

**IN THE MATTER OF
UNIVERSITY OF MARYLAND
UPPER CHESAPEAKE
MEDICAL CENTER
Docket No. 19-12-CP017**

*** BEFORE THE
* MARYLAND
* HEALTH CARE
* COMMISSION

STAFF REPORT AND RECOMMENDATION

**CERTIFICATE OF ONGOING PERFORMANCE
FOR PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION
SERVICES**

May 21, 2020

I. INTRODUCTION

A. Background

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

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

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

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

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

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

B. Applicant

University of Maryland Upper Chesapeake Medical Center

The University of Maryland Upper Chesapeake Medical Center (UMMC) is a 161-bed general hospital that is located in Bel Air (Harford County). UMMC is part of the University of Maryland Medical System and does not have a cardiac surgery program on-site.

UMMC began providing primary PCI services on April 4, 2008. This approval authorized UMMC to provide primary PCI services for a one-year period. In March 2009, the Commission approved a two-year waiver for UMMC, allowing it to continue to provide primary PCI services without on-site cardiac surgery. UMMC subsequently received renewals of its waiver to provide primary PCI services in March 2011 and April 2013. UMMC obtained a Certificate of Conformance, allowing it to provide elective PCI services as well as primary PCI services, in December 2014. This authorization, based on the 2012 legislation outlined above, allows UMMC to provide PCI services subject to periodic review of its ongoing performance. This report and recommendation is the first ongoing performance review of this PCI program.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. Harford County is in the Baltimore/Upper Shore region, which also includes Anne Arundel, Baltimore, Baltimore City, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties. The regions are defined by the patient origin of cardiac surgery patients. Fourteen hospitals in this region provide PCI services. Five of these hospitals provide both cardiac surgery and PCI services and seven, including UMMC, provide both primary PCI and elective PCI services. Two hospitals in the region, since the inception of their PCI services, have only provided primary PCI services. In April 2020, one of those hospitals, Howard County General Hospital, in Columbia (Howard) was authorized to introduce elective PCI services.

Staff Recommendation

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

II. PRODEDURAL HISTORY

UMMC filed a Certificate of Ongoing Performance application on March 22, 2019. MHCC staff reviewed the application and requested additional information on February 5, 2020 and March 20, 2020. Additional information was submitted on February 27, 2020 and April 3, 2020.

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.

UCMC stated that no deficiencies in data collection or reporting have been identified. Data for all ST-segment elevation myocardial infarction (STEMI)¹ and non-STEMI (NSTEMI) patients are entered into the American Heart Association Get With the Guidelines-Coronary Artery Disease (AHA GWTG-CAD) database and data for all STEMI, NSTEMI, and elective patients who receive interventions are recorded in the National Cardiac Data Registry (NCDR) CathPCI database of catheterization cases. UCMC shares data from the NCDR CathPCI database with MHCC as requested.

Staff Analysis and Conclusion

UCMC has complied with the requirement to submit NCDR data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of NCDR data to validate that hospitals submitted accurate and complete information to NCDR. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of UCMC's data reported during the audit period. MHCC staff receives duplicate data as required and concludes that UCMC 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.

UCMC provided a table of all cardiac catheterization laboratory (CCL) closures between January 2015 and January 2019 along with reason for the closures.

Table 1: UCMC CCL Closures

Room	Start Date	Duration of Closure (hours)	Reason/Explanation*
1	2/15/15	~15 days [^]	Fire
2	2/15/15	52	Fire
2	2/16/15	5	Hardware issue
2	6/1/15	1	Preventive maintenance ¹

¹ An ST-segment elevation myocardial infarction is a heart attack in which there is cardiac muscle damage resulting from an acute interruption of blood supply to a part of the heart that can be demonstrated by a change of ST-segment elevation on an electrocardiogram. An NSTEMI is a less common type of heart attack.

1	6/1/15	1	Issue with monitor
2	8/6/15	5.5	C-arm malfunction
1	9/16/15	3	Preventive maintenance
2	10/2/15	4	C-arm malfunction and hardware replacement
2	1/19/16	2.25	Preventive maintenance
2	3/4/16	3.75	Preventive maintenance
2	3/8/16	1.75	Preventive maintenance
2	4/15/16	3.75	Hardware replacement
1	4/20/16	3.5	Preventive maintenance
1	5/16/16	1.5	Air conditioning malfunction
1	5/25/16	3	Preventive maintenance
2	7/6/16	3	Preventive maintenance
1	8/15/16	4	Fuse blown on ACDC board
2	9/16/16	2.5	Hardware issue
2	10/21/16	6.3	Hardware issue and replacement
1	10/28/16	3	Preventive maintenance
2	11/1/16	1.25	Preventive maintenance
2	1/30/17	3.75	Preventive maintenance
1	5/4/17	1	Preventive maintenance
2	5/9/17	1.33	Preventive maintenance
1	7/20/17	3.75	Software issue and repair
2	7/31/17	3	Preventive maintenance
1	9/27/17	2.75	Issue with ribbon cable/collimation
1	12/14/17	3.75	Preventive maintenance
2	1/8/18	28.17	Hardware failure and replacement
2	1/26/18	3.75	Preventive maintenance
1	6/29/18	40	Hardware replacement
1	7/26/18	3.5	Preventive maintenance
2	7/30/18	4	Preventive maintenance
1	1/9/19	8.5	Malware attack on IT system
2	1/20/19	3.5	Preventive maintenance
2	1/24/19	1	Software malfunction
1	1/29/19	3.5	Preventive maintenance

Source: UCMC Application, Q2; *MHCC analysis

^ This room was replaced by a mobile unit on March 2, 2015 after a fire until construction and testing of the restored CCL could take place

¹ UCMC reported that during preventive maintenance session, the system is able to be brought back into service within a few minutes, if needed emergently

UCMC also stated that the Maryland Institute for Emergency Medical Services Systems and MHCC were notified via email of the 2015 fire and later reopening of the CCL. UCMC reported that infection control concerns with the smoke from the fire rendered all of the supplies in the laboratory unusable. On February 16, 2015, replacement supplies were obtained and, on the following day, UCMC came off a 52-hour period of STEMI reroute status. The Interventional Angiography Laboratory, which normally serves as the back-up CCL, became the primary laboratory for cardiac catheterizations. UCMC reported that on February 18, 2015, it was again able to perform elective PCI procedures. As a result of the closure due to fire, two STEMI cases were diverted and two additional patients who did not meet STEMI criteria but were noted to have left bundle branch block were sent to other hospitals as a precautionary measure.

UCMC also noted that during all other times (shown on the table) that the primary CCL (Room 1) was unavailable, all services were still available in the second CCL (Room 2).

Staff Analysis and Conclusion

MHCC staff reviewed the table of CCL closures during the period January 2015 to January 2019. During the incident of the fire, MHCC staff received notification via email and the hospital took steps to expedite restoration of services. Staff determines that this closure was unavoidable. UCMC’s use of two CCLs ensured that primary PCI was available 24 hours per day, 7 days per week for the rest of the review period.

MHCC staff concludes that UCMC meets 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.

UCMC provided a signed statement from Lyle E. Sheldon, FACHE, President and Chief Executive Officer, stating that door-to-balloon (DTB) times, exclusive of transfer patients, will not exceed 90 minutes from patient arrival at the hospital to revascularization for at least 75 percent of appropriate patients. Mr. Sheldon also stated that the program will continue to track DTB times for all STEMI patients coming directly to the facility as well as transfer cases and that UCMC performs an extensive review of each individual case to identify and evaluate opportunities for improvement. UCMC provided quarterly counts of non-transfer patients who received primary PCI and the number who had a DTB time of less than 90 minutes. UCMC also provided quarterly counts of transfer patients who received primary PCI and the number of such cases who had a DTB time of less than 120 minutes. UCMC provided median DTB times for 2015 through 2019 for non-transfer and transfer STEMI cases.

Staff Analysis and Conclusion

MHCC staff concludes that UCMC meets this standard based on the letter of commitment provided and review of the data provided in UCMC’s application.

Table 2a: Quarterly Door-to-Balloon Times for STEMI Primary PCI Cases, UCMC

Quarter ending	Total STEMI cases, primary PCI	STEMI patients with DTB time <90 minutes	Percentage of DTB time <90 minutes*	Median DTB Time for STEMI patients (minutes)
3/31/2015	32	26	81.3%*	67
6/30/2015	27	23	85.2%*	66
9/30/2015	15	14	93.3%*	49
12/31/2015	40	35	87.5%*	67
3/31/2016	34	26	76.5%*	70
6/30/2016	26	20	76.9%*	66

9/30/2016	28	20	71.4%*	70
12/31/2016	25	21	84.0%*	58
3/31/2017	31	26	83.9%*	61
6/30/2017	29	24	82.8%*	52
9/30/2017	32	28	87.5%*	64
12/31/2017	26	22	84.6%*	68
3/31/2018	25	16	64.0%*	74
6/30/2018	20	16	80.0%*	70
9/30/2018	21	19	90.5%*	67
12/31/2018	29	28	96.6%*	58
3/31/2019	29	23	79.3%	70
6/30/2019	20	18	90.0%	54
9/30/2019	28	24	85.7%	73
12/31/2019	18	15	83.3%	62
Total*	535*	444*	83.0%*	Not provided

Source: UCMC Application, Q4 and Updated Q4; *MHCC analysis

Over the above quarterly periods, median DTB times ranged from 49 to 74 minutes and the proportion of patients with a DTB time of 90 minutes or less ranged from 64% to 96.6%. UCMC failed to meet the benchmark² for only two of the 20 quarters between January 2015 and December 2019. On a calendar year basis, benchmark performance was achieved for 2015 through 2019, as shown in the following table.

Table 2b: Annual Door-to-Balloon Times for STEMI Primary PCI Cases, UCMC

Year	Total STEMI cases, primary PCI	STEMI patients with DTB time <90 minutes	Percentage of DTB <90 minutes
2015	114	98	86.0%
2016	113	87	77.0%
2017	118	100	84.7%
2018	95	79	83.2%
2019	95	80	84.2%
Total	535	444	83.0%

Source: MHCC analysis

UCMC provided the number of transfer cases with DTB times of less than 120 minutes.

Addressing the two quarters in which the DTB time benchmark was not achieved, UCMC reported that patients with delayed DTB were often patients who needed a computed tomography imaging procedure prior to entering the CCL for treatment. Another factor identified by UCMC in delayed treatment was identification of STEMI patients, especially when patients present in the emergency department without the usual signs of a heart attack. To address this issue, UCMC decided that whenever there is an unclear electrocardiogram (EKG), staff will be directed to activate the STEMI pager. UCMC reported that this has helped to reduce the number of patients with an ambiguous EKG who experience a DTB time in excess of 90 minutes. The Emergency Department (ED) physicians have also continued to work within their group to prepare for the

² DTB time of less than 90 minutes for at least 75% of primary PCI cases.

variety of ways that STEMI patients describe their symptoms and have incorporated this knowledge into how they rule out a cardiac etiology early in the assessment.

UCMC continues to use LIFENET modems for all of Harford and Cecil Counties for transmission of EKGs to the EDs for review for STEMI and direction to drive directly to UCMC for intervention. This allows the STEMI team to prepare for the arrival of patients. UCMC noted that it is providing ongoing education to EMS about use of the LIFENET system.

UCMC also provided other explanations for individual cases in which the DTB time standard was not met. MHCC staff reviewed the details provided and concluded that many of the delays described were unavoidable.

MHCC staff concludes that the 90% level of achievement, when considered on a quarterly basis, and the 100% level of achievement, when considered on a calendar year basis, over five years, is an acceptable level of performance and recommends that the Commission find that UCMC meets the standard.

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

UCMC provided a table to show the number of physicians, nurses, and technicians staffing the CCLs.

Table 3a: CCL Staffing, UCMC

	Number or Full-Time Equivalent (FTE) Staff	Cross Training
Physician	N=4	Interventional Cardiologist
Nurse	12.1 FTEs	Scrub - 2 Circulate - All Monitor - All
Technician	6.9 FTEs	Scrub and Monitor - All

Source: UCMC Application, Q6a

Staff Analysis and Conclusion

MHCC staff compared the staffing levels described by UCMC to information reported in the Certificate of Ongoing Performance applications submitted recently by three other programs with similar volumes.

Table 3b: CCL Staffing, UCMC and Selected Other PCI Programs

Program & Year Reported	Total PCI Case Volume in Prior Year	Number (N) or FTE Interventionalists	Nurse FTEs	Technician FTEs
UCMC	465	N = 4	12.1	6.9
Anne Arundel Hospital 2019	447	3.4 FTEs	7.5	6.0

University of Maryland Medical Center 2019	515	N = 10	11.0	7.5
Saint Agnes Hospital 2019	465	N = 4	7.2	5.0

Sources: UCMC 2019 PCI Certificate of Ongoing Performance Application, Anne Arundel Hospital 2019 PCI Certificate of Ongoing Performance Application, University of Maryland Medical Center 2019 PCI Certificate of Ongoing Performance Application, Saint Agnes Hospital 2019 PCI Certificate of Ongoing Performance Application

UCMC’s reported staffing level is similar to the levels reported by programs with similar case volume.

MHCC staff concludes that UCMC has adequate levels of nursing and technical staff to provide its volume of PCI services.

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

UCMC provided a signed letter from Lyle E. Sheldon, FACHE, President and Chief Executive Officer, committing UCMC to providing primary PCI services in accord with the requirements established by the Commission. Mr. Sheldon stated that the hospital administration remains 100% committed to the PCI program as a key component of its Heart and Vascular service line and the critical level of care this program provides to the community.

Staff Analysis and Conclusion

MHCC staff concludes that UCMC meets this standard based on the letter of commitment provided.

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.

UCMC provided a description of the staff involved with these functions. UCMC employs a 0.9 FTE STEMI Coordinator who collects and enters data into the AHA GWTG-CAG database and a full-time PCI Registry Coordinator who collects and enters data into the CathPCI database. These coordinators also report on quarterly outcomes and review all cases at weekly STEMI review meetings and monthly STEMI Process Action Team meetings. A Quality Management Specialist (1.0 FTE), shared with other specialties, is primarily responsible for facilitating ongoing professional practice evaluation and for-cause focused professional practice evaluation activities for medical staff, facilitating peer review activities, abstracting data and preparing reports for the National Hospital Quality Measures. The Quality Management Specialist is responsible for obtaining a list of all PCI procedures and sending this to the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ), an external review organization. This individual maintains and reports the results to leadership and monitors all PCI cases and other cardiac catheterizations performed at the facility and reports data to administration/ leadership on a regular basis.

Staff Analysis and Conclusion

Based on this information, MHCC staff concludes that UCMC 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.

Dr. Michael N. Drossner, an interventional cardiologist, was appointed Medical Director of the UCMC CCL in 2008. The Medical Director of the CCL is medically and legally responsible for the program. The Medical Director will supervise and direct the program and any liaison role that may be necessary to assure the efficiency and efficacy of the program. Dr. Drossner is responsible for defining and implementing credentialing criteria and for reviewing, standardizing, and approving processes, procedures and order sets related to the delivery of care and service in the CCL. He assures that appropriate internal and external peer review is conducted, and provides medical oversight to the monthly STEMI/Elective Angioplasty Process Action Team, and assures that the hospital meets all other requirements of COMAR 10.24.17. Dr. Drossner maintains ongoing communications with the Manager of the Cardiac Catheterization and Angiography Laboratories and the Director of the Heart and Vascular Institute to ensure quality, efficiency, and effectiveness in all aspects of the program's operations.

Staff Analysis and Conclusion

MHCC staff concludes that UCMC 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.

UCMC requires that registered nurses complete at least twenty continuing education hours and that technicians complete at least five continuing education hours per year. These requirements are tracked by the Education Department in "UMMS U," the education program utilized by University of Maryland Medical System. All classes and educational activities are recorded into UMMS U and can be reviewed by the manager to ensure that all education requirements have been met. UCMC also states that, on occasion, CCL staff receive education in the form of continuing education units or contact hours from vendor-partners. These activities are also recorded in the UMMS U system. In addition, nurses and technicians participate in annual competency reviews that are closely tracked by the Education Department. All team members at UCMC have mandatory corporate training requirements. A list of these classes was submitted to MHCC for review. UCMC provided a list of the continuing educational programs and activities that staff in the cardiac catheterization lab and intensive care unit participated in from 2013 and 2018³.

Staff Analysis and Conclusion

³ UCMC does not have a distinct coronary care unit.

MHCC staff concludes that the continuing medical education programming for staff includes appropriate topics and is consistent with the types of activities previously reported by hospitals seeking renewal of their waivers for primary and elective PCI services.

MHCC staff concludes that UCMC 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.

The applicant documented a 2011 agreement with the University of Maryland Medical Center, a tertiary care center, to accept unconditionally the transfer of patients who have undergone cardiac catheterizations or primary angioplasty services at UCMC for any required additional care, including emergent or elective cardiac surgery or PCI, and to provide timely transmission of required follow-up data on transferred patients.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that UCMC meets this standard.

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

Lyle Sheldon signed and dated an agreement with Maryland ExpressCare, a division of the University of Maryland Medical System, for cardiac support emergency services. The agreement guarantees the arrival of an air or ground ambulance within 30 minutes of a request for the transport of a primary PCI patient to a tertiary care center.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement submitted by UCMC and has concluded that the hospital meets this standard.

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.

UCMC provided a list of the dates, attendee names, credentials, and titles for the interventional case review meetings from January 2017 through November 2018. Attendance

records and dates from January 2015 through December 2016 could not be located but UCMC reported that meetings did take place. UCMC also described the case review meetings, which include review of all PCI cases and all patients who are transferred for coronary artery bypass graft procedures. The applicant stated that the Medical Director of the CCL and interventional cardiologists are present for reviews.

Staff Analysis and Conclusion

MHCC reviewed dates and attendance records for interventional case review meetings. UCMC reported holding 10 meetings in 2017 and 12 meetings in 2018. MHCC staff concludes that UCMC complies with this standard but recommends that the hospital exercise more care, going forward, in maintaining appropriate documentation of meetings involving PCI case review for consideration in future regulatory oversight processes.

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.

UCMC submitted dates attendee names, credentials, and titles for the multiple care area group (i.e. STEMI/Elective PCI meetings) between December 2012 and December 2018. UCMC also submitted minutes for these multiple care area group meetings.⁴

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for meetings in 2015 through 2018 and discovered that several monthly meetings had been cancelled. In 2015, UCMC held 10 meetings. Two meetings were cancelled due to the CCL fire and rebuilding activities. In 2016, UCMC held 11 meetings; the October 2016 meeting was cancelled because key physicians were away from the hospital or on vacation. In 2017, UCMC held 11 meetings; the October 2017 meeting was cancelled because, again, key physicians were away from the hospital or on vacation. In 2018, UCMC held 10 meetings; the March 2018 meeting was cancelled due to inclement weather and the October 2018 meeting was cancelled because key physicians were away from the hospital or on vacation. MHCC staff also reviewed the titles of attendees and determined that leaders in each care area, as well as other relevant organizations (e.g. Harford County Emergency Medical Services, UMMS Transport) attended the meetings.

MHCC staff concludes that UCMC satisfies this standard.

10.24.17.07C(4)(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

⁴ UCMC could not locate meeting minutes for the June 2017 meeting.

UCMC provided copies of external review reports for 2015 through June 2019. MACPAQ, an MHCC-approved external review organization, conducted the reviews.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. While only one report was submitted in 2015, it did include case reviews that occurred throughout the entire year. UCMC submitted reports for external reviews that were conducted semiannually in 2016, 2017, 2018, and 2019. The percentage of cases reviewed per year was greater than 5%, as required. Additionally, MHCC staff determined that at least three cases, semiannually, or six cases annually (2015) were reviewed per interventionalist.

Table 4: UCMC External Review, 2015-2019

Review Period (CY)	Elective PCI Case Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Number of external reviews completed	Requirements by physician met*
2015	290	28	9.7%	1	Yes
2016	298	27	9.1%	2	Yes
2017	358	26	7.3%	2	Yes
2018	408	28	6.9%	2	Yes
2019	197	14	7.1%	1	Yes

Source: MHCC Analysis, UCMC Application Q28, and MACPAQ Reports

^ Data only available through June 2019

* Each semiannual review included three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

UCMC 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 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 5 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 review reports, UCMC provided information regarding its internal review processes. The applicant stated that internal peer review is performed on an ongoing continuous basis throughout the year. Cases are brought individually or in small batches for review by an interventional cardiologist. The UCMC Quality Management team reviews all of the interventional cardiology cases and a monthly list of complications is obtained from the Cath PCI Registry. These cases are summarized and distributed among the interventional cardiologists who perform PCI for peer review. The peer-reviewing physician provider will either score the case or send it to the Interventional Cardiology Peer Review Committee if there are concerns. This committee meets twice per year. Specific case issues and concerns are discussed in detail, and scores are given for patient outcome, the standard of care, documentation, and other issues. The committee may ask for additional information from the provider and the physician is provided with an opportunity to respond. When issues are identified, the provider is notified via an outcome letter and a referral may be made to the hospital's Multi-disciplinary Evaluation Committee or Performance Improvement Committee, if needed.

Staff Analysis and Conclusion

In 2015, MHCC staff noted that the review requirements outlined in the Cardiac Surgery Chapter may be subject to varying interpretation. COMAR 10.24.17.07D(5)(c) provides that at least five cases per interventionalist must be reviewed semi-annually via external review, or all cases if the interventionalist performed fewer than five cases during a review period. While COMAR 10.24.17.07C(4)(c) requires that at least three cases per interventionalist must be reviewed semi-annually via external review, or all cases if the interventionalist performed fewer than three cases during a review period. MHCC staff issued a bulletin in October 2015 clarifying that external review of cases may be used to satisfy the hospital's review of the individual interventionalist's PCI cases. The bulletin states that at least three cases or 10% of cases, whichever is greater, per interventionalist must be reviewed semi-annually via external review.⁵

With the exception of one high volume interventionalist, the external review was sufficient to cover approximately ten percent of the non-primary PCI case volume of individual interventionalists. The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because it includes a review of angiographic images, medical test results, and patients' medical records. In addition to external review of individual interventionalists, UCMC's internal review processes include a review of all cases. Therefore, UCMC is exceeding the requirement that at least 10% of PCI cases be reviewed for each individual interventionalist. UCMC also has a formal process for providing feedback to interventionalists for PCI cases with poor outcomes for patients.

MHCC staff concludes that UCMC satisfactorily conducts individual interventionalist review as outlined in the October 2015 bulletin.⁶

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.

UCMC submitted an affidavit from Lyle Sheldon 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 semi-annual interventionalist reviews consistent with COMAR 10.24.17.07C(4)(c).

⁵https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

⁶ Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the external review and individual interventionalist review requirements.

Staff Analysis and Conclusion

MHCC staff concludes that UCMC meets this standard based on UCMC's certification that it has completed the required quality assurance activities and on its commitment to continue to do so.

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.***

UCMC provided copies of the external review reports from January 2015 through June 2019 and also submitted meeting minutes for the Peer Review Committee (January 2015 through December 2019), STEMI Process Action Team, and the NCDR outcomes committee (December 2018 through January 2019). UCMC also provided information about the hospital's quality management team and provided a list of its quality improvement efforts.

Staff Analysis and Conclusion

MHCC staff concludes that UCMC complies with this standard based on the meeting minutes and list of quality assurance activities provided.

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

mortality rate for non-STEMI PCI cases, calculated from the CathPCI Registry data; and

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

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

UCMC submitted adjusted mortality rates by rolling 12-month reporting period for Q1 2015 through Q2 2019 when available. These data are not available for any hospitals participating in the ACC CathPCI data registry for the rolling 12-month period of Q3 2017 through Q2 2018.

Table 5b: UCMC Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI				NONSTEMI			
	Hospital AMR	95% CI	National AMR	Meets MHCC Standard	Hospital AMR	95% CI	National AMR	Meets MHCC Standard
2018q3-2019q2	5.42	[1.49, 13.5]	6.38	Yes	1.41	[0.39, 3.59]	1.00	Yes
2018q2-2019q1	5.12	[1.06, 14.56]	6.13	Yes	1.69	[0.62, 3.64]	1.00	Yes
2018q1-2014q4	7.75	[2.13, 19.24]	6.00	Yes	1.58	[0.58, 3.41]	0.99	Yes
2017q4-2018q3	8.66	[2.85, 19.54]	6.54	Yes	1.26	[0.15, 4.51]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	8.37	[3.11, 17.72]	6.91	Yes	2.38	[0.65, 6.04]	1.03	Yes
2017q1-2017q4	6.1	[2, 13.88]	6.89	Yes	1.66	[0.45, 4.22]	0.99	Yes
2016q4-2017q3	4.68	[1.29, 11.71]	6.75	Yes	2.11	[0.69, 4.88]	0.98	Yes
2016q3-2017q2	8.19	[3.59, 15.66]	6.64	Yes	1.21	[0.15, 4.34]	0.95	Yes
2016q2-2017q3	7.77	[2.89, 16.43]	6.77	Yes	0.62	[0.02, 3.41]	0.97	Yes
2016q1-2017q4	8.23	[3.35, 16.45]	6.82	Yes	2.26	[0.27, 8.11]	0.95	Yes
2015q4-2016q3	7.81	[2.9, 16.58]	6.71	Yes	0.82	[0.02, 4.52]	0.95	Yes
2015q3-2016q2	3.05	[0.37, 10.79]	6.66	Yes	0.83	[0.02, 4.57]	0.93	Yes
2015q2-2016q1	1.49	[0.04, 8.15]	6.45	Yes	1.58	[0.19, 5.66]	0.9	Yes
2015q1-2015q4	3.06	[0.37, 10.82]	6.26	Yes	0.86	[0.02, 4.76]	0.9	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports from the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between January 2015 and March 2018

Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) included the National AMR or indicated statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or Non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI or non-STEMI cases, as applicable.

Staff Analysis and Conclusion

MHCC staff reviewed the AMR data by rolling 12-month period for both STEMI and NONSTEMI and determined that the national AMR is within the 95% confidence interval for UCMC AMR for all 12-month periods between 2015 Q1 and 2019 Q2. MHCC staff concludes that UCMC meets 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.

UCMC submitted a log of primary and elective PCI cases at the applicant hospital for four interventionalists (Drs. Drossner, Voss, Alborno, and Plack) as well as cases performed by these physicians at other hospitals by quarter from 2015 through 2018. Each physician signed and dated an affidavit affirming under penalties of perjury that the information contained in the table on the doctor's form is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed reported physician volume for four current interventionalists (at the time of application submission). Staff determined that each interventionalist performed at least 50 cases on average annually on a rolling eight quarter basis between 2015 and 2018. UCMC complies with this standard.

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

UCMC responded that this regulation is not applicable for the time period covered by this review.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to UCMC. While the hospital does not have on-site cardiac surgery, each physician performing primary PCI performed 50 PCI procedures annually when averaged over a 24-month period.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI

procedures annually averaged over a 24 month period, who took a leave of absence of less than one year during the 24 month period measured, may resume the provision of primary PCI provided that:

- (i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;*
- (ii) The physician continues to satisfy the hospital's credentialing requirements; and*
- (iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.*

UCMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to UCMC. While the hospital does not have on-site cardiac surgery, each physician performing primary PCI performed 50 PCI procedures annually averaged over a 24-month period.

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.

UCMC submitted a signed and dated statement from Dr. Drossner acknowledging that all physicians performing primary PCI services at UCMC (i.e. Drs. Drossner, Plack, Voss, and Albornoz) are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff concludes that UCMC meets this standard based on the letter provided.

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

UCMC submitted signed and dated attestations from Drs. Drossner, Plack, Albornoz, and Voss as documentation that each of these physicians has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC staff concludes that UCMC meets this standard based on the statements provided.

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

UCMC submitted a signed statement from Dr. Drossner, acknowledging that each physician who has performed primary PCI services between January 1, 2015 and March 2019 has participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. UCMC also submitted a copy of the on-call schedules for October 2018 to March 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedules for October 2018 through March 2019 and observed that Drs. Drossner, Voss, Alborno, and Plack were all scheduled to be on-call at different times during the month. MHCC staff concludes that UCMC meets this standard based on the statement provided as well as review of the on-call schedules submitted.

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.

UCMC provided a table identifying the number of primary PCI, elective PCI, and total PCI cases for 2014 to 2018.

Table 6: UCMC PCI Case Volume

Calendar Year	Primary PCI Cases	Elective PCI Cases	Total PCI Cases
2014	153	0	153
2015	132	290	422
2016	136	298	432
2017	137	358	495
2018	109	408	517
2019	123	356	479

Source: UCMC Application, Q28 and Updated Q28

Staff Analysis and Conclusion

In 2014, UCMC did not perform elective PCI procedures. In the following years, annual elective PCI case volume ranged from 290 to 408 cases and total annual PCI case volume ranged from 422 to 517 cases.

MHCC staff concludes that UCMC meets this target.

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.

UCMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

Between 2015 and 2019, between 109 and 153 primary PCI cases per year were performed at UCMC. Because the hospital exceeded the minimum requirement, a focused review was not required. MHCC staff concludes that, under these circumstances, this standard does not apply.

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

UCMC provided the number of primary PCI cases by interventionalist quarterly from January 2015 to December 2018.

Staff Analysis and Conclusion

MHCC staff reviewed the tables submitted by UCMC. According to the tables, between 2015 and 2018, at least 11 primary PCI procedures were completed by each interventionalist per year, on a rolling four quarter basis. MHCC staff concludes that UCMC 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.***

UCMC responded that no patients have been deemed inappropriate for receiving elective PCI services based on both internal and external reviews.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports submitted and determined that there were no issues identified by MACPAQ. However, in reviewing the hospital's performance on the appropriate criteria evaluation without acute coronary syndrome (line# 1587) included in the

hospital's reports from the American College of Cardiology for the CathPCI data registry over the period January 2015 through the first quarter of 2018, MHCC staff observed that UCMC was an outlier compared to other hospitals, with a greater number of cases labeled as inappropriate for cardiac catheterization, among patients without acute coronary syndrome. Although the number of cases categorized in this way was low relative to the total volume of PCI cases performed at UCMC, MHCC staff requested additional information.

UCMC responded that the reports from the ACC contradicted all of the external peer review reports and the internal review process. UCMC also stated that the specific metric from the ACC report had not been a focus of the program prior to 2018 and formed a sub-committee to investigate the issue raised. This committee concluded that data collection practices drove the results, rather than inappropriate treatment of patients. UCMC also stated that the hospital will continue to look at additional opportunities to assure compliance as well as accurate reporting.

MHCC staff concludes that UCMC 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.***

UCMC responded that no patients have received thrombolytic therapy at the hospital and that no patients were found to be treated inappropriately based on internal review.

Staff Analysis and Conclusion

MHCC concludes that UCMC complies with this standard.

RECOMMENDATION

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