

**IN THE MATTER OF**  
  
**SUBURBAN HOSPITAL**

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

**Docket No.: 19-15-CP031**

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

**October 21, 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 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 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**

### **Suburban Hospital**

Suburban Hospital (Suburban) is a 228-bed general hospital located in Bethesda (Montgomery County). Suburban 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. Suburban is in the Metropolitan Washington health planning region. This region includes Calvert, Charles, Frederick, Montgomery, Prince George's and Saint Mary's Counties and the District of Columbia. Seven Maryland hospitals in this health planning region provide PCI services. One of these programs 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 that provide PCI services also provide cardiac surgery services.

## **C. Staff Recommendation**

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

## **II. PRODEDURAL HISTORY**

Suburban filed a Certificate of Ongoing Performance application on September 21, 2019, in accordance with the review schedule determined by the Commission. MHCC staff reviewed the application and requested additional information on April 22, 2021, April 28, 2021, and August 10, 2021. Additional information was submitted on May 18, 2021, June 17, 2021, and September 13, 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.*

Suburban noted that the Clinical Outcomes Analyst for the NCDR CathPCI Registry is responsible for submitting both quarterly National Cardiovascular Registry data and the quarterly report to the MHCC. Suburban also stated that the hospital has not received notification of any deficiencies in data collection or reporting.

### **Staff Analysis and Conclusion**

Suburban has complied with the submission of ACC-NCDR data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of the ACC-NCDR data to validate that all participating Maryland hospitals submitted accurate and complete information to the ACC-NCDR registry. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of Suburban's data reported during the audit period.

MHCC staff concludes that Suburban 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.*

Suburban stated that the hospital's cardiac catheterization laboratory (CCL) includes three rooms and that the rooms were never taken out of service simultaneously for preventative maintenance. The hospital noted that all episodes of planned maintenance only impact one CCL at a time, and the remaining two CCLs are always available to allow emergent cardiac cases to be performed. Over the review period, Suburban reported that there was downtime on two days in calendar year 2019, which was required for the power transfer to the newly constructed North building and the movement of all power sources to a new control center. Suburban noted that during these periods of downtime, plans were put in place to transfer patients to the Washington Hospital Center as needed. A Lifestar Advanced Cardiac Life Support (ACLS) transfer unit was stationed at Suburban Hospital during the downtime on both April 26, 2019, and May 10, 2019, to facilitate rapid cardiac transfers if needed. Suburban stated the hospital did not have any emergency cases during this time, so activation of these plans was not necessary.

### **Staff Analysis and Conclusion**

MHCC staff reviewed the information provided on closures of the CCLs and determined that the times when PCI services were not available were unavoidable. Staff also reviewed the logs for the maintenance performed on all three of the CCLs provided by Suburban. These logs did not label the maintenance for each CCL, but the hospital has agreed that in the future it will track downtime for individual CCL rooms.

MHCC staff concludes that Suburban 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 DTB times for transfer cases and evaluate areas for improvement.**

Suburban provided a signed statement from Jessica T. Melton, M.H.A, President of Suburban, stating that the hospital commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, and that it commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement.

As shown in Table 2A, the information reported by Suburban indicates that the annual percentage of primary PCI patients with a DTB time of 90 minutes or less ranged from 75% to 100% between January 2015 and December 2019.

**Table 2A: Suburban Reported Compliance with DTB Benchmark by Quarter, January 2015- December 2019**

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	12	11	91.66%
CY2015 Q2	8	6	75.00%
CY2015 Q3	8	8	100.0%
CY2015 Q4	15	12	80.00%
CY2016 Q1	18	16	83.33%
CY2016 Q2	19	16	84.21%
CY2016 Q3	8	6	75.00%
CY2016 Q4	15	10	66.67%
CY2017 Q1	12	10	83.33%
CY2017 Q2	12	10	83.33%
CY2017 Q3	11	10	90.91%
CY2017 Q4	16	13	81.25%
CY2018 Q1	16	15	93.75%
CY2018 Q2	11	11	100.0%
CY2018 Q3	16	16	100.0%
CY2018 Q4	15	15	100.0%
CY2019 Q1	14	13	92.86%
CY2019 Q2	17	13	76.47%
CY2019 Q3	9	8	88.89%
CY2019 Q4	10	9	90.00%

Source: Suburban application, updated Q4.

As shown in Table 2B, Suburban also submitted DTB times for transfer patients who received PCI within 120 minutes for January 2015 through December 2019. Suburban described the steps that the hospital has taken to improve DTB times for transfer patients. Suburban maintains a cardiac access tracking system known as the Beat Line to facilitate urgent cardiac transfers from one healthcare facility to another in a safe and efficient manner. When the Beat Line is connected to facilitate transfer of a primary PCI/STEMI patient, it facilitates physician to physician

communication to ensure safe handover and then makes transportation arrangements in an expeditious manner. This ensures efficiency and safety in patient care.

Suburban also reported that the Beat Line staff have made changes to workflow to improve transport times and provide safe care. For example, Suburban communicates with Sibley Hospital after every transfer event, and both hospitals evaluate areas to improve. Suburban reported that at the end of 2019, it decided to utilize air transport for all transfers to reduce delays. This change did result in shorter transfer times.

**Table 2B: Suburban Transfer DTB Times by Quarter, January 2015- December 2019**

Quarter	Total Primary PCI Volume	Cases with DTB <= 120 minutes	Percent of Cases With DTB <=120 Minutes
CY2015 Q1	5	0	0%
CY2015 Q2	1	0	0%
CY2015 Q3	2	0	0%
CY2015 Q4	2	0	0%
CY2016 Q1	1	0	0%
CY2016 Q2	1	1	100.0%
CY2016 Q3	1	0	0%
CY2016 Q4	1	1	100%
CY2017 Q1	3	0	0%
CY2017 Q2	5	1	20.0%
CY2017 Q3	1	0	0%
CY2017 Q4	3	1	33.3%
CY2018 Q1	5	0	0%
CY2018 Q2	3	0	0%
CY2018 Q3	2	1	50.0%
CY2018 Q4	2	0	0%
CY2019 Q1	1	0	0%
CY2019 Q2	3	0	0%
CY2019 Q3	3	0	0%
CY2019 Q4	4	0	0%

Source: Suburban application, updated Q4.

### Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer ST-elevation myocardial infarction (STEMI) cases and noted that Suburban missed the DTB time standard in several 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 in reviewing compliance with this standard. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital’s performance over longer periods that include multiple quarters.

Suburban provided additional information on cases with DTB time greater than 90 minutes in all quarters prior to 2019 where MHCC staff found that fewer than 75% of cases had a DTB of 90 minutes or less and there was no non-system reason for delay coded in the ACC-NCDR

CathPCI registry. In four cases, the DTB standard was missed by only one minute. In two cases, the DTB was not missed, but data entry errors led to an incorrect calculation of the DTB time. Other reasons for delays included difficult vascular access, patient complications, delays in on-call staff arriving due to traffic, and simultaneous cases in the CCL.

As shown in Table 3, over rolling eight-quarter periods, Suburban complied with this standard in the ten most recent periods, but not in first six periods ending between 2017 Q1 and 2018 Q2. With respect to the hospital's performance during CY 2020, staff notes that an MHCC bulletin issued in March 2020 announced the waiving of specific standards for PCI and cardiac surgery programs, including the door-to-balloon times standard, as part of the state emergency declared on March 5, 2020, in response to the COVID-19 pandemic. Another MHCC bulletin issued in August 2021 states that the calculation of compliance with the door-to-balloon time standard in COMAR 10.24.17.07D(4)(b) will be reported for the period January 2020 through December 2021, but compliance with the standard for that entire period will be waived because the state of emergency spanned 18 months in that period, and it will simplify the periods used for determining compliance to waive the standard for a full 24 continuous months.

MHCC staff concludes that Suburban complies with this standard.

**Table 3: Suburban 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	N/A	N/A	N/A			
2015q2	13	7	53.8%			
2015q3	8	7	87.5%			
2015q4	17	13	76.5%			
2016q1	20	15	75.0%			
2016q2	22	16	72.7%			
2016q3	11	7	63.6%			
2016q4	19	10	52.6%			
2017q1	13	9	69.2%	123	84	68.3%
2017q2	19	14	73.7%	129	91	70.5%
2017q3	16	11	68.8%	137	95	69.3%
2017q4	16	12	75.0%	136	94	69.1%
2018q1	12	11	91.7%	128	90	70.3%
2018q2	16	16	100.0%	122	90	73.8%
2018q3	16	15	93.8%	127	98	77.2%
2018q4	17	15	88.2%	125	103	82.4%
2019q1	15	13	86.7%	127	107	84.3%
2019q2	18	13	72.2%	126	106	84.1%
2019q3	9	8	88.9%	119	103	86.6%
2019q4	12	9	75.0%	115	100	87.0%
2020q1	21	16	76.2%	124	105	84.7%
2020q2	15	11	73.3%	123	100	81.3%
2020q3	9	5	55.6%	116	90	77.6%
2020q4	13	9	69.2%	112	84	75.0%

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2015- CY 2020.

Note: N/A means not available.

***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, Suburban provided the number of physicians, nurses, and technicians who can provide cardiac catheterization services to acute myocardial infarction patients, one week prior to the due date of the application.



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

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	7	
Nurse	5.4 (FTE)	S, C, M
Technician	6.7 (FTE)	S, C, M

Source: Suburban application, Q6a.

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

**Staff Analysis and Conclusion**

MHCC staff compared Suburban’s reported staffing levels to the levels reported by three other hospitals with primary and elective PCI programs and similar PCI case volumes. A comparison of volume and staffing levels for Suburban, Saint Agnes Hospital, Anne Arundel Hospital, Anne Arundel Hospital, and UM Chesapeake Medical Center is shown in Table 4B. MHCC staff observed that Suburban has a lower number of full-time equivalent (FTE) nurses than the three other programs. However, Suburban reported a greater number of technician FTEs than all three programs, with two of the three programs (Saint Agnes Hospital and Anne Arundel Hospital) performing a lower volume of PCI cases than Suburban. UM Chesapeake Medical Center performed a slightly higher volume of PCI cases than Suburban, as shown in Table 4B.

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

Program	Total PCI Volume in Year Prior*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
Suburban 2019	486	N = 7.0	5.4	8.0
Saint Agnes Hospital 2019	465	N = 4.0	7.2	5.0
Anne Arundel Hospital 2019	447	N = 3.4	7.5	6.0
UM Chesapeake Medical Center 2019	517	N = 4.0	12.05	6.9

Sources: Suburban 2019 PCI Certificate of Ongoing Performance application; Saint Agnes Hospital 2019 PCI Certificate of Ongoing Performance application; Anne Arundel Hospital 2019 PCI Certificate of Ongoing Performance application; and UM Chesapeake Medical Center 2019 PCI Certificate of Ongoing Performance application.

\*Volumes for either fiscal or calendar year.

MHCC staff concludes that Suburban has adequate nursing and technical staff to provide services.

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

Suburban provided a signed letter of commitment from Ms. Melton stating that Suburban will provide primary PCI services in accord with the requirements established by the Commission.

**Staff Analysis and Conclusion**

MHCC staff reviewed the letter of commitment provided and concludes that Suburban 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.***

Suburban reported that the hospital retains a Clinical Outcomes Analyst (1.0 FTE) for its CathPCI data registry functions. This role is responsible for data management, reporting, and coordination with institutional quality improvement efforts.

#### **Staff Analysis and Conclusion**

MHCC staff reviewed the information provided and concludes that Suburban 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.***

Gregory Kumkumian, M.D., interventional cardiologist, was appointed as the medical director of the CCL at Suburban in January 2011. Dr. Kumkumian is responsible for the medical oversight of the CCL and ensures that physicians, technologists, and nursing staff are complying with all regulatory requirements as it relates to patient care. In addition, Dr. Kumkumian ensures that the CCL meets all external standards and benchmarks for quality and safety, as applicable.

#### **Staff Analysis and Conclusion**

MHCC staff concludes that Suburban complies with this standard.

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

Suburban provided a list of education activities for staff in the Critical Care Unit and CCL held between January 2015 and December 2019. Specifically, Suburban reported that clinical staff attend yearly annual reviews, which focus on low frequency tasks, high risk tasks, and procedures such as intra-aortic balloon pump and left ventricular assist devices. In addition, clinical staff attend hospital orientation and complete computerized educational offerings and in-services with to maintain clinical competencies.

Annually, all nurses and technicians are assigned mandatory education. This education is determined by either policy mandates, skill level, identified needs, or learning assessments. Suburban noted that ACLS certification is required for all nursing staff with a two-year renewal, and that all staff are certified in basic life support. Suburban described the required annual education modules and reported that the continuing education is provided through online learning, in-services, and skills days. All educational modules and events are tracked in a hospital-wide information technology program.

## **Staff Analysis and Conclusion**

MHCC reviewed the information provided and concludes that Suburban 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.***

Suburban provides on-site cardiac surgery; this standard is not applicable to Suburban.

## **Staff Analysis and Conclusion**

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

***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.***

Suburban provides on-site cardiac surgery; this standard is not applicable to Suburban.

## **Staff Analysis and Conclusion**

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

## **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.***

Suburban provided attendance records for several of the Quality Interventional Cardiac Catheterization (QICC) meetings held between January 2015 and December 2020. Suburban noted that the hospital's QICC team generally meets monthly, although COMAR regulations only require that meetings be held every other month. During these meetings, physicians, nursing staff, cardiovascular technicians, and radiologic technologists review primary and elective PCI cases.

## **Staff Analysis and Conclusion**

MHCC staff reviewed the documentation for the QICC meetings. The documentation submitted by Suburban for QICC meetings included attendance records and meeting minutes for three meetings in 2015, two meetings in 2016, nine meetings in 2017, ten meetings in 2018, nine meetings in 2019, and ten meetings in 2020. Suburban reported that an additional six meetings occurred each year for calendar years 2015 and 2016; however, documentation of these meetings

was unavailable. MHCC staff noted that it appears technicians rarely attended meetings between 2015 and 2018. However, Suburban demonstrated compliance with this standard, in records submitted in both CY 2019 and CY 2020.

MHCC staff recommends that the Commission find that Suburban 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.***

Suburban reported that the hospital's Door to Balloon Committee (DTBC) meets monthly to review ED STEMI cases and compliance in meeting the 90-minute DTB time. The DTBC is composed of physician and nursing representation from ED, critical care cardiology units, cardiovascular interventional lab, quality department, and the BEAT Line. The Montgomery County Fire Department Quality Improvement Officer also participates in these meetings. Suburban provided a list of meeting dates, participants, and meeting notes for meetings held between February 2019 and June 2020. Suburban reported that from 2015 through 2018 informal meetings were held about four to six times per year; however, documentation for many of these meetings was not available. Suburban noted that tracking of attendance and minutes has been identified as an area for improvement.

### **Staff Analysis and Conclusion**

MHCC staff reviewed the documentation provided and noted that attendance records and meeting minutes were missing for several months between CY 2015 through CY 2019. The documentation submitted by Suburban for DTBC meetings included attendance records for one meeting each in 2016 and 2017, five meetings in 2018, nine meetings in 2019, and two meetings in the first half of CY 2020. Additionally, Suburban reported that between four to six informal meetings took place per year from 2015 to 2018, but the meeting minutes and attendance records were not completed for those meetings.

MHCC staff notes that attendance records, when available, show attendance of staff from the CCL, intensive care unit, ED, and CCU. However, during the review period the hospital has often held meetings less often than required and attendance has not been documented.

MHCC staff recommends that the Commission find that Suburban meets this standard and recommends the following condition be included in a Certificate of Ongoing Performance issued to Suburban:

Suburban 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 Suburban 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.***

Suburban submitted information about its external review process, the volume of cases reviewed for individual cardiologists, and external review reports from January 2015 through December 2019. Suburban reported that external review of cases is performed by the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), an MHCC-approved peer review system.

**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 in 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 9.6% and 20.7% of PCI cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed externally.

**Table 5: Suburban External Review of PCI Cases by Year, CY 2015- CY 2019**

<b>Calendar Year</b>	<b>PCI Volume^</b>	<b>Number of Cases Reviewed</b>	<b>Percentage of Cases Reviewed</b>	<b>Review Frequency</b>	<b>Meets Standard*</b>
<b>2015</b>	425	41	9.6%	Annual	Yes
<b>2016</b>	406	84	20.7%	Semi-annual	Yes
<b>2017</b>	376	72	19.1%	Semi-annual	Yes
<b>2018</b>	352	66	17.3%	Semi-annual	Yes
<b>2019</b>	422	60	14.2%	Semi-annual	Yes

Source: MHCC staff analysis of MACPAQ reports.

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

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

In 2016, it appears that one operator should have had an additional case reviewed. The hospital attributed this oversight to a data entry error. Additionally, in 2016 and 2017, there were minor discrepancies between the number of cases reviewed for a few operators. Suburban advised that in one case this discrepancy is largely due to a single procedure performed in tandem with two operators. The hemodynamic system (McKesson) is unable to determine a primary and secondary operator when a single procedure is performed in tandem with two operators. The result is that

one operator was entered into the ACC NCDR CathPCI, while another operator was attributed to the case in the review for MACPAQ.

MHCC staff recommends that the Commission find that Suburban complies with this standard because the deviations from the standard for external review were minor.

***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 described above, Suburban stated that internal review consists of additional random selection of PCI cases including primary and non-primary PCI cases for all interventionalists, in accordance with COMAR 10.24.17.09. Suburban's QICC peer review group meets monthly to conduct internal review of cases selected both randomly and on a non-random basis. In addition, a sampling of all PCI procedures is reviewed to assure appropriateness. If an interventionalist performs greater than 25 cases per year, at a minimum, 10% of cases are reviewed. If the interventionalist performs less than 10 cases per year, all cases are reviewed internally.

### **Staff Analysis and Conclusion**

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number of cases to be reviewed for each interventionalist, but both standards provide 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).<sup>1</sup>

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

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<sup>1</sup>[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiacare/documents/con\\_cardiac\\_csac\\_bulletin\\_pci\\_cases\\_20151020.pdf](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf)

MHCC staff concluded that the minimum number of cases were included in the external review through analysis of the ACC-NCDR CathPCI data submitted for the period January 2015 through December 2019, with a few exceptions, as previously noted. For interventionalists who did not have the required number of cases reviewed externally, MHCC staff requested information about the internal review of those physicians' cases. The information provided by Suburban indicates that the standard for evaluation of individual interventionalists was met through a combination of external and internal review.

MHCC staff concludes that Suburban 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).<sup>2</sup>

***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.***

Suburban submitted an affidavit from Ms. Melton, 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 Suburban 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.***

Suburban provided a description of its processes for quality improvement. Primarily, assurance occurs through the QICC and DTBC meetings. The QICC is a standing committee of the medical staff that meets monthly to discuss and review routine PCI and complications.

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<sup>2</sup> Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the individual interventionalist review requirements.



Suburban noted that cases for peer review are gleaned from several sources and identified cases are screened by the appropriate chair or designee prior to each meeting.

The DTBC meets monthly to review ED STEMI cases and compliance in meeting the 90-minute DTB standard. Suburban explained that this team is tasked with the evaluation of the care of primary PCI/STEMI patients from the time of first contact with Emergency Medical Services (EMS) until receipt of coronary intervention that restores or improves coronary blood flow preventing further heart muscle damage. In addition to the responsibilities listed above, the DTBC is also responsible for establishing and reviewing policies and protocols related to the care of PCI patients, reviewing DTB activation occurrences, investigating cases that exceed DTB times, monitoring and addressing quality and or safety issues, investigating opportunities for quality improvement and reporting data to evaluate performance.

Suburban provided two examples of a quality assurance initiatives carried out by both committees. One example is that in October 2017, the QICC and DTBC determined the need to improve physician response time which negatively affected DTB times. The LEAN process improvement method was utilized with a facilitator to ensure that the group's objectives were met. The group developed physician report cards which track their arrival in the ED within the agreed upon 30-minute time frame. Each event was reviewed with the DTBC, and physician report cards were shared with the group at the QICC meetings. Suburban reported that an immediate outcome of this process change was improved DTB times.

### **Staff Analysis and Conclusion**

MHCC staff reviewed the information on quality assurance activities and concludes that Suburban 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.***

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

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

Reporting Period	STEMI				NONSTEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2020q2- 2021q1	14.07	[6.25, 26.11]	7.55	Yes	1.5	[0.41, 3.81]	1.21	Yes
2020q1- 2020q4	9.79	[4.03, 19.22]	6.89	Yes	0.88	[0.11, 3.14]	1.13	Yes
2019q4-2020q3	6.91	[2.28, 15.45]	6.37	Yes	0.67	[0.08, 2.40]	1.06	Yes
2019q3-2020q2	4.44	[0.93, 12.47]	6.06	Yes	0.41	[0.01, 2.24]	1.00	Yes
2019q2-2020q1	2.59	[0.32, 9.06]	5.99	Yes	0.37	[0.01, 2.05]	0.95	Yes
2019q1-2019q4	4.5	[0.94, 12.60]	6.01	Yes	0.31	[0.01, 1.69]	0.95	Yes
2018q4-2019q3	6.54	[1.81, 16.00]	6.06	Yes	0.52	[0.06, 1.88]	0.98	Yes
2018q3-2019q2	8.38	[2.77, 18.68]	6.38	Yes	1.06	[0.29, 2.68]	1.00	Yes
2018q2-2019q1	11.68	[3.86, 25.90]	6.13	Yes	1.18	[0.38, 2.73]	0.99	Yes
2018q1-2018q4	11.62	[3.84, 25.92]	6.00	Yes	1.35	[0.44, 3.13]	1.00	Yes
2017q4-2018q3	8.17	[1.7, 22.99]	6.54	Yes	1.31	[0.27, 3.80]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry							
2017q2-2018q1	8.4	[3.44, 16.56]	6.91	Yes	1.27	[0.15, 4.54]	1.03	Yes
2017q1-2017q4	8.67	[3.56, 17.03]	6.89	Yes	1.3	[0.16, 4.66]	0.99	Yes
2016q4-2017q3	10.27	[5.07, 17.87]	6.75	Yes	1.86	[0.39, 5.41]	0.98	Yes
2016q3-2017q2	8.48	[3.76, 15.81]	6.64	Yes	1.28	[0.16, 4.59]	0.95	Yes
2016q2-2017q3	7.92	[2.97, 16.38]	6.77	Yes	1.12	[0.14, 4.02]	0.97	Yes
2016q1-2017q4	6.01	[1.98, 13.41]	6.82	Yes	1.05	[0.13, 3.77]	0.95	Yes
2015q4-2016q3	4.64	[1.28, 11.38]	6.71	Yes	0.52	[0.01, 2.90]	0.95	Yes
2015q3-2016q2	4.03	[0.84, 11.32]	6.66	Yes	0.89	[0.11, 3.19]	0.93	Yes
2015q2-2016q1	3.5	[0.43, 12.10]	6.45	Yes	0.52	[0.01, 2.86]	0.90	Yes
2015q1-2015q4	4.48	[0.55, 15.16]	6.26	Yes	0.67	[0.02, 3.69]	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: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark 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 benchmark for STEMI or non-STEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEM and non-STEMI cases for each reporting period.

## **Staff Analysis and Conclusion**

This standard is not applicable for most of the review periods included in Suburban's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar earlier standard referenced a statewide average as the benchmark, as recommended by MHCC's Clinical Advisory Group in 2012. However, MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk-adjusted mortality for the period between January 2015 and December 2018. MHCC staff has provided information in Table 6 that shows Suburban'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 from the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for Suburban for all 12-month reporting periods between January 2015 and March 2021, when an adjusted mortality rate was reported. MHCC staff concludes that Suburban would have met this standard if it had been applicable for the entire period reviewed. 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 Suburban 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.***

Suburban responded that this standard is not applicable because the hospital performs on-site cardiac surgery.

## **Staff Analysis and Conclusion**

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

***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.***

Suburban responded that this regulation is not applicable.

## Staff Analysis and Conclusion

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

***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.***

Suburban responded that this regulation is not applicable.

## Staff Analysis and Conclusion

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

***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.***

Suburban submitted a signed and dated statement from Dr. Kumkumian acknowledging that all physicians performing primary PCI services at Suburban are board certified in interventional cardiology.

## Staff Analysis and Conclusion

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

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

Suburban submitted signed and dated attestations from Drs. Kumkumian, Lieberman, Bigham, Deychak, Bodurian, Flyer, and Marshall stating that each physician has completed a

minimum of 30 hours of continuing medical education credits in interventional cardiology in the last two years.

### **Staff Analysis and Conclusion**

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

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

Suburban submitted a signed statement from Dr. Kumkumian acknowledging that each physician who 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 since January 2015. Suburban also submitted a copy of its on-call schedule for September 2019.

### **Staff Analysis and Conclusion**

MHCC staff reviewed the on-call schedule submitted, information on case volume provided by Suburban, and ACC-NCDR CathPCI registry data.

MHCC staff concludes that Suburban 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.***

Suburban provided PCI case volume information for FY 2015 through FY 2019, as shown in Table 7. This information shows that Suburban performed between 403 and 490 cases annually.

**Table 7: Suburban PCI Volume**

<b>Calendar Year</b>	<b>Total PCI</b>
<b>2015</b>	403
<b>2016</b>	490
<b>2017</b>	475
<b>2018</b>	456
<b>2019</b>	486

Source: Suburban application, updated Q28

**Staff Analysis and Conclusion**

MHCC staff reviewed the PCI case volume information submitted by Suburban and analyzed the ACC-NCDR CathPCI data submitted. Staff determined at least 200 PCI cases were performed on an annual basis over the five fiscal years reviewed (FY 2015-FY 2019).

MHCC staff concludes that Suburban meets 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.*

Suburban provided the number of primary PCI cases by quarter between January 2015 and December 2019.

**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.

**Table 8: Suburban Primary PCI Volume**

<b>Calendar Year</b>	<b>Volume</b>
<b>2015</b>	N/A
<b>2016</b>	93
<b>2017</b>	91
<b>2018</b>	96
<b>2019</b>	89
<b>2020</b>	93

Source: MHCC staff analysis of ACC-NCDR CathPCI Data.

This analysis shows primary PCI case volume ranged from 89 to 96 cases in each year and confirmed that Suburban met the threshold of 49 cases annually referenced in the standard.

MHCC staff determined that this standard does not apply to Suburban.

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

Suburban provided the number of primary PCI cases by interventionalist for 2015 through 2019 for all physicians.

**Staff Analysis and Conclusion**

MHCC staff first notes that 11 primary PCI cases is a target rather than a strict requirement. MHCC staff reviewed the information submitted by Suburban. Staff also analyzed the data in the ACC-NCDR CathPCI registry for CY 2015 through CY 2020 and noted that all but one of the interventionalists performing primary PCI at the hospital in 2019 performed at least 11 primary

PCI procedures in 2019. In 2020, all but two of seven interventionalists who performed primary PCI for at least a year at the hospital performed at least 11 primary PCI procedures in 2020.

MHCC staff concludes that Suburban complies with this standard.

### **Patient Selection**

***10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:***

- (a) Patients described as appropriate elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.***
- (b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, are not suitable for elective PCI.***

Suburban submitted external review reports from CCCL indicating that no patients received elective PCI services inappropriately.

### **Staff Analysis and Conclusion**

MHCC staff reviewed the external review reports from January 2015 through December 2019 and requested additional information on cases performed between January 2015 and June 2019 that were determined to be “rarely appropriate” with respect to one or more of the following: clinical criteria; angiographic criteria; and ACC/AHA appropriateness criteria. Suburban provided additional information about the follow-up on cases deemed rarely appropriate by external review. Suburban stated that all the cases were reviewed by the quality committee during an internal peer review meeting, which included the operators involved with these cases. No trends were identified with these cases.

MHCC staff determines that Suburban complies with the standard.

***10.24.17.07D(9). A hospital shall commit to providing primary PCI services only for suitable patients. Suitable patients are:***

- (a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.***



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

Suburban stated that, over the review period, there were no patients who received thrombolytic therapy. Suburban also reported that no patients received primary PCI services inappropriately based on internal or external review.

#### **Staff Analysis and Conclusions**

MHCC staff determines that Suburban complies with the standard.

#### **RECOMMENDATION**

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

Suburban 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 Suburban from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.