

**IN THE MATTER OF
ADVENTIST HEALTH CARE
WHITE OAK
MEDICAL CENTER**

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

Docket No.: 19-15-CP032

**STAFF REPORT AND RECOMMENDATION
CERTIFICATE OF ONGOING PERFORMANCE
FOR PRIMARY & ELECTIVE PERCUTANEOUS CORONARY INTERVENTION
SERVICES**

November 18, 2021

I. INTRODUCTION

A. Background

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

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

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

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

The Cardiac Surgery Chapter contains standards for evaluating the performance of established PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services

authorizes a hospital to continue to provide PCI services, either primary or both primary and elective (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

Adventist Health Care White Oak Medical Center

Adventist Health Care White Oak Medical Center (WOMC) is a 188-bed general hospital located in Silver Spring (Montgomery County). WOMC is part of the Adventist HealthCare 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. WOMC is in the Metropolitan Washington health planning region. This region includes Calvert, Charles, Frederick, Montgomery, Prince George's, and Saint Mary's Counties; the District of Columbia is also included in the region. Seven Maryland hospitals in this health planning region provide PCI services. Holy Cross Hospital has only provided primary PCI services since its inception; all the other programs provide both primary and elective PCI services. Three of the seven Maryland hospitals also provide on-site cardiac surgery services.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

WOMC filed a Certificate of Ongoing Performance application on October 19, 2020, in accordance with the review schedule established by the Commission. MHCC staff reviewed the application and requested additional information on April 13, 2021, July 13, 2021, September 24, 2021, and October 25, 2021. Additional information was submitted on May 25, 2021, July 27, 2021, September 29, 2021, and November 2, 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.

WOMC stated that the program participates in the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR). WOMC reports there have been no deficiencies in data collection or reporting to the ACC-NCDR or MHCC.

Staff Analysis and Conclusion

WOMC 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 WOMC's data for the audit period.

MHCC staff concludes that WOMC 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.

WOMC responded that all downtime is tracked and reported, and there have been only two days between January 2015 and December 2020 when all rooms were out of service simultaneously. PCI services were not available on October 18 from 10:00 p.m. to midnight and on October 19 from midnight until 6:00 a.m. because the hospital scheduled installing emergency stops from the main lead that provides power to the Universal Power Source supporting all the CCLs at White Oak Medical Center. WOMC reported that it had plans in place for the transfer of any STEMI or urgent NSTEMI patients while PCI services were unavailable. Specifically, an ambulance was kept on-site at WOMC for transport of patients to Shady Grove Medical Center. The hospital also informed the Maryland Institute for Emergency Medical Services System and Emergency Management Systems (EMS) for Regions 3, 4, and 5 of its plans.

WOMC provided a report of downtime and maintenance for the four CCL rooms between January 2016 and December 2020. WOMC reported that the downtime logs for calendar year 2015

were unavailable because of staffing changes and the transition of closing Washington Adventist Hospital (WAH) in Takoma Park and opening WOMC in Silver Spring, Maryland.

WOMC reported that for required equipment maintenance, CCLs undergo maintenance in a staggered fashion to avoid interruption in service. Each CCL is also connected to a Universal Power Source to avoid interruption related to power outage. In addition, during the transition from WAH to WOMC, dual operations were maintained, including on-call STEMI teams for both facilities, until all patients were successfully transferred to the new facility.

Staff Analysis and Conclusion

MHCC staff reviewed the downtime documentation for CY 2016 through CY 2020. As shown in Table 1, there was rarely downtime for each room, except in 2019, the year in which the hospital relocated to Silver Spring. MHCC staff determined that the downtime on October 18 and October 19 in 2019, totaling only eight hours when PCI service were unavailable was unavoidable.

Table 1: WOMC Reported Frequency of Downtime by CCL and Time Period, January 2015 - December 2020

Time Period	Number of Downtime Occurrences				Overlapping Downtime
	CCL 1	CCL 2	CCL 3	CCL 4	
CY 2015	NR	NR	NR	NR	NR
CY 2016	2	2	2	2	No
CY 2017	2	2	2	1	No
CY 2018	2	1	4	6	No
CY 2019	4	10	7	10	Yes
CY 2020	1	2	3	5	No

Source: WOMC Application Q2, WOMC updated Q2 response

Notes: NR means not reported. WOMC was not able to locate downtime logs for calendar year 2015.

MHCC staff concludes that WOMC 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.

WOMC provided a signed statement from Anthony Stahl, President of WOMC, acknowledging that all physicians contracted for STEMI¹ call are required to follow protocols to maintain a door-to-balloon (DTB) time not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases at minimum 75% of the time and WOMC commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement.

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.

Additionally, WOMC provided quarterly DTB times for the period from January 2015 through December 2019, as shown in Table 2a.

Table 2A: WOMC 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	10	10	100.0%
CY 2015 Q2	10	9	90.0%
CY 2015 Q3	8	8	100.0%
CY 2015 Q4	11	11	100.0%
CY 2016 Q1	11	10	90.9%
CY 2016 Q2	5	5	100.0%
CY 2016 Q3	7	7	100.0%
CY 2016 Q4	11	10	90.9%
CY 2017 Q1	9	9	100.0%
CY 2017 Q2	12	12	100.0%
CY 2017 Q3	5	5	100.0%
CY 2017 Q4	11	11	100.0%
CY 2018 Q1	11	11	100.0%
CY 2018 Q2	7	6	85.7%
CY 2018 Q3	4	4	100.0%
CY 2018 Q4	7	7	100.0%
CY 2019 Q1	4	4	100.0%
CY 2019 Q2	4	3	75.0%
CY 2019 Q3	6	5	83.3%
CY 2019 Q4	5	4	80.0%

Source: WOMC Application, Q4, updated Q4, July 2021.

As shown in Table 2B, WOMC provided information about DTB times for transfer cases between January 2015 and December 2019. During the reporting period of January 2015 through December 2019, WOMC reported three transfers: one patient in 2016 with a transfer DTB time of 53 minutes, one patient in 2017 with a transfer DTB time of 124 minutes, and one patient in 2019 with a transfer DTB time of 100 minutes. WOMC reported that it is developing refinements to the One Call System to encompass transfers of STEMI patients. WOMC explained 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 and nurse supervisor on-call. Once the interventionalist on-call has accepted the patient, One Call contacts the hospital nurse supervisor to activate the STEMI team. Calls from the referring hospital must be answered within three rings, and the response process must be completed within ten to twelve minutes.

**Table 2B: WOMC DTB Times by Quarter for Transfer Cases
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	13	10	76.9%
CY 2015 Q2	10	10	100.0%
CY 2015 Q3	8	7	87.5%
CY 2015 Q4	12	10	83.3%
CY 2016 Q1	12	9	75.0%
CY 2016 Q2	7	6	85.7%
CY 2016 Q3	6	6	100.0%
CY 2016 Q4	14	11	78.6%
CY 2017 Q1	9	6	66.7%
CY 2017 Q2	13	12	92.3%
CY 2017 Q3	5	5	100.0%
CY 2017 Q4	11	9	81.8%
CY 2018 Q1	11	11	100.0%
CY 2018 Q2	9	6	66.7%
CY 2018 Q3	4	4	100.0%
CY 2018 Q4	9	8	88.9%
CY 2019 Q1	6	5	83.3%
CY 2019 Q2	8	7	87.5%
CY 2019 Q3	9	6	66.7%
CY 2019 Q4	7	6	85.7%

Source: WOMC, Q4, updated Q4, July 2021.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data and noted that over rolling eight quarter periods, WOMC complied with the DTB standard in all periods, except for four periods in which WOMC fell slightly short of the standard; in the rolling eight quarter periods ending in 2016 Q2, 71.4% of cases met the DTB standard. In 2018 Q2, 2019 Q1 and 2019 Q3, 66.7% of cases met the DTB standard.

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.

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

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

Time Period	Quarter			Rolling 8-Quarters		
	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	13	10	76.9%			
2015q2	10	10	100.0%			
2015q3	8	7	87.5%			
2015q4	12	10	83.3%			
2016q1	12	9	75.0%			
2016q2	7	5	71.4%			
2016q3	6	6	100.0%			
2016q4	14	11	78.6%	82	68	82.9%
2017q1	9	7	77.8%	78	65	83.3%
2017q2	13	12	92.3%	81	67	82.7%
2017q3	5	5	100.0%	78	65	83.3%
2017q4	11	9	81.8%	77	64	83.1%
2018q1	11	11	100.0%	76	66	86.8%
2018q2	9	6	66.7%	78	67	85.9%
2018q3	4	4	100.0%	76	65	85.5%
2018q4	9	8	88.9%	71	62	87.3%
2019q1	6	4	66.7%	68	59	86.8%
2019q2	8	7	87.5%	63	54	85.7%
2019q3	9	6	66.7%	67	55	82.1%
2019q4	7	6	85.7%	63	52	82.5%

Source: MHCC staff analysis of ACC CathPCI data

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, WOMC provided the number of physicians, nurses, and technicians who were able to provide cardiac catheterization services to acute myocardial infarction patients as of September 2019. WOMC reported that these were typical staffing levels for the reporting period.

Table 4A: WOMC Cardiac Catheterization Laboratory Staff

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	6	
Nurse	7 (FTE)	5 (S/C/M), 2 (C/M)
Technician	10 (FTE)	M, S

Source: WOMC Application.

*Scrub (S), circulate (C), monitor (M).

Staff Analysis and Conclusion

MHCC staff compared the reported staffing levels at WOMC to the staffing levels for programs at three other hospitals with similar case volumes. A comparison of volume and staffing levels for WOMC, Meritus Medical Center, St. Agnes Hospital, and University of Maryland Upper Chesapeake Medical Center is shown in Table 4B. Meritus Medical Center has a comparable level of PCI volume. WOMC reported seven nurse FTEs and 10 technician FTEs compared to 12.05 nurse FTEs and 6.9 technician FTEs for the University of Maryland Upper Chesapeake Medical Center (UM UCMC). The PCI volume for St. Agnes Hospital and UM UCMC are lower than the PCI volume for WOMC. However, the nurse volume is slightly higher at Meritus than WOMC, 8.5 and seven FTEs, respectively. The interventionalists volume is slightly lower at St. Agnes and UM UCMC with both at four FTEs compared to six FTEs for both Meritus and WOMC.

Table 4B: CCL Staffing for WOMC and Other Select PCI Programs

Program & Year Reported	Total PCI Volume in Year Prior*	Number of Interventionalists	Nurse FTEs	Technician FTEs
Adventist Healthcare White Oak Medical Center 2019	768	6	7	10
Meritus Medical Center 2019	852	6	8.5	5
St. Agnes Hospital 2019	465	4	7.2	5
UM UCMC 2019	517	4	12.05	6.9

Sources: Adventist Healthcare White Oak Medical Center 2019 PCI Certificate of Ongoing Performance Application, Meritus Medical Center 2019 PCI Certificate of Ongoing Performance Application, St. Agnes Hospital 2019 PCI Certificate of Ongoing Performance Application, University of Maryland Upper Chesapeake Medical Center 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 WOMC 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.

WOMC provided a signed letter of commitment from President, Mr. Stahl acknowledging that WOMC 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 WOMC 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.

WOMC reported that data collection, management, and reporting for PCI services is done by the Data Coordinators who work within the cardiac and vascular service line. WOMC has 2.0 FTEs dedicated to these activities. In addition, a Chest Pain Coordinator is dedicated to improving chest pain management processes and performs data collection as it relates to Chest Pain Accreditation requirements. There is also coordination with a Quality Advisor in the Quality and Patient Safety Department to monitor and sustain institutional quality and performance improvement efforts.

Staff Analysis and Conclusion

MHCC staff concludes that WOMC 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.

WOMC reported that its PCI program is led by three physician leaders who work collaboratively to ensure the program meets or exceeds standards. Dr. Michael S. Chen is the Medical Director of the CCL. He began this role in 2014 and is responsible for oversight of operational aspects of the CCL including equipment, quality management, and review conferences. Dr. Fayaz Shawl is the Medical Director of Interventional Cardiology and has served in this role since 1999. Dr. Shawl's responsibilities include defining and implementing credential criteria for staff working in the CCL. Dr. David Brill is responsible for primary PCI program management, including physician call schedules. He has been in this role since 2009.

Staff Analysis and Conclusion

MHCC staff concludes that WOMC complies with this standard.

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

WOMC provided a list of the continuing educational programs and activities in which staff in the CCL, Intensive Care Unit, and Progressive Care Unit participated between January 2015 and December 2019. WOMC stated that staff participate in continuing education trainings and services throughout the year as needed or required. Staff are required to have a minimum number of continuing education credits based on their license. WOMC reports that staff are responsible

for obtaining continuing education credits and providing a dated certificate for any credits received to the manager who tracks license renewals. These educational activities may include independent assigned learning, staff meetings, clinical inquiry meetings, best practice meetings, and PCI performance meetings. WOMC provides a core online competency training specific to the CCL staff which includes training in Code Blue, Code Stroke, Code STEMI, and Early Heart Attack Care. Annual training and core competency trainings are required every six months. Additional online courses are available to operational staff annually.

Staff Analysis and Conclusion

MHCC staff concludes that WOMC 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.

WOMC provides cardiac surgery on-site, so this standard is not applicable to WOMC.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to WOMC.

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 WOMC provides cardiac surgery on site, this standard is not applicable. However, WOMC submitted an agreement with Butler Medical Transport, LLC that provides ground ambulance and specialty services to WOMC, including advance life support and cardiac transports. WOMC also submitted an agreement with MedSTAR Transport Service that provides emergent air medical transportation.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to WOMC.

Quality

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

WOMC stated that the Cardiac, Vascular and Interventional Radiology (CVIR) Cath Conference Meetings are formal, regularly scheduled meetings at least every other month for interventional case review that require attendance by interventionalists and other physicians, nurses and technicians who care for primary PCI patients. Technicians attend the meetings depending on availability. WOMC reported that holding one meeting allows staff from multiple disciplines to receive education and to conduct a review of operations at the same time.

WOMC reported that ten meetings of the CVIR were held in 2015; nine meetings were held in 2016; 11 meetings were held in 2017; nine meetings were held in 2018; seven meetings were in 2019; and seven meetings were held in 2020. Five meetings have been held through June 2021. The documentation submitted by WOMC included meeting minutes and sign in sheets for meetings held from January 2015 through June 2021, with limited exceptions.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for the hospital's meetings for interventional case review. The hospital did not hold the required number of meetings, and nurses and technicians do not regularly attend these meetings.

Staff recommends that the Commission find that WOMC complies with this standard and include the following condition on the Certificate of Ongoing Performance:

WOMC shall hold bi-monthly interventional case review meetings, as required in COMAR 10.24.17.07D(5)(a) and shall submit to Commission staff attendance lists for each of these meetings held between January and June by August 1 of each year and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2023. After this date, the Executive Director may release WOMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

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.

WOMC reported that the ACS-PCI (Acute Coronary Syndrome & Percutaneous, Coronary Intervention) a multiple care area group) that includes physician and nursing leadership of each care area and that meets monthly to review all issues related to the primary PCI system, identify problem areas, and develop solutions. If a meeting is canceled, then cases for that month are reviewed at the next meeting.

WOMC provided meeting minutes for meetings held from January 2015 through June 2021, with limited exceptions. WOMC reported that 11 meetings were held in 2015, seven

meetings were held in 2016, 12 meetings were held in 2017 and ten meetings were held in 2018, seven meetings were held in 2019 and 2020. Four meetings have been held through June 2021.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for the hospital's multiple care area group and interventional case review group meetings. Staff noted that meeting were held less often than required.

MHCC staff recommends that the Commission find that WOMC complies with this standard and include the following condition on the Certificate of Ongoing Performance.

WOMC shall hold monthly multiple care area group meetings, as required in COMAR 10.24.17.07D(5)(b) and shall submit to Commission staff attendance lists for each of these meetings held between January and June by August 1 of each year and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2023. After this date, the Executive Director may release WOMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

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.

WOMC submitted copies of its external review reports for the period from September 2014 through August 2020. WOMC uses an MHCC approved review organization, the Cardiac Community Core Lab (CCCL), to review medical records and 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 5% and 17.2% of cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed.

Table 5: WOMC External Reviews, September 2014- August 2020

Time Period	Elective PCI Cases	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard*
09/14-03/15*	314	16	5%	Semiannual	Yes
03/15-08/15	360	18	5%	Semiannual	Yes
09/15-02/16	314	54	17.2%	Semiannual	Yes
03/16-08/16	332	52	15.7%	Semiannual	Yes
09/16-02/17	344	50	14.5%	Semiannual	Yes
03/17-08/17	351	44	12.5%	Semiannual	Yes
09/17-02/18	374	48	12.8%	Semiannual	Yes
03/18-08/18	356	43	12.1%	Semiannual	Yes
09/18-02/19	382	46	12%	Semiannual	Yes
03/19-08/19	401	45	11.2%	Semiannual	Yes
09/19-02/20	340	50	14.7%	Semiannual	Yes
03/20-08/20	296	51	17.2%	Semiannual	Yes

Source: MHCC analysis of CCCL Reports.

* Each semiannual review after October 2015 included at least three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

The regulations in place prior to October 2015 did not require a minimum number of cases per interventionalist. After October 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. For the period between September 2014 and August 2020, MHCC staff verified that, if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by CCCL, as required.

WOMC complies with this standard.

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

- (i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or***
- (ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital’s randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than 3 cases during the relevant period, as provided in Regulation .08; or***
- (iii) A quarterly or other review period conducted in a manner approved by Commission’s Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraphs .07C(4)(d)(i).***

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

- (i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or**
- (ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08; or**
- (iii) For a hospital with both primary and elective PCI programs, a quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraphs .07C(4)(c) and .07D(5)(c).**

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

- (i) Include a review of angiographic images, medical test results, and patients' medical records; and**
- (ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.**

In addition to the external reviews completed by CCCL described above, WOMC stated that internal review consists of a monthly review of 10% of individual interventionalists' PCI cases. All PCI cases performed, both primary and elective, are reviewed monthly. These reviews include review of angiographic images, medical test results, and patients' medical records. WOMC reports that the Director for the CCL evaluates all cases based on Appropriate Use Criteria (AUC), except his own cases or his associates' cases. The hospital has a contract with two other physicians who are unaffiliated with WOMC, and these unaffiliated physicians perform internal case review for cases done by the Director of the CCL or his partners. The hospital also created a tracking sheet for individual physicians and sets a goal for the number of cases to be reviewed based on yearly volume. The number of cases reviewed by internal review per interventionalist per year is targeted at 10% of each interventionalist's yearly volume. The results of each annual review are shared during quality assurance meetings for the CCL.

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).²

In addition to the external review, WOMC 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 CCCL meets the requirements of 10.24.17.07D(5)(d) because CCCL has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by CCCL includes a review of angiographic images, medical test results, and patients' medical records.

At least six cases per interventionalist were reviewed per year, as applicable, and additional cases were reviewed via internal review, as applicable. The requirement for external review changed with the adoption of an updated Cardiac Surgery Chapter in October 2015; for the period January to June 2015, a hospital was not required to include at least three cases per physician in its external review. The external reviews conducted by CCCL meet the requirements of 10.24.17.07D(5)(d) because CCCL has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by CCCL includes a review of angiographic images, medical test results, and patients' medical records.

MHCC staff concludes that WOMC satisfactorily conducts individual interventionalist review as provided in COMAR 10.24.17.07C(4)(d) and described in the October 2015 bulletin, with respect to COMAR 10.24.17.07D(5)(c).³

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

WOMC submitted an affidavit from Mr. Stahl, President, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities,

²https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

³ Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the individual interventionalist review requirements.

including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, and quarterly interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that WOMC complies with this standard.

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

- (i) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.***
- (ii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.***

WOMC provided some examples of quality assurance activities related to PCI patients. WOMC reported that the CVIR meetings are held at least bi-monthly to review practice patterns and establish process improvement goals to ensure optimal patient outcomes. All cases with a DTB over the standard in ACC/AHA guidelines are reviewed, as well as PCI cases with complications tracked in the hospital's incident reporting system. All PCI cases are reviewed individually to ensure quality care and process improvement.

WOMC also reported that at the departmental level, the ACS-PCI (Acute Coronary Syndrome & Percutaneous Coronary Intervention) is held monthly to review quality assurance measures and processes to improve patient outcomes. ACS-PCI meetings are held to provide a collaborative multi-disciplinary environment to ensure excellent outcomes for patients with Acute Coronary Syndrome. WOMC requires that all staff attend at least 50% of ACS-PCI meetings. On a quarterly basis, the ACS-PCI meeting is replaced by the Cardiovascular Center of Excellence Committee (CVCOE) meeting. The CVCOE focuses on accreditation compliance, planning and quality improvement reviews of the CCL and Chest Pain Center, and recommendations from accreditation reviewers. All committee members are required to attend at least two CVCOE meetings per year. Both interdisciplinary committees are responsible for monitoring and evaluating the care and activities that relate to the cardiac patient from EMS contact through the full continuum of care.

WOMC reported that in addition to external peer review of a randomized selection of elective PCI cases to ensure appropriate care delivery and internal peer review of cases with complications, the Director for the CCL reviews all PCI cases performed and provides feedback to operators. The Director of the CCL shares external review reports with individual operators. WOMC reports that the Director for the CCL reviews all cases against AUC criteria except his own cases or his associates' cases, which are reviewed by physicians not affiliated with WOMC.

In response to MHCC staff's request for examples of quality initiatives undertaken, WOMC provided three examples. In 2015, WOMC implemented an initiative to improve the hospital's risk adjusted acute kidney injury (AKI) rates in post PCI patients because since Q1 2013 the hospital's AKI rates had been consistently 26.4% higher than the U.S. 50th percentile. WOMC reported that its initiative was multidisciplinary and included updates to pre-set Cath/PCI orders in April of 2015. Since the beginning of the initiative in 2015, WOMC's risk adjusted kidney injury rate for PCI patients has improved, reflecting the hospital's efforts to improve quality of service.

WOMC reported that in 2017, the hospital set a goal to decrease the time from first medical contact with a STEMI patient to reperfusion in the Cath Lab. The Chest Pain Center Committee defined three outcome indicators targeting the three phases of STEMI patient care: EMS phase, ED phase, and CCL. The hospital collected data for all STEMI patients for each phase to determine baseline performance. Staff identified factors contributing to prolonged care phases, defined as greater than 30 minutes, and the hospital implemented countermeasures as needed. WOMC reported that in 2020, 100% of STEMI patients presenting to the ED received primary PCI services within 90 minutes or less of first medical contact.

Staff Analysis and Conclusion

MHCC staff reviewed meeting minutes and descriptions of quality assurance activities and concludes that WOMC 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.

WOMC 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: WOMC 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
2020q4-2021q1	1.79	[0.05, 9.53]	7.55	Yes	1.80	[0.73, 3.69]	1.21	Yes
2020q3-2020q4	1.80	[0.05, 9.56]	6.89	Yes	1.16	[0.32, 2.95]	1.13	Yes
2020q2-2020q3	3.11	[0.38, 10.58]	6.37	Yes	0.74	[0.15, 2.16]	1.06	Yes
2020q1-2020q2	1.66	[0.04, 8.77]	6.06	Yes	0.26	[0.01, 1.44]	1.00	Yes
2019q4-2020q1	3.96	[0.48, 13.4]	5.99	Yes	0.22	[0.01, 1.24]	0.95	Yes
2019q1-2019q4	5.94	[1.25, 15.98]	6.01	Yes	0.65	[0.13, 1.89]	0.95	Yes
2018q4-2019q3	4.80	[0.59, 16.02]	6.06	Yes	0.98	[0.27, 2.50]	0.98	Yes
2018q3-2019q2	8.04	[0.99, 26.28]	6.38	Yes	1.05	[0.29, 2.69]	1.00	Yes
2018q2-2019q1	5.22	[0.13, 26.87]	6.13	Yes	0.95	[0.26, 2.42]	0.99	Yes
2018q1-2018q4	NR	[0.00, 15.69]	6.00	Yes	0.63	[0.13, 1.82]	1.00	Yes
2017q4-2018q3	3.85	[0.10, 20.36]	6.54	Yes	0.73	[0.20, 1.85]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry							
2017q2-2018q1	4.16	[0.11, 22.12]	6.91	Yes	1.33	[0.49, 2.88]	1.03	Yes
2017q1-2017q4	3.18	[0.08, 16.85]	6.86	Yes	1.60	[0.65, 3.28]	0.99	Yes
2016q4-2017q3	NR	[0.00, 12.79]	6.75	Yes	0.81	[0.22, 2.07]	0.98	Yes
2016q3-2017q2	NR	[0.00, 12.69]	6.64	Yes	0.74	[0.24, 1.73]	0.95	Yes
2016q2-2017q1	5.07	[0.62, 17.24]	6.77	Yes	0.64	[0.18, 1.63]	0.97	Yes
2016q1-2016q4	5.84	[0.71, 19.84]	6.82	Yes	0.60	[0.16, 1.54]	0.95	Yes
2015q4-2016q3	3.93	[0.48, 13.34]	6.71	Yes	0.92	[0.34, 1.99]	0.95	Yes
2015q3-2016q2	3.57	[0.44, 12.14]	6.66	Yes	0.97	[0.32, 2.25]	0.93	Yes
2015q2-2016q1	3.75	[0.46, 12.84]	6.45	Yes	0.66	[0.18, 1.68]	0.90	Yes
2015q1-2015q4	4.18	[3.37, 11.17]	6.26	Yes	0.51	[0.11, 1.48]	0.90	Yes

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

Notes: "NR" means not reported. When a hospital has zero deaths for a reporting period, the hospital's AMR is labeled NR. 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 WOMC'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 WOMC's performance relative to the current standard over the period between January 2015 and March 2021.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for WOMC for all 12-month reporting periods between January 2015 and September 2020, when an adjusted mortality rate was reported. MHCC staff concludes that WOMC would have met this standard if it had been applicable for the period January 2015 through March 2021. The hospital meets the benchmark for both STEMI and non-STEMI cases for the periods ending December 2019, March 2020, June 2020, September 2020, December 2020 and March 2021.

MHCC staff concludes that WOMC complies with this standard.

Physician Resources

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

Because WOMC 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 WOMC 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.*

WOMC provides cardiac surgery; this standard is not applicable to WOMC.

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.

WOMC submitted a signed and dated statement from Dr. Fayaz Shawl, Director, Interventional Cardiology, acknowledging that each physician performing primary PCI services at WOMC is board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the letter provided and concludes that WOMC 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.

WOMC submitted signed and dated attestations from Drs. Brill, Ahsan, Ali, Kelley, and Ashai 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 WOMC meets this standard.

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

WOMC submitted a signed statement from Dr. Michael Chen, acknowledging that each physician who has performed primary PCI services during the performance review period has participated in an on-call schedule. WOMC 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. Brill, Ahsan, Ali, Kelley, and Ashai were all scheduled to be on-call at different times during the month. MHCC staff concludes that WOMC 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.

WOMC provided PCI volume information by fiscal year 2015 through 2019, as shown in Table 7. This information shows that WOMC performed between 669 and 796 cases annually.

**Table 7: WOMC PCI Case Volume,
FY 2014 - FY 2019**

Fiscal Year	Total PCI Cases
2014	669
2015	691
2016	703
2017	764
2018	768
2019	796

Source: WOMC Application Q28, updated Q28.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI volume information submitted by WOMC and analyzed the ACC-NCDR CathPCI data submitted. Staff determined at least 200 PCI procedures were completed per calendar year in for all reporting periods.

MHCC staff concludes that WOMC 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.

WOMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI case volume for CY 2015 through CY 2019, as shown in Table 8. This analysis shows primary PCI volume ranged from 49 to 73 cases each calendar year and confirms that WOMC exceeded the threshold of 49 cases annually referenced in the standard.

**Table 8: WOMC Primary PCI Volume,
CY 2015 - CY 2019**

Calendar Year	Primary PCI Volume
2015	73
2016	62
2017	59
2018	52
2019	49
2020	53

Source: MHCC staff analysis of CathPCI data CY 2015- CY 2020

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI case volume for CY 2015 through CY 2020, as shown in Table 8. This analysis is consistent with the case volume reported by WOMC and confirms that WOMC exceeded the threshold of 49 cases annually referenced in the standard.

MHCC concludes that WOMC meets this standard.

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

WOMC provided the number of primary PCI cases by interventionalist for the period of January 2015 through December 2019 by quarter, both at WOMC and at other Maryland hospitals. Between 2015 Q1 and 2019 Q4, at least 11 primary PCI procedures were completed per year, for practicing interventionalists at the time of application, with four exceptions. One physician completed only ten cases in 2017 and performed only nine cases in 2018. A second physician completed only ten cases in 2016 and performed only eight cases in 2019. Two additional physicians performed less than 11 primary PCI procedures for all quarters between 2015 and 2019.

Staff Analysis and Conclusion

MHCC staff notes that 11 primary PCI cases is a target rather than a strict standard. MHCC staff reviewed the information submitted by WOMC for the period from January 2015 through December 2019. MHCC staff also analyzed the ACC-NCDR Cath PCI registry data. This analysis is consistent with the information provided by WOMC that two physicians performed less than 11 primary PCI procedures for two years of the review period, and two physicians performed less than 11 primary PCI procedures for all four years of the review period.

MHCC staff concludes that WOMC meets this standard.

Patient Selection

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for appropriate patients, as described in Expert Guidelines for hospitals with and without cardiac surgery on-site.

WOMC stated that its external reviews have not identified any cases as inappropriate.

Staff Analysis and Conclusion

Staff reviewed external review reports between September 2014 and August 2020 and notes that seven 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. Four of the seven cases identified as inappropriate by at least one criteria were performed between March 2015 and August 2016. For two of the seven cases, the chair of the Cardiac Catheterization Peer Review Committee discussed the cases with the operators for the cases. For three other cases performed between March 2019 and February 2020, the CCL director, Dr. Chen discussed the cases with the operator. All results from the external reviews conducted by CCCL were also reviewed at Cardiac Catheterization Peer Review meetings.

MHCC staff concludes that WOMC 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 Expert Guidelines.***
- (b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician (s) reasonably concludes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.***
- (c) Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.***
- (d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) reasonably concludes that transfer to a tertiary institution may be harmful to the patient.***

The application stated that WOMC has not encountered a patient who received primary PCI services inappropriately from 2015 Q1 to 2019 Q2 based on internal review. WOMC also reported that from 2015 Q1 to 2018 Q1 there were three cases of failed thrombolytic therapy at WOMC, formerly Washington Adventist Hospital.

Staff Analysis and Conclusions

MHCC staff concludes that WOMC complies with the standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff recommends that the Commission find that WOMC meets all 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 WOMC to continue providing primary and elective percutaneous coronary intervention services for four years subject to the following conditions:

1. WOMC shall hold bi-monthly interventional case review meetings, as required in COMAR 10.24.17.07D(5)(a) and shall submit to Commission staff attendance lists for each of these meetings held between January and June by August 1 of each year and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2023. After this date, the Executive Director may release WOMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition; and
2. WOMC shall hold monthly multiple care area group meetings, as required in COMAR 10.24.17.07D(5)(b) and shall submit to Commission staff attendance lists for each of these meetings held between January and June by August 1 of each year and attendance lists for meetings held between July and December by February 1 of each year until at least February 1, 2023. After this date, the Executive Director may release WOMC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.