quality Officer. UM PGHC affirmed that compliance with State regulations will be closely monitored and reported during the Quality Executive Oversight meetings.

Staff Analysis and Conclusion

MHCC staff noted that six case review meetings were held in 2015, eight meetings were held in 2016, eight meetings were held in 2017, seven meetings were held in 2018, and six meetings were held in 2019. No meetings were held between January and April 2015, November 2015 through February 2016, March to June 2017, or June through August 2019. However, at least six meetings were held annually in 2015 through 2019. In addition, while quality improvement

[2] Advanced Cardiac Life Support.

and data coordinators attend case review meetings, other nurses and technicians did not regularly attend prior to November 2020. MHCC staff reviewed attendance records for the November 2020 and January 2021 meetings and notes that at least one nurse and one technician were present at each meeting.

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.

UM PGHC submitted meeting dates for STEMI meetings, CCL Quality meetings, and Chest Pain Program meetings from January 2015 through February 2021. UM PGHC also submitted attendance records for meetings, when available.

While meetings were not held every month during most of the review period, UM PGHC stated that the program has a new Nursing Director and Medical Director who are committed to adherence to the meeting frequency requirements mandated by the regulations.

Staff Analysis and Conclusion

UM PGHC stated that six meetings were held in 2015, nine meetings were held in 2016, eight meetings were held in 2017, eight meetings were held in 2018, three meetings were held in 2019, and four meetings were held in 2020. While UM PGHC provided meeting dates between January 2015 and February 2021, attendance records could not be provided for one of the meetings in 2015, one meeting in 2016, three meetings in 2017, and five meetings in 2018. UM PGMH noted that meetings were suspended between March 2020 and August 2020 due to COVID-19.

MHCC staff notes that meetings were held monthly between September 2020 and February 2021. Additionally, attendance records, when available, show attendance from CCL, intensive care unit, ED, and CCU staff, among others. MHCC staff recommends that UM PGHC ensure that attendance is tracked separately for each meeting and that meetings are held monthly.

MHCC staff recommends that the Commission find that UM PGHC meets this standard and recommends a condition requiring semiannual submission to MHCC staff of documentation of attendance for each meeting and documentation that meetings are held every month.

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 PGHC submitted copies of its external review reports for the period from January 2015 through December 2019. UM PGHC uses an MHCC approved review organization, the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), to review medical records and CCL images for elective PCI cases on a semiannual basis.

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, beginning in the second half of 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. As shown in Table 5, between 10.8% and 19.1% of cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed.

Table 5: Description of UM PGHC External Review Of Elective PCI Cases by Year

Time Period	Elective PCI Cases Forwarded to MACPAQ	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard*
CY 2015	260	36	13.8%	Annual	No
CY 2016	201	36	17.9%	Semiannual	Yes
CY 2017	263	34	12.93%	Semiannual	Yes
CY 2018	277	30	10.8%	Semiannual	Yes
CY 2019	157	30	19.1%	Semiannual	Yes

Source: MACPAQ Reports, MHCC Analysis and UM PGHC updated Q15, February and March 2021.
* Each semi-annual review contained three cases per physician or all cases if the interventionalist performed fewer than three cases during the review period.

For the period of January 2015 to December 2019, MHCC staff analyzed the NCDR CathPCI data and verified that at least five percent of elective PCI cases were reviewed. MHCC staff verified that if fewer than three cases were performed by an interventionalist, then all cases were reviewed by MACPAQ, as required, with few exceptions.

In 2015, two operators only had five cases reviewed via external review when six should have been reviewed. UM PGHC detailed that additional cases had been requested by MACPAQ but incomplete records were submitted by the hospital. After an extended period and several requests, MACPAQ completed the 2015 report with existing cases. Additionally, in 2015, one interventionalist did not have an elective case reviewed due to a misunderstanding by the external review agency and lack of clarity on whether the single procedure was a primary or elective case. A similar issue occurred for one case during the July to December 2016 review period.

MHCC staff recommends that the Commission find that UM PGHC complies with this standard because the deviations from the standard for external review were minor and occurred years ago.

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 peer review process, UM PGHC conducts internal case review. Cases are randomly selected to generate a list for annual review of at least ten cases or 10% of randomly selected PCI cases, whichever is greater, performed by each interventionalist at the hospital. If the interventionalist performs fewer than ten cases at the hospital, UM PGHC stated that all cases are reviewed. The final list of cases is blinded and assigned to physician peers for review. The peer review includes review of angiographic images, medical test results, and patient medical records. The internal peer review is documented on a Cardiac Catheterization Peer Review Form and submitted to the Cardiac Peer Review Chair for review. Cases are escalated to the Cardiac Catheterization Committee, as necessary. Additional patient cases that have adverse outcomes or events are reviewed throughout the year on an ongoing basis.

UM PGHC acknowledged that an exception to its internal case review process occurred for one case in 2016. This was the same case where MACPAQ concluded the case was not an elective PCI case and did not review it. UM PGHC was not able to provide information on why the case was not reviewed internally.

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 case reviews necessary to satisfy the requirements for review of individual interventionalists.

The MHCC 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).[3]

In addition to the external review, UM PGHC performs peer review of PCI cases that includes a review of angiographic images, medical test results, and patient medical records. The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records.

MHCC staff concluded that the minimum number of cases were included in the external review through analysis of the ACC-NCDR CathPCI data submitted for the period January 2015 through December 2019, with a few exceptions, as previously noted. For interventionalists who did not have a sufficient number of cases reviewed externally, MHCC staff requested information

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

about the internal review of those physicians' cases. The information provided by UM PGHC indicates that the standard for evaluation of individual interventionalists was met through a combination of external and internal review, with the exception of one interventionalist in 2016.

MHCC staff recommends that the Commission find that UM PGHC satisfactorily conducts individual interventionalist review as stated 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).[4]

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 PGHC submitted an affidavit from the Chief Executive Officer, Nathaniel Richardson Jr, 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 affidavit states that the performance of the individual interventionalists is evaluated semi-annually.

Staff Analysis and Conclusion

MHCC staff concludes that UM PGHC 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 confidential.***

UM PGHC submitted select meeting minutes from STEMI Committee meetings between January 2015 and December 2019. UM PGHC also explained its efforts to improve outcomes related to hematomas and retroperitoneal bleeds, including implementation of the NCDR bleeding risk tool kit and early identification and management of hematomas and retroperitoneal bleeds.

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

UM PGHC staff elected to use the NCDR bleeding risk tool kit to assess the patient's potential for bleeding risk. The bleeding risk calculator was installed on every desktop and the bleeding risk score of each patient is calculated so that the result can be provided to the interventionalist. The provider then determines access and anticoagulant based on the risk score.

A retroperitoneal bleed protocol was created within the hospital for early identification and training was provided to staff for the CCL and coronary care unit. UM PGHC submitted its Post PCI Sheath Removal Checklist and explained that the implementation of this protocol is tracked in peer review. As evidence of the success of this protocol, UM PGHC submitted a graph of CCL complications that in fiscal year (FY) 2020 showed a decrease in hematoma complications. UM PGHC also submitted a graph of post procedure blood transfusions for FY 2020, noting that some improvement was reflected but that a deeper understanding of the causes for post-procedure transfusions is still needed.

Staff Analysis and Conclusion

MHCC staff reviewed meeting minutes and descriptions of quality assurance activities and concludes that UM PGHC complies with this standard.

Patient Outcome Measures

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

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

(c) A hospital with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average 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 30-day risk-adjusted mortality rate for primary PCI cases.

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

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

(c) A hospital with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average 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 30-day risk-adjusted mortality rate for primary PCI cases.

UM PGHC submitted adjusted mortality rates by rolling 12-month reporting period for STEMI and non-STEMI cases 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 12-month period of 2017 Q3 through 2018 Q2.

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

Reporting Period	STEMI				NON-STEMI			
	Hospital AMR	95% Confidence Interval	National Benchmark	Meets MHCC Standard	Hospital AMR	95% Confidence Interval	National Benchmark	Meets MHCC Standard
2019q4-2020q3	10.03	[4.14, 19.43]	6.37	Yes	1.07	[0.03, 5.87]	1.06	Yes
2019q3-2020q2	10.00	[4.74, 17.66]	6.06	Yes	1.01	[0.03, 5.58]	1.00	Yes
2019q2-2020q1	10.28	[4.25, 19.91]	5.99	Yes	1.70	[0.56, 3.92]	0.95	Yes
2019q1-2019q4	10.84	[4.82, 20.05]	6.01	Yes	1.79	[0.59, 4.12]	0.95	Yes
2018q4-2019q3	8.11	[3.61, 14.93]	6.06	Yes	1.37	[0.45, 3.15]	0.98	Yes
2018q3-2019q2	7.53	[1.82, 15.60]	6.38	Yes	1.34	[0.44, 3.08]	1.00	Yes
2018q2-2019q1	7.56	[2.49, 16.84]	6.13	Yes	0.46	[0.01, 2.54]	0.99	Yes
2018q1-2018q4	4.16	[0.87, 11.55]	6.00	Yes	1.23	[0.25, 3.53]	1.00	Yes
2017q4-2018q3	10.25	[2.84, 24.90]	6.54	Yes	3.03	[0.83, 7.52]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry							
2017q2-2018q1	13.53	[5.09, 27.72]	6.91	Yes	1.93	[0.53, 4.85]	1.03	Yes
2017q1-2017q4	10.39	[3.44, 22.88]	6.86	Yes	1.42	[0.39, 3.58]	0.99	Yes
2016q4-2017q3	11.90	[3.94, 26.33]	6.75	Yes	1.14	[0.24, 3.27]	0.98	Yes
2016q3-2017q2	12.16	[4.55, 25.17]	6.64	Yes	1.43	[0.39, 3.59]	0.95	Yes
2016q2-2017q3	11.54	[3.83, 25.44]	6.77	Yes	1.50	[0.41, 3.75]	0.97	Yes
2016q1-2017q4	14.21	[4.71, 31.32]	6.82	Yes	2.01	[0.55, 5.02]	0.95	Yes
2015q4-2016q3	7.90	[1.65, 21.85]	6.71	Yes	1.97	[0.41, 5.61]	0.95	Yes
2015q3-2016q2	4.09	[0.50, 14.29]	6.66	Yes	3.56	[1.16, 8.16]	0.93	**No**
2015q2-2016q1	6.82	[0.83, 23.52]	6.45	Yes	3.44	[1.12, 7.91]	0.90	**No**
2015q1-2015q4	12.14	[3.36, 29.60]	6.26	Yes	4.71	[1.29, 11.90]	0.90	**No**

Source: MHCC staff compilation of results from the hospital's quarterly reports form the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between January 2015 and September 2020.

Notes: A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significant better performance than the national benchmark for 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 benchmark is 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 period for UM PGHC's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar standard that was adopted previously referenced a statewide average as the benchmark, and 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 PGHC'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 period for 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 PGHC for all 12-month reporting periods between 2015 Q1 and 2020 Q3. MHCC staff concludes that UM PGHC would have met this standard, if it had been applicable for the entire period reviewed. However, the standard only applies to the periods ending in December 2019, March 2020, June 2020, and September 2020.

For non-STEMI patients, MHCC staff determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark except for three periods, because the national benchmark fell within the 95% confidence interval for UM PGHC for all but three 12-month reporting periods between January 2015 and September 2020. The hospital's adjusted mortality rate was significantly different than the national benchmark for the reporting periods ending in 2015 Q4, 2016 Q1, and 2016 Q2.

UM PGHC reported several factors that contributed to the hospital's risk adjusted mortality rates that were statistically significantly higher than the national benchmark for non-STEMI patients in three reporting periods. In some of these cases, death was not cardiac-related, and was attributed to patients experiencing a post-PCI arrhythmia or cardiogenic shock. UM PGHC listed opportunities for improvement that were identified and discussed such as improved documentation, timely consultation, and improvement in data extraction and reporting. Mortality cases for recent periods were also reviewed. UM PGHC determined that patients often had at least three comorbidities or additional medical problems that contributed to their mortality. The hospital also submitted a description of the Risk Tool that the data coordinator uses to assist with the accuracy of reporting outcomes and capturing variables predictive of mortality.

MHCC staff concludes that UM PGHC meets the standard for the period in which the current standard applies.

<u>Physician Resources</u>

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.

Because UM PGHC provides cardiac surgery, this standard is not applicable.

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.

This standard does not apply to UM PGHC because it provides cardiac surgery.

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 PGHC provides cardiac surgery; this standard is not applicable to UM PGHC.

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 PGHC submitted a signed and dated statement from Dr. Bahl, Medical Director of the CCL, acknowledging that each physician performing primary PCI services at UM PGHC is board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the letter provided and concludes that UM PGHC meets these standards.

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 PGHC submitted signed and dated attestations from Drs. Shetty, Ashai, Sarfarazi, Bahl, and Dakak stating that each physician completed a minimum of 30 hours of continuing medical education credits in interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC reviewed the statements provided and concludes that UM PGHC meets this standard.

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

UM PGHC submitted a signed statement from Dr. Bahl, acknowledging that each physician who has performed primary PCI services during the performance review period has participated in an on-call schedule. UM PGHC also submitted a copy of the on-call schedule for September 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for September 2019 and observed that Drs. Shetty, Sarfarazi, Ashai, Bahl, and Dakak were all scheduled to be on-call at different times during the month. MHCC staff concludes that UM PGHC 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 PGHC provided the number of total PCI cases for fiscal years 2015 through 2019, as shown in Table 7.

Table 7: UM PGHC PCI Case Volume, FY 2015- FY 2019

Fiscal Year	Total PCI Cases
2015	360
2016	305
2017	213
2018	247
2019	270

Source: UM PGHC Application, Q28, and updated Q28.

Staff Analysis and Conclusion

MHCC staff reviewed the table submitted by UM PGHC and analyzed the ACC NCDR CathPCI data. Staff determined at least 200 PCI procedures in each year of the review period. MHCC staff concludes that UM PGHC complies with this standard.

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

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI case volume for CY 2015 through CY 2019, as shown in Table 8. This analysis is consistent with the case volume reported by UM PGHC and confirms that UM PGHC exceeded the threshold of 49 cases annually referenced in the standard.

Table 8: UM PGHC Primary PCI Volume, CY 2015- CY 2019

Calendar Year	Primary PCI
2015	67
2016	101
2017	61
2018	77
2019	67

Source: MHCC staff analysis of ACC-NCR CathPCI data, CY 2015- CY 2019.

MHCC staff determined that this standard does not apply to UM PGHC because it met the required case volume.

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

UM PGHC responded to this standard noting that the current interventionalists all meet the requirements of primary PCI within hospitals in Maryland.

Staff Analysis and Conclusion

MHCC staff notes that 11 primary PCI cases is a "target" rather than a strict requirement. Staff analyzed the data in the ACC-NCDR CathPCI registry for CY 2015 to CY 2019. In 2019, there was one operator who only performed eight primary PCI cases. Additionally, in 2017, two interventionalists fell below the target volume for primary PCI, with one performing only one primary PCI case and the other performing five primary PCI cases.

MHCC staff concludes that UM PGHC meets this standard.

Patient Selection

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.

UM PGHC stated that according to the results of external reviews, UM PGHC has not had a case identified as inappropriate.

Staff Analysis and Conclusion

Staff reviewed external review reports between January 2015 and December 2019 and notes that nine cases were determined to be "rarely appropriate" based on one or two of the appropriateness criteria (i.e. angiographic, clinical, ACC/AHA). Staff notes that no cases were determined to be rarely appropriate by all criteria. Six of the cases identified were performed between January and December 2015; four of these cases were performed by the same operator. Physicians met with the chair of the Cardiac Catheterization Peer Review Committee on a one-on-one basis to review their cases, as needed. For two of the cases reviewed in the January to June 2016 MACPAQ report, the chair of the Cardiac Catheterization Peer Review Committee discussed the cases with the operators for the cases. The final case was identified in the January to June 2019 MACPAQ report, and the CCL director discussed the case with the operator. The results of the MACPAQ report were also reviewed at the Cardiac Catheterization Peer Review meeting.

MHCC staff concludes that UM PGHC complies with the 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.

The application stated that UM PGHC has not encountered a patient who received primary PCI services inappropriately. UM PGHC also reported that no PCI patients received thrombolytic therapy that subsequently failed during the review period.

Staff Analysis and Conclusions

MHCC staff concludes that UM PGHC 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 PGHC 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 UM PGHC to continue providing primary and elective percutaneous coronary intervention services for four years subject to the following conditions:

1. University of Maryland Prince George's Hospital Center shall consistently track continuing medical education activities for staff, particularly the cardiac catheterization laboratory and coronary care unit (CCU) staff and, on a semiannual basis, submit documentation of the continuing medical education activities of staff for the CCL and CCU, as required in COMAR 10.24.17.07D(4)(g);

2. University of Maryland Prince George's Hospital Center shall track attendance at meetings with interventional case review and, on a semiannual basis, submit attendance lists to Commission staff documenting that technicians and nurses for primary PCI patients participated in case review and that meetings were held at least every other month, as required in COMAR 10.24.17.07D(5)(a); and

3. University of Maryland Prince George's Hospital Center shall track attendance at multiple care area group meetings and, on a semiannual basis, submit attendance lists to Commission staff documenting that meetings are held monthly, as required in COMAR 10.24.17.07D(5)(b).