IN THE MATTER OF	*	**BEFORE THE**
ANNE ARUNDEL	*	**MARYLAND**
MEDICAL CENTER	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 19-02-CP010	*	

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STAFF REPORT AND RECOMMENDATION

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

July 16, 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 (non-primary) 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

Anne Arundel Medical Center

Anne Arundel Medical Center (AAMC) is a 349-bed general hospital located in Annapolis (Anne Arundel County). AAMC does not have a cardiac surgery program on site.

AAMC began providing primary PCI services under a research waiver in 2002 through participation in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials. Subsequently, the hospital was authorized to provide primary PCI on a regular basis, subject to ongoing performance requirements and periodic waiver renewal. AAMC last applied for a primary PCI waiver in February 2013 and the two-year waiver was issued on May 16, 2013. On December 31, 2008, the Commission granted a two-year research waiver to AAMC to participate in the Atlantic Cardiovascular Patient Outcomes Research Team Trial: Elective Angioplasty Study (C-PORT E). The C-PORT E study concluded enrollment on March 31, 2011 and MHCC released applications in April 2011 for hospitals with existing C-PORT E research waivers to seek continuation through participation in a follow-on elective PCI registry. AAMC filed its application on April 15, 2011 and the waiver was approved in November 2011. Currently, AAMC provides primary and elective PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. AAMC is in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties and Baltimore City. Fourteen hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; all the other programs provide both primary and elective PCI services. Five of the fourteen hospitals also provide cardiac surgery services, and one additional hospital in this region has a Certificate of Need to establish a cardiac surgery program.

Staff Recommendation

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

II. PRODEDURAL HISTORY

AAMC filed a Certificate of Ongoing Performance application on March 22, 2019. MHCC staff reviewed the application and requested additional information on February 11, 2020, April 7, 2020, and June 19, 2020. AAMC submitted additional information on March 3, 2020, March 28, 2020, June 4, 2020, and June 30, 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.

AAMC participates in the American College of Cardiology (ACC)-NCDR registry and submits duplicate information to MHCC. AAMC stated that there have been no deficiencies in data collection or reporting communicated to AAMC.

Staff Analysis and Conclusion

AAMC 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 the ACC-NCDR CathPCI 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 AAMC's data reported during the audit period.

MHCC staff concludes that AAMC 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.

AAMC stated that in October 2015, its interventional program expanded from two rooms to three rooms for cardiac catheterization procedures. From March 2016 through June 2016, AAMC closed one of the three laboratory rooms for modernization and equipment upgrades; the other two remained in operation. AAMC states that all cardiac catheterization labs have regular hours of operation from Monday through Friday, from 7am-5:30pm, except holidays. After regular hours of operation and on weekends and holidays, the rooms are available on-call. Between January 1, 2015 and February 8, 2018, downtimes for individual rooms did not result in

interruption of AAMC primary PCI services, except once. On February 8, 2018, AAMC had a planned interruption of services due to the need to move services connected to the MACLAB monitoring system. The interruption lasted for one hour, and AAMC notified the appropriate agencies and organizations, including MHCC, Maryland Institute for Emergency Medical Services Systems (MIEMSS), and local emergency medical services. AAMC also planned for how to handle walk-in or inpatient STEMI patients. AAMC provided a detailed list of downtimes, service, and repair for rooms in the cardiac catheterization laboratory (CCL) for the period January 1, 2015 through December 31, 2018, as shown in Table 1.

Table 1: AAMC CCL Downtime by Room

Room	Date	Duration of Closure	Reason/Explanation
4	4/22/15	3 hours	Preventative maintenance
4	1/7/16	3 hours	Chiller repair
4	3/31/16	2.8 hours	Rotor board replaced
4	4/19/16	6.5 hours	Replacement part for chiller
4	4/19/16	2 hours	Preventative maintenance
4	5/25/16	5.5 hours	Collimator blade not working; replaced motor
4	7/12/16	5.5 hours	Vertical positioner not working; recalibrated
4	8/23/16	3 hours	Vertical positioner replaced
4	8/25/16	3 hours	C-arm motor control switch replaced
4	10/1/16	3.5 hours	Preventative maintenance
4	10/17/16	1 hours	Preventative maintenance
4	10/17/16	3 hours	Preventative maintenance
4	2/6/17	2.75 hours	Chiller repair
5	2/23/15	2 hours	Smart box replaced
5	2/14/15	4 hours	Preventative maintenance
5	3/23/15	3 hours	Joystick replaced
5	6/8/15	6 hours	Reboot failure
5	8/16/15	4.5 hours	Preventative maintenance
5	9/3/15	6 hours	Software issue; Windows reinstalled
5	3/9/16	48 days	Closed for renovation and updates
5	8/25/16	5.5 hours	Gantry problem
5	9/5/16	4 hours	Replaced drive
5	11/19/16	3.5 hours	Preventative maintenance
5	4/7/17	7 days	Construction on unit below
6	2/4/16	4 hours	Full disc message – storage problems
6	6/23/16	2 hours	Full disc message
6	7/26/16	2 hours	Disc full message boot – disc failure
6	10/20/16	1 hours	Foot pedal issues
6	10/25/16	2 hours	Disc full message, unable to archive images
6	6/11/18	2.5 hours	Unable to boot MACLAB; GE service hard drive
6	6/25/18	8 hours	MACLAB shut down during case; patient moved
6	7/23/18	4 hours	Scheduled maintenance; new tube installed
6	8/24/18	1 hours	MACLAB interface to monitor is blank
6	12/19/18	0.5 hours	MACLAB did not boot after weekly shutdown
6	12/19/18	3 hours	Chiller failure; room temperature correction

Source: AAMC application, Q2.

Staff Analysis and Conclusion

MHCC staff reviewed the table of CCL closures from January 2015 and beyond. MHCC staff concludes that AAMC 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.

AAMC provided a signed statement from Victoria W. Bayless, the hospital President and Chief Executive Officer, stating that AAMC is dedicated to a reperfusion strategy of primary PCI for STEMI not to exceed 90 minutes from patient arrival for at least 75% of appropriate patients. AAMC's application states that in 2013, AAMC's cardiac multidisciplinary team committed to improving door-to-balloon times by setting an internal door-to-balloon (DTB) goal of less than or equal to 60 minutes for 75% of STEMI arrivals. This team proposed the development of standard operating procedures that would restructure and simplify processes for patients who arrive for STEMI care. The impetus for these changes was that, for CY 2012, AAMC found that 76% of the off-hour arrivals did not meet the 60 minutes or less DTB goal compared to 24% of the day shift arrivals.

AAMC reported further modifications to the process for handling STEMI patients in subsequent years to improve efficiency and maintain quality of care. Changes were made after consulting with referring institutions such that the on-call interventional cardiologist is not always the first physician called for the STEMI patient. AAMC sought to develop mutually agreed upon protocols with referral institutions. AAMC sends real time feedback with case reviews and data metrics for all STEMI cases transferred from Shore Health Systems. AAMC also increased the size of their on-call team in October 2016.

As shown in Table 2, AAMC provided quarterly percentages of non-transfer patients who received PCI within 90 minutes and case counts for January 2015 through June 2019. AAMC also provided quarterly percentages and case counts for transfer cases that were 120 minutes or less for January 2015 through June 2019.

Table 2: AAMC Reported Compliance with DTB Benchmark by Quarter January 2015- June 2019

	Non-Transfer Cases			Transfer Cases		
Quarter	PCI w/in 90 min.	Total Primary PCI cases	Percentage DTB 90 min. or Less	PCI w/in 120 min.	Total Primary PCI cases	Percentage DTB 120 min. or Less
CY2015 Q1	34	36	94%	2	2	100%
CY2015 Q2	29	31	94%	3	3	100%
CY2015 Q3	21	23	91%	3	3	100%
CY2015 Q4	30	30	100%	3	3	100%
CY2016 Q1	21	23	91%	1	2	50%
CY2016 Q2	21	22	95%	1	1	100%
CY2016 Q3	20	21	95%	2	2	100%
CY2016 Q4	23	26	88%	1	1	100%
CY2017 Q1	28	29	97%	2	3	67%
CY2017 Q2	39	39	100%	1	1	100%
CY2017 Q3	31	32	97%	2	2	100%
CY2017 Q4	29	29	100%	2	2	100%
CY2018 Q1	23	29	89%	n/a	0	n/a
CY2018 Q2	24	28	86%	n/a	0	n/a
CY2018 Q3	32	35	91%	1	1	100%
CY2018 Q4	34	35	97%	n/a	0	n/a
CY2019 Q1	28	29	97%	1	1	100%
CY2019 Q2	27	32	84%	1	1	100%

Source: AAMC Application, updated Q4

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases and found that AAMC met the door-to-balloon time standard in quarters, as shown in Table 3. MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, AAMC complied with this standard, with between 92% and 96% of PCI cases meeting the door-to-balloon time standard over rolling eight-quarter periods, as shown in Table 3A.

Regarding transfer cases, MHCC staff also analyzed the ACC-NCDR CathPCI data and found that in most quarters the DTB time was less than 120 minutes, which is the appropriate benchmark for transfer cases. Staff's analysis is consistent with the information reported by AAMC, as shown in Table 3B.

MHCC staff concludes that AAMC complies with this standard.

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

Quarter				Rolling 8-Quarters		
Time Period	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes
2015q1	36	33	91.7%			
2015q2	31	29	93.5%			
2015q3	30	27	90.0%			
2015q4	32	30	93.8%			
2016q1	28	23	82.1%			
2016q2	27	27	100.0%			
2016q3	22	21	95.5%			
2016q4	29	26	89.7%	235	216	92%
2017q1	32	31	96.9%	231	214	93%
2017q2	41	40	97.6%	241	225	93%
2017q3	30	30	100.0%	241	228	95%
2017q4	30	30	100.0%	239	228	95%
2018q1	27	24	88.9%	238	229	96%
2018q2	29	23	79.3%	240	225	94%
2018q3	33	29	87.9%	251	233	93%
2018q4	33	32	97.0%	255	239	94%

Source: MHCC staff analysis of ACC-NCDR CathPCI registry data, CY 2015- CY 2018.
Note: Calculations for each quarter are based on the procedure date.

Table 3B: AAMC Transfer Primary PCI Case Volume and Percentage of Cases With DTB Less Than or Equal to 90 Minutes, by Quarter

Quarter	Total Primary PCI Volume	Cases With DTB <=120 Minutes	Percent of Cases With DTB <=120 Minutes
2015q1	2	2	100.0%
2015q2	2	2	100.0%
2015q3	4	3	75.0%
2015q4	4	4	100.0%
2016q1	2	1	50.0%
2016q2	2	2	100.0%
2016q3	1	1	100.0%
2016q4	2	2	100.0%
2017q1	3	2	66.7%
2017q2	1	1	100.0%
2017q3	3	1	33.3%
2017q4	3	2	66.7%
2018q1	0	n/a	n/a
2018q2	0	n/a	n/a
2018q3	1	1	100.0%
2018q4	0	n/a	n/a

Source: MHCC staff analysis of ACC-NCDR CathPCI registry data, CY 2015- CY 2018.
Note: Calculations for each quarter are based on the procedure date.

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

AAMC provided the number of physicians, nurses, and technicians who provide cardiac catheterization services to acute myocardial infarction patients as of one week before the due date of the application, as shown in Table 4A. AAMC also stated that the staffing reported is consistent with the typical staffing levels for the AAMC CCL.

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

Staff Category	FTEs	Cross Training (S/C/M)
Physician	3.4 FTEs	
Nurse	7.5 (FTE)	M, C
Technician	6.0 (FTE)	S, M

Source: AAMC application, Q6a
Notes: AAMC also has one contingent part-time employee; cross training abbreviations are: scrub (S), circulate (C), monitor (M)

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by AAMC to information reported in AAMC's 2013 waiver application for primary PCI services. In 2013, AAMC reported having seven interventionalists, 5.0 nurse FTEs and 4.6 technician FTEs. Staff also compared AAMC staffing levels for its CCL to the staffing levels at four other hospitals, as reported in each hospital's application for a Certificate of Ongoing Performance. As shown in Table 4B, St. Agnes had a similar level of PCI volume to AAMC and the FTEs for nurse and technical staff are similar. The PCI volume for the University of Maryland Baltimore Washington Medical Center is lower than the PCI volume for AAMC and staffing is lower too. Both the University of Maryland Upper Chesapeake Medical Center and the University of Maryland Medical Center have a higher volume of PCI services compared to AAMC, and a higher level of staffing compared to AAMC.

Table 4B: CCL Staffing, AAMC and Select Other PCI Programs, 2019

Program & Year Reported	2018 Total PCI Volume	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
AAMC 2019	447	3.4 FTEs	7.5	6.0
Saint Agnes Hospital 2019	465	N = 4	7.2	5.0
University of Maryland Baltimore Washington Medical Center 2019	315	N = 3	5.0	5.0
University of Maryland Upper Chesapeake Medical Center 2019	517	N = 4	12.05	6.9
University of Maryland Medical Center 2019	515	N = 10	11.0	7.5

Sources: Anne Arundel Hospital 2019 PCI Certificate of Ongoing Performance Application, Saint Agnes Hospital 2019 PCI Certificate of Ongoing Performance Application, University of Maryland Baltimore Washington Medical Center 2019 PCI Certificate of Ongoing Performance Application, University of Maryland Upper Chesapeake Medical Center 2019 PCI Certificate of Ongoing Performance Application, University of Maryland Medical Center 2019 PCI Certificate of Ongoing Performance Application.

MHCC staff concludes that there is adequate nursing and technical staff to provide services; AAMC 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.

AAMC provided a signed letter of commitment from Victoria W. Bayless, President and Chief Executive Officer, acknowledging that AAMC will provide primary PCI services in accordance with requirements established by the MHCC. In her letter, Ms. Bayless states that the administration of AAMC pledges to allocate staff, funding, and resources necessary to continue to deliver this service to the community.

Staff Analysis and Conclusion

MHCC staff concludes that AAMC 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.

AAMC provided a description of the staff involved with these functions. The 1.0 FTE Cardiac Program Coordinator is responsible for the ongoing development of the cardiac program with the goal of ensuring the provision of high quality, cost-effective health care. The coordinator will integrate, monitor, and analyze all data relevant to primary and elective angioplasty and other cardiac patients and provide a communication link among the interdisciplinary team. The coordinator is also responsible for assisting in the development, implementation, and evaluation of the cardiac program services with the goals of maintaining and enhancing the quality of care delivered to patients and ensuring compliance with MHCC, MIEMSS and ACC Chest Pain Center with PCI standards. AAMC also describes the role of the 1.0 FTE Performance Improvement Nurse, Patient Quality and Safety RN (PI Nurse). The PI Nurse collects and analyzes data related to performance improvement, and outcomes management. The PI nurse abstracts data from the medical record and other sources onto the following abstracts: NCDR ACTION Registry, GWTG, CathPCI Registry and Mission Lifeline. The PI Nurse is an active member of AAMC's multidisciplinary cardiac team and works collaboratively with support staff and medical staff to assure completed, reliable, and valid data abstraction and reporting. In addition, the PI Nurse assists with quality improvement projects and related activities within the Cardiac Interventional Program.

Staff Analysis and Conclusion

Based on this information, MHCC staff concludes that AAMC is compliant with this standard.

10.24.17.07D(4)(f) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

Dr. Scott M. Katzen, Interventional Cardiologist, was appointed at the Medical Director of the CCL at AAMC on January 12, 2017. Prior to Dr. Katzen's appointment, Dr. Jonathan Altschuler, Interventional Cardiologist, was the Medical Director of the CCL beginning in 2002, at the time of program inception. The Medical Director of the CCL is responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management and administrative oversight. The medical director is responsible for the equipment, personnel, and physician call schedules and serves as the contact person for all clinical and administrative issues that relate to interventional cardiology. The medical director is also

responsible for approving privileges for primary PCI, selecting new providers, and oversight of all procedures. All angiographic cases performed in the CCL are reviewed by the medical director. The medical director also leads or attends several meetings or conferences and reports CCL quality and performance metrics to Medicine Quality, Executive Quality, and the Cardiac Advisory Committee.

Staff Analysis and Conclusion

MHCC staff concludes that AAMC is compliant 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.

AAMC provided a list of internal continuing educational programs held between January 2015 and December 2018. AAMC also reported that there is no minimum number of continuing education credits required for staff. However, there are annual mandatory educations modules for all hospital employees as well as clinical and non-clinical education modules for all registered nurses in the adult hospital pavilion. There are also mandatory annual education and skill requirements for staff working in areas specific to the care of patients with acute coronary syndrome.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that AAMC 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 PCl, for hospitals performing primary PCI without on-site cardiac surgery.

AAMC submitted a signed and dated transfer agreement with Washington Hospital Center (WHC). This agreement includes an addendum that underlines the responsibility of WHC to accept unconditionally the transfer of patients enrolled in the PCI program for any required additional care, including emergent or elective cardiac surgery or PCI. This addendum is signed by Linda C. Holmgren, Chief Operating Officer, AAMC, Janis M. Orlowski, M.D., Senior Vice President, Medical Affairs, and Chief Medical Office, WHC, and Mark Smith, M.D., Director of Emergency Services, WHC.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that AAMC 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.

Sherry B. Perkins, COO/CNO, signed an agreement with Washington Hospital Center, MedStar Transport Service stating that helicopter transportation will arrive at AAMC within thirty minutes of request for transport with the exception of weather limitations, aircraft maintenance, or multiple flight requests. AAMC also submitted an agreement with Procare Ambulance of Maryland signed by William A. Chapelle, Director, Supply Chain Corporation, stating that in an emergent situation, emergency response at any level means an immediate response where the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the request.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement submitted by AAMC. Staff determined that the agreement with MedStar Transport Service is sufficient to comply with the standard. While the agreement with Procare Ambulance of Maryland does not guarantee arrival within thirty minutes, AAMC uses Procare ground transportation as a back-up to helicopter transport. AAMC also submitted an agreement with All American Ambulance and Transport, initiated in 1995; All American Ambulance and Transport also serves as a backup for AAMC.

MHCC staff concludes that AAMC complies with 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.

AAMC stated that the AAMC Interventional Cardiology Mortality and Morbidity Conference convenes on the 4th Thursday of every month, with limited exceptions. This conference is open to all AAMC RN, RT, and medical staff. AAMC reported that this meeting is well attended by cardiologists, nurses, and technicians who care for interventional cardiac patients. AAMC provided a table identifying the dates of Interventional Cardiology Mortality and Morbidity Conference between January 2015 and January 2019.

Staff Analysis and Conclusion

AAMC holds monthly case review meetings that include a review of PCI cases. The Medical Director of the CCL and the interventional cardiologists are present for reviews. Although some monthly meetings were cancelled, meetings were still held at least every other month.

MHCC staff concludes that AAMC complies with this standard.

10.24.17.07D(5)(b) A hospital shall create a multiple care area group (emergency department,

coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

AAMC's Cardiac Interventional Work Group meets monthly and is responsible for providing executive level oversight of the PCI programs and for ensuring that compliance with requirements for MHCC, MIEMSS, and the ACC. AAMC submitted meeting dates and attendance information for meetings in 2015 through 2018.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation provided and noted that several monthly meetings had been cancelled. AAMC explained that the Cardiac Interventional Workgroup is scheduled to meet monthly, with limited exceptions. In CY 2014 through CY 2018, these instances included illness, travel, offsite conferences, an offsite visit Same Day Discharge for Cath PCI, and STEMI activation. MHCC staff observed that several meetings were cancelled in 2018 (i.e. January, March, July, and August). AAMC responded that these meetings were cancelled due to conflict with Cardiac Surgery Work Plan meetings. The Cardiac Interventional Workgroup has changed dates and times to avoid further conflict.

MHCC staff concludes that AAMC satisfied the requirements in the 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.

AAMC submitted copies of external review reports for PCI cases performed between January 2015 and June 2019. The external review organization, the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), has been approved by MHCC as an external review organization that meets the requirements in COMAR 10.24.17 for conducting external reviews of PCI cases.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 5. Although only 5% of cases are required to be reviewed, beginning in the second half of 2015, a minimum number of cases to be reviewed for each interventionalist was specified in COMAR 10.24.17. MHCC staff analyzed the ACC-NCDR CathPCI to confirm that when less than three cases were reviewed in a review cycle, it was because the interventionalist performed less than three cases. As shown in Table 5, between 10% and 14% of cases were reviewed for each review cycle, and for each interventionalist, at least the minimum number of cases was evaluated in each review cycle.

MHCC staff concludes that AAMC complies with this standard.

Table 5: AAMC External Review, January 2015- June 2019

Time Period	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2015	285	29	10%	Semi-annually	Yes
CY 2016	260	26	10%	Semi-annually	Yes
CY 2017	272	37	14%	Semi-annually	Yes
CY 2018	315	32	10%	Semi-annually	Yes
2019 Q1Q2	126	13	10%	Semi-annually	Yes

Source: MHCC analysis of ACC-NCDR CathPCI data; AAMC application; AAMC response to MHCC June 30, 2020 questions; and MACPAQ Reports

* Each review cycle contained three cases per physician or all cases if an interventionalist performed fewer than three cases during the review period.

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

(i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or

(ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than 3 cases during the relevant period, as provided in Regulation .08; or

(iii) A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraphs .07C(4)(d)(i).

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

(i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or

(ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of

PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08*; *or

(iii) For a hospital with both primary and elective PCI programs, a quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraphs .07C(4)(c) and .07D(5)(c).

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

(i) Include a review of angiographic images, medical test results, and patients' medical records; and

(ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.

In addition to external review, PCI cases are reviewed internally at the monthly Interventional Cardiology Mortality and Morbidity (M&M) Conferences. The CCL Medical Director selects primary and elective cases for review. Case selection for review at M&M conferences are not random; however, cases with potential concerns are reviewed. For example, cases where DTB times exceed 90 minutes, complications, and complex cases are a priority to review too. The AAMC Quality Review Program for PCI states that all cases are reviewed retrospectively by the CCL Medical Director, and the Cardiac Program Coordinator reviews primary PCI patient information including EMS provider documentation. Cases needing further review are referred to AAMC's Quality Review Panel.

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 cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of cases to be reviewed to satisfy the requirements for review of individual interventionalists. The bulletin states that a semi-annual review of at least three cases or 10% of cases, whichever is greater, per interventionalist, as part of an external review meets the standard, and the requirements in COMAR 10.24.17.07D(5)(c) are equivalent to those in COMAR 10.24.17.07C(4)(d).[1]

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

At least six cases per interventionalist were reviewed per year, as applicable, and additional cases were reviewed via internal review. Through the additional internal review of cases, at least 10% of cases per interventionalist were reviewed annually, as required. The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records.

MHCC staff concludes that AAMC satisfactorily conducts individual interventionalist review as stated in COMAR 10.24.17.07C(4)(d) and described in the October 2015 bulletin, with respect to COMAR 10.24.17.07D(5)(c).[2]

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

AAMC submitted an affidavit from Tori Bayless, Chief Executive Officer, 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 review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that AAMC complies with this standard.

10.24.17.07D (5)(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review cases.

(i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.

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

(iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

AAMC holds a Cardiac Interventionalist Meeting bimonthly. This meeting involves a focused examination of external review findings, intra- and post-procedural complications, and in-hospital mortality. AAMC provided meeting minutes for meetings held between January 2016 and

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

December 2018. Additionally, AAMC provided a copy of the CCL Quality Review Program Policy.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and observed that AAMC documented several quality improvement initiatives in meeting minutes. The meeting minutes also document discussion about external review reports and outcomes over time.

AAMC complies with this standard.

Patient Outcome Measures

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.

AAMC submitted adjusted mortality rates by rolling 12-month reporting period for 2015 Q1 through 2019 Q2 when available, as shown in Table 6. These data are not available for any hospitals participating in the ACC-NCDR CathPCI data registry for the rolling 12-month period of 2017 Q3 through 2018 Q2.

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

	STEMI				NONSTEMI			
Reporting Period	**Hospital AMR**	**95% CI**	**National AMR**	**Meets MHCC Standard**	**Hospital AMR**	**95% CI**	**National AMR**	**Meets MHCC Standard**
2018q3-2019q2	3.76	[1.23, 8.54]	6.38	Yes	0.68	[0.02, 3.76]	1.00	Yes
2018q2-2019q1	3.81	[1.25, 8.66]	6.13	Yes	NR	[0.00, 2.8]	0.99	Yes
2018q1-2018q4	5.46	[2.39, 10.42]	6.00	Yes	NR	[0.00, 2.44]	1.00	Yes
2017q4-2018q3	4.55	[1.25, 11.35]	6.54	Yes	NR	[0.00, 2.46]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry							
2017q2-2018q1	6.49	[1.78, 16.22]	6.91	Yes	1.94	[0.4, 5.61]	1.03	Yes
2017q1-2017q4	1.79	[0.05, 9.81]	6.86	Yes	1.89	[0.39, 5.45]	0.99	Yes
2016q4-2017q3	4.51	[0.93, 12.89]	6.75	Yes	2.44	[0.67, 6.16]	0.98	Yes
2016q3-2017q2	4.15	[0.86, 11.82]	6.64	Yes	0.97	[0.02, 5.38]	0.95	Yes
2016q2-2017q3	4.85	[1.33, 12.05]	6.77	Yes	0.63	[0.02, 3.46]	0.97	Yes
2016q1-2017q4	7.09	[2.64, 14.91]	6.82	Yes	0.71	[0.02, 3.92]	0.95	Yes
2015q4-2016q3	6.98	[2.60, 14.69]	6.71	Yes	NR	[0.00, 2.77]	0.95	Yes
2015q3-2016q2	7.42	[3.25, 14.12]	6.66	Yes	NR	[0.00, 2.21]	0.93	Yes
2015q2-2016q1	7.19	[3.15, 13.71]	6.45	Yes	NR	[0.00 2.94]	0.90	Yes
2015q1-2015q4	6.95	[2.84, 13.74]	6.26	Yes	NR	[0.00 3,75]	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 June 2019.

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 as long as the hospital's 95% confidence interval (CI) includes the National AMR or indicates 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

This standard is not applicable for the majority of the review period for AAMC'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 were 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. However, MHCC staff has provided information below on how AAMC performed over the period between January 2015 and June 2019.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for both STEMI and NONSTEMI cases 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 AAMC for all 12-month reporting periods between 2015 Q1 and 2019 Q2, when the hospital had an adjusted mortality rate. For the NSTEMI patients, AAMC had no deaths for half the reporting periods shown in Table 6. When a hospital has no deaths during a reporting period, then no adjusted mortality rate is reported. MHCC staff concludes that AAMC would have met this standard, if it was applicable for the period reviewed. A report for the hospital's performance for the period ending December 2019, will be the first period for which the current standard applies.

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.

AAMC submitted a log of primary and elective PCI cases at the applicant hospital as well as at other hospitals by quarter. Drs. Altschuler (2015 and 2016), Treuth (2015 and 2016), Mahidhar (2015, 2016, and Q1 2017), Reineck (2015 through 2018), Katzen (2015 through 2018), Czarny (2017 and 2018), and Ginsberg (2017 and 2018) signed and dated affidavits affirming under penalties of perjury that the information contained in the table on their form is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed reported physician volumes for Drs. Altschuler, Treuth, Mahidhar, Reineck, Katzen, Czarny, and Ginsberg and analyzed the ACC-NCDR CathPCI data. MHCC staff determined that while practicing at AAMC, these interventionalists performed a minimum of 50 PCI procedures annually on average over a 24-month period. For interventionalists who performed less than 50 PCI procedures annually on average at AAMC, the interventionalists performed procedures at AAMC for less than 24-months.

AAMC 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.

AAMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to AAMC. While AAMC does not have on-site cardiac surgery each physician performing primary PCI performed 50 PCI procedures annually averages 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.

AAMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

While AAMC does not have on-site cardiac surgery each physician performing primary PCI performed 50 PCI procedures annually on average 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.

AAMC submitted a signed and dated statement from Dr. Scott Katzen, Medical Director of the CCL, acknowledging that all physicians performing primary PCI services during the review period at AAMC are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the letter provided and concludes that AAMC 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.

AAMC submitted signed and dated attestations from Dr. Elizabeth Reineck, Dr. Matthew Czarny, Dr. Eric Ginsberg, Dr. Scott Katzen, and Dr. Mark Treuth, stating he/she has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years. Drs. Altschuler and Mahidar no longer perform PCI at AAMC; therefore, AAMC did not submit continuing education credit attestations for these interventionalists.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that AAMC meets this standard.

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

AAMC submitted a signed statement from the Medical Director of the CCL, Dr. Scott Katzen, acknowledging that each physician who has performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. AAMC also submitted a copy of the on-call schedule from July 2018 through February 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for from July 2018 through February 2019 and observed that Dr. Elizabeth Reineck, Dr. Matthew Czarny, Dr. Eric Ginsberg, and Dr. Scott Katzen were all scheduled to be on-call at different times during the month. Dr. Trueth does not appear on the on-call schedules; Dr. Trueth no longer performs PCI at AAMC.

MHCC staff concludes that AAMC meets this standard.

<u>Volume</u>

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.

AAMC provided the total case volume by calendar year for 2015 through 2018, as shown in Table 7. AAMC also provided the volumes for quarters three and four in 2014.

Table 7: AAMC PCI Volume

Calendar Year	Total PCI
2015	438
2016	369
2017	429
2018	447
2019	374

Source: AMCC Application, Q28, Updated Q28

Staff Analysis and Conclusion

MHCC staff reviewed the table submitted by AAMC. For calendar years 2015 through 2019, the CCL had a total of between 369 and 447 cases per year. Staff determined at least 200 PCI procedures were completed per year, on a rolling four quarter basis, during this time period.

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.

AAMC responded that this regulation is not applicable and provided data that shows over 100 primary PCI cases were performed each year between CY 2015 and CY 2019.

Table 8: AAMC Primary PCI Volume, CY 2015- CY 2018

Year	Number of Cases
CY 2015	144
CY 2016	113
CY 2017	149
CY 2018	130
CY 2019	140

Source: AAMC response to MHCC questions, June 30, 2020.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2018. This analysis is consistent with the volume reported by AAMC, and it confirms that AAMC exceeded the threshold of 49 cases annually referenced in the standard.

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

AAMC provided the number of primary PCI cases by interventionalist from September 2014 to December 2018.

Staff Analysis and Conclusion

MHCC staff analyzed the data in the ACC-NCDR CathPCI registry for CY 2015 to CY 2018 and concluded that each interventionalist met the target of 11 or more primary PCI cases annually for calendar years 2015 through 2018, as applicable, when the interventionalist performed cases at AAMC over the entire 12-month period. One interventionalist performed only seven primary PCI cases in one calendar year, but the interventionalist performed PCI cases at AAMC for less than half of that year.

MHCC staff concludes that AAMC 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 Guidelines for Percutaneous Coronary Intervention, are not suitable for elective PCI.

AAMC provided external review reports of elective PCI cases from January 2015 through June 2019. The hospital also provided a summary of the appropriateness determinations for July 2014 through December 2017 and noted that two cases in 2016 were found to be rarely appropriate based on angiographic criteria. The reviewer also disagreed with use of IVUS to measure severity of the lesions. AAMC noted that at the time of the peer review meeting to review the MACPAQ report, the interventionalist responsible for those two cases was no longer providing PCI services at AAMC.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from 2015 through June 2019. With the exception of two cases in 2016, there were no cases determined to be "rarely appropriate" with respect to clinical criteria, angiographic criteria, or ACC/AHA appropriateness criteria.

MHCC staff concludes that AAMC 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

AAMC responded that during the review period, there have been no cases in which a patient received primary PCI inappropriately. Additionally, AAMC responded that no patients received thrombolytic therapy that subsequently failed during the review period.

Staff Analysis and Conclusion

MHCC staff determines that AAMC complies with the standard.

RECOMMENDATION

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