IN THE MATTER OF	*	**BEFORE THE**
ADVENTIST HEALTHCARE	*	**MARYLAND**
SHADY GROVE MEDICAL	*	**HEALTHCARE**
CENTER	*	**COMMISSION**

Docket No.: 19-15-CP030

*** ***

STAFF REPORT AND RECOMMENDATION

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

July 15, 2021

I. INTRODUCTION

A. Background

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

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

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

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

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

authorizes a hospital to continue to provide PCI services, either primary or both primary and elective PCI services, for a specified period of time that cannot exceed five years. At the end of the specified 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

Adventist HealthCare Shady Grove Medical Center

Adventist HealthCare Shady Grove Medical Center (SGMC) is a 329-bed general hospital located in Rockville (Montgomery County) that is part of the Adventist HealthCare system. SGMC does not have a cardiac surgery program on site.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. SGMC 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. Holy Cross Hospital only provides primary PCI services. All the other programs in this health planning region provide both primary and elective PCI services. Three of the seven Maryland hospitals in this health planning region also provide on-site cardiac surgery services.

Staff Recommendation

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

II. PRODEDURAL HISTORY

SGMC filed a Certificate of Ongoing Performance application on October 26, 2020. MHCC staff reviewed the application and requested additional information on March 2, 2021, May 6, 2021, June 16, 2021, and June 25, 2021. MHCC received additional information on March 23, 2021, May 21, 2021, June 28, 2021, and July 2, 2021.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

<u>Data Collection</u>

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.

SGMC responded that there are currently no deficiencies in data collection or reporting that have been identified by MHCC staff.

Staff Analysis and Conclusion

SGMC has complied with the submission of the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of ACC-NCDR CathPCI data to validate that 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 SGMC's data reported during the audit period.

MHCC staff concludes that SGMC 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.

SGMC stated that the hospital's cardiac catheterization laboratory (CCL) includes two CCL rooms that were never taken out of service simultaneously for preventative maintenance, as shown in Table 1. However, over the review period of January 2015 through May 21, 2021, SGMC reported one unplanned downtime on May 21, 2019, when PCI services were unavailable for approximately 57 minutes total due to an IT upgrade. The IT upgrade resulted in the hemodynamic monitoring system being unavailable, which is necessary to perform PCI services. SGMC reported that patient care was not affected by the downtime, and the Maryland Institute for Emergency Medical Services was notified of the downtime. For all other reported downtimes, the facility had a CCL room available to perform PCI cases. SGMC reports that there were no other overlapping downtimes, as shown in Table 1.

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

Time Period	Number of Downtime Occurrences		Overlapping Downtime
	CCL ROOM 1	CCL ROOM 2	
CY 2015	5	8	No
CY 2016	7	6	No
CY 2017	3	6	No
CY 2018	6	7	No
CY 2019	6	7	Yes*
CY 2020	6	5	No

Source: SGMC Application Q2, SGMC updated Q2 response.
*Note: overlapping downtime occurred once on May 21, 2019.

Staff Analysis and Conclusion

MHCC staff recommends the Commission find that SGMC complies with the 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.

SGMC provided a signed statement from Daniel L. Cochran, President of SGMC, stating that SGMC commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases at a minimum 75% of the time and SGMC commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement. SGMC reported that it receives STEMI transfer patients from Germantown Emergency Center (GEC), which is Adventist HealthCare's own free-standing medical center (FMF), as well as from Holy Cross Germantown Hospital (HCH-GT). Michael Oxenford oversees emergency services as the GEC Manager. The GEC Manager is an integral part of SGMC's STEMI meetings, and ED staff float between both locations. Because GEC is already part of the SGMC system, SGMC reported that transferring patients is a seamless operation as patients are already registered in their system. SGMC reported that it reviews the STEMI cases that are transferred from HCH-GT to SGMC and discuss aspects of care that went well and opportunities for improvement.

SGMC reported that for two transfer cases in 2019 with a DTB over 120 minutes, the reason was a delay in obtaining an EKG at the transferring facility. Both the Chest Pain Center Coordinator and Operations Manager for Cardiovascular and Interventional Radiology communicated with the Emergency Department Nursing and Medical Directors at the transferring facility to reiterate the importance of obtaining an EKG immediately on arrival for patients with any possible acute coronary symptoms, including epigastric pain and nausea, as is the established process. SGMC reported for another transfer case in 2019 with a prolonged DTB time, the patient had an unusual presentation. SGMC reported this case was discussed at its monthly cardiovascular team meeting, and specific action was taken to reduce the potential for delays with similar patients in the future.

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

Table 2a: SGMC Reported Compliance with DTB Benchmark by Quarter for Non-Transfer Cases January 2015- December 2019

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	36	34	94%
CY2015 Q2	25	24	96%
CY2015 Q3	33	27	82%
CY2015 Q4	23	18	78%
CY2016 Q1	30	28	93%
CY2016 Q2	36	34	94%
CY2016 Q3	26	24	92%
CY2016 Q4	30	25	83%
CY2017 Q1	33	28	85%
CY2017 Q2	21	18	86%
CY2017 Q3	21	20	95%
CY2017 Q4	34	32	94%
CY2018 Q1	31	27	87%
CY2018 Q2	26	23	89%
CY2018 Q3	27	23	85%
CY2018 Q4	30	27	90%
CY2019 Q1	20	20	100%
CY2019 Q2	25	19	76%
CY2019 Q3	32	30	94%
CY2019 Q4	27	21	78%

Source: SGMC application and updated response for Q4.

Table 2b: SGMC Reported DTB Performance by Quarter for Transfer Cases, January 2015- June 2019

Quarter	Total Primary PCI Volume	Cases With DTB <= 120 Minutes	Percent of Cases With DTB <=120 Minutes
CY2015 Q1	6	5	83%
CY2015 Q2	5	5	100%
CY2015 Q3	4	4	100%
CY2015 Q4	8	7	88%
CY2016 Q1	5	5	100%
CY2016 Q2	8	7	88%
CY2016 Q3	3	1	**33%**
CY2016 Q4	6	6	100%
CY2017 Q1	3	2	**66%**
CY2017 Q2	3	3	100%
CY2017 Q3	4	3	75%
CY2017 Q4	6	5	83%
CY2018 Q1	5	4	80%
CY2018 Q2	5	4	80%
CY2018 Q3	2	2	100%
CY2018 Q4	3	3	100%
CY2019 Q1	4	3	75%
CY2019 Q2	8	4	**50%**
CY2019 Q3	5	3	**60%**
CY2019 Q4	6	6	100%

Source: SGMC application, updated response for Q4.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer ST-elevation myocardial infarction (STEMI) cases, as shown in Table 3. MHCC staff found that SGMC met the DTB benchmark for non-transfer cases in all quarters. 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. Over rolling eight quarter periods, SGMC complied with this standard, with between 87.6% and 90.5% of PCI cases meeting the DTB time standard as shown in Table 3.

MHCC staff concludes that SGMC complies with this standard.

Table 3: SGMC 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	37	34	91.9%			
2015q2	26	25	96.2%			
2015q3	33	29	87.9%			
2015q4	21	16	76.2%			
2016q1	30	28	93.3%			
2016q2	37	35	94.6%			
2016q3	27	24	88.9%			
2016q4	27	22	81.5%	238	213	89.5%
2017q1	32	27	84.4%	233	206	88.4%
2017q2	19	17	89.5%	226	198	87.6%
2017q3	21	19	90.5%	214	188	87.9%
2017q4	33	31	93.9%	226	203	89.8%
2018q1	31	27	87.1%	227	202	89.0%
2018q2	25	22	88.0%	215	189	87.9%
2018q3	22	19	86.4%	210	184	87.6%
2018q4	28	25	89.3%	211	187	88.6%
2019q1	20	20	100.0%	199	180	90.5%
2019q2	23	19	82.6%	203	182	89.7%
2019q3	33	30	90.9%	215	193	89.8%
2019q4	24	20	83.3%	206	182	88.3%

Source: MHCC analysis of ACC-NCDR CathPCI data CY 2015- CY 2019.
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.

As shown in Table 4A, below, SGMC reported the number of physicians, nurses, and technicians who were available to 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	N = 5	Interventional Cardiologist
Nurse	6 .0	C/M
Technician	6.5	S/C
Technician	1 .0	S/C/M

Source: SGMC Application, Q6a, updated Q6a.
*Scrub (S), circulate (C), monitor (M)
**At the time of application, there were 5 total FTE technician positions. SGMC is actively recruiting for 3 full time RN positions and 1 full time technician.
***At the time of application, there were additional part-time staff: 1 limited PT nurse, 5 limited PT technicians.

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by SGMC to information reported by three other existing PCI program applications for Certificates of Ongoing Performance. MHCC staff observed that SGMC has fewer full-time equivalent (FTE) interventionalists than Johns Hopkins Bayview Medical Center (JH BMC), the same number of interventionalists as University of Maryland Prince George's Hospital Center (UM PGHC), and more than University of Maryland Shore Regional Health (UM SRH). SGMC reported the same number of nurse FTEs as JH BMC, less than UM SRH, and nearly half as many nurse FTEs as UM PGHC (6 FTEs and 10 FTEs respectively). SGMC reported fewer technician FTEs than JH BMC, which performed a similar volume of PCI cases as SGMC, as well as fewer technician FTEs than UM PGHC. SGMC reported more technician FTEs than UM SRH, shown in Table 4B. SGMC also stated that multiple positions for nurses and technicians were open at the time of the application.

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

Program	2018 Total PCI Volume*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
SGMC	269	N = 5	6	5.0
Johns Hopkins Bayview Medical Center	200	N = 10	6	5.8
UM Prince George's Hospital Center	247	N = 5	10	6.0
UM Shore Regional Health	202	N = 3	8	4.0

Sources: SGMC 2019 PCI Certificate of Ongoing Performance Application, Johns Hopkins Bayview Medical Center 2019 PCI Certificate of Ongoing Performance Application, UM Prince George's Hospital Center 2019 PCI Certificate of Ongoing Performance Application, UM Shore Regional Health 2019 PCI Certificate of Ongoing Performance Application.
*Volumes for either fiscal or calendar year

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

SGMC provided a signed letter of commitment from Daniel L. Cochran, President, acknowledging that SGMC will provide primary PCI services in accordance with the requirements established by the Commission.

Staff Analysis and Conclusion

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

SGMC provided a description of the staff involved with these functions. SGMC reported that the hospital established a Center for Cardiac and Vascular Research in 2004. This department consists of 4.5 FTEs and one manager with the title of Chest Pain Center Coordinator, who is responsible for data abstraction and entry for both the ACC CathPCI and GWTG-CAD registries. The Chest Pain Center Coordinator participates in the Maryland Cardiac Data Coordinators' Committee, interfaces with the Quality Services department in performance improvement initiatives and internal and external case reviews, uploads data and reports to MHCC, leads monthly facility-wide cardiovascular team meetings to present data, and performs data abstraction and entry for an accreditation conformance database. SGMC also reported there is a full time Quality Advisor in the Quality Services department who is responsible for quality outcomes and initiatives. This role facilitates internal and external peer review and oversees performance improvement projects for the department.

Staff Analysis and Conclusion

MHCC staff concludes that SGMC 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.

Dennis Friedman, MD, FACC, has been the Medical Director of the CCL since May 1, 2002. In addition, he serves as the Medical Director for Cardiology, Cardiac Rehab and Cardiovascular Research at SGMC. Dr. Friedman is the President and Managing Partner for Cardiac Associates, P.C. SGMC provided a detailed description of the responsibilities of Dr. Friedman that include reviewing the performance of staff, developing and implementing performance improvement plans, annually reviewing policies and procedures, assuring compliance with regulations and accreditation standards, and ensuring coverage for all hours of operation.

Staff Analysis and Conclusion

MHCC staff concludes that SGMC 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.

SGMC provided a list of the continuing educational programs and activities in which staff in the CCL, Intensive Care Unit, and Progressive Care Unit participated between January 2015 and December 2019. SGMC stated that staff participate in continuing education trainings and services throughout the year as needed or required. These educational activities may include independent assigned learning, staff meetings, clinical inquiry meetings, best practice meetings, and PCI performance meetings.

Staff Analysis and Conclusion

MHCC staff concludes that SGMC 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.

Dennis Hansen, former President and CEO, signed an amended revised transfer agreement with Washington Adventist Hospital, which is now known as Adventist HealthCare White Oak Medical Center. The amendment states that transfer of a PCI patient who requires additional care, including emergent or elective cardiac surgery, will not be subject to any conditions, including the availability of beds, policies, or procedures of a facility or hospital. SGMC reports that the originally submitted transfer agreement, effective February 1, 2008, remains the current binding transfer agreement between SGMC and White Oak Medical Center. SGMC is in the process of obtaining an updated agreement to reflect the new name of White Oak Medical Center, but a signed copy is not yet available.

Staff Analysis and Conclusion

MHCC staff reviewed the updated patient transfer agreement and concludes that SGMC 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.

James Lee, Executive Vice President and Chief Financial Officer, signed an agreement with Butler Medical Transport, LLC and William Rosenberg, Chief Operating Officer that covers

ground transportation services to SGMC. The agreement provides that, for emergent transport requests, Butler is required to arrive at the sending facility for pick-up within 30 minutes of a request. Mr. Hansen, former President, signed a Helicopter Transport Agreement with Washington Hospital Center MedSTAR Transport and Joni E. King, Director of Operations. The agreement provides that, for emergent transport requests, WHC MedSTAR is required to arrive at the sending facility for pick-up within 30 minutes of a request.

Staff Analysis and Conclusion

MHCC staff reviewed the transport agreements submitted by SGMC. The agreement with Butler Medical Transport LLC (Butler) states that the transport company will arrive at SGMC no more than thirty minutes after the receipt of a request for transfer of a PCI patient. Coverage will be provided 24-hours-a-day, seven-days-a-week. If Butler is unable to meet the thirty-minute deadline, Butler will be responsible for obtaining and compensating a secondary source of transport of equal quality and services and ensure that this service arrives at SGMC within 30-minutes of the original request for transportation. Similarly, in the MedSTAR Transport agreement, it has agreed to provide a 24-hour-a-day, seven day-a-week commitment to respond within 30-minues of a request for a patient transport.

MHCC staff concludes that SGMC 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.

SGMC stated that its Cardiovascular and Interventional Radiology (CVIR) Cath Conference Meetings are formal, regularly scheduled meetings at least every other month on Thursdays for interventional case review. The meetings are led by interventionalist cardiologists and other physicians, nurses and technicians who care for primary PCI patients must regularly attend these meetings. SGMC provided meeting minutes and sign in sheets for meetings held from January 2015 through December 2020, with limited exceptions. If the regular meeting date is cancelled due to a lack of staff availability or scheduling conflicts, then cases to be discussed at that meeting are reviewed at the next meeting.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for the CVIR Cath Conference Meetings. The documentation shows that physicians, nurses and technicians regularly attend. The documentation submitted by SGMC included attendance records for twelve meetings in 2015, eleven meetings in 2016, ten meetings in 2017 and 2018, and ten meetings in 2019 and 2020. The reasons for cancellations included meeting participants not being available and scheduling conflicts. SGMC noted that whenever a meeting was cancelled, then cases for that month are reviewed at the next meeting.

MHCC staff recommends that the Commission find SGMC 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.

SGMC reported that its multiple care area groups are an Acute Coronary Syndrome and PCI group and a Cardiovascular Center of Excellence (CVCOE) group. The CVCOE group includes all attendees of the ACS-PCI, as well as additional staff. These meetings cover similar topics as the ACS-PCI meetings, but also include discussion of accreditation compliance and recommendations from accreditation reviewers. All committee members are required to attend at least two CVCOE meetings per year. Both interdisciplinary committees are responsible for monitoring and evaluating the care and activities that relate to the cardiac patient from EMS contact through the full continuum of care. SGMC provided a list of meeting dates, meeting minutes, and invited participants that attended multiple care area group meetings held between January 2015 and December 2020. If a meeting was cancelled, SGMC reported that relevant information was sent to participants electronically.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for the two multiple care area groups. The documentation submitted by SGMC included meeting minutes for meetings held from January 2015 through December 2020, with limited exceptions. Ten meetings were held in 2015, nine meetings were held in 2016, eleven meetings were held in 2017, ten meetings were held in 2018 and 2019, and twelve meetings were held in 2020. SGMC reported a total of ten meeting cancellations during the review period. The reasons for cancellations included meeting participants not being available and scheduling conflicts.

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

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

SGMC submitted copies of the external review reports for PCI cases performed between January 2015 and June 2019.

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. As shown in Table 5, although only 5% of cases are required to be reviewed externally, between 10.1% and 19.7% of cases were reviewed semi-annually.

Table 5: SGMC External Review, October 2014- March 2020

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
10/14-03/15*	72	9	12.5%	Semi-annually	Yes
04/15-09/15*	79	8	10.1%	Semi-annually	Yes
10/15-03/16	84	13	15.5%	Semi-annually	Yes
04/16-09/16	87	14	16.1%	Semi-annually	Yes
10/16-03/17	71	11	15.5%	Semi-annually	Yes
04/17-09/17	98	12	12.2%	Semi-annually	Yes
10/17-03/18	61	12	19.7%	Semi-annually	Yes
04/18-09/18	76	14	18.4%	Semi-annually	Yes
10/18-03/19	65	10	15.38%	Semi-annually	Yes
04/19-09/19	71	13	18.31%	Semi-annually	Yes
10/19-03/20	68	13	19.12%	Semi-annually	Yes
04/20-09/20	67	13	19.40%	Semi-annually	Yes

Source: MHCC staff analysis of CCCL reports.
* Each semiannual review after October 2015 included at least three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

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

SGMC complies with this standard.

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

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

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

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

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

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

- *(ii)* ***For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08; or***

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

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

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

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

In addition to the external reviews completed by Cardiac Community Core Lab (CCCL) described above, SGMC stated that internal review consists of a review of individual interventionalists' PCI cases. All PCI cases performed (primary and elective) are reviewed on a weekly basis to include a review of angiographic images, medical test results, and patients' medical records.

Staff Analysis and Conclusion

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number of cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the

case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of 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]

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

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

SGMC submitted an affidavit from Daniel L. Cochran, President, 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 quarterly interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that SGMC 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.

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

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

(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.

SGMC reported that CVIR Cath Conference meetings are held at least bi-monthly to review practice patterns and establish process improvement goals to ensure optimal patient outcomes. All cases with a DTB over the standard in the ACC/AHA guidelines are reviewed, as well as PCI cases with complications tracked in the hospital's incident reporting system. All PCI cases are reviewed individually to ensure quality care and process improvement. SGMC also reported that in addition to external peer review of a randomized selection of elective PCI cases and internal peer review of cases with complications, the Medical Director for the CCL reviews all PCI cases performed and provides feedback to the operators.

SGMC described a quality initiative in its application that addresses a source for delays in preparing patients for transport to the CCL. SGMC reported that education was provided to staff in the ED regarding how to reduce the time from arrival at the hospital to arrival in the CCL. SGMC achieved measurable improvement in the median time of arrival at the facility to arrival in the CCL from 2018 to 2020, and the median time from arrival in the CCL to device time also improved during this period. SGMC reported that it is currently engaged in a process improvement project to further improve on those metrics.

SGMC also reported on its efforts to reduce the time for in-house primary PCI patients to obtain PCI services. As part of SGMC's quality assurance activities, the hospital instituted inpatient STEMI drills and made in-house STEMI flowcharts accessible on the intranet. SGMC achieved measurable success following these changes. SGMC also reported implementation of a system of using an ink stamp to clearly document the EKG which was qualifying for STEMI for primary PCI in cases in which more than one EKG was performed. This has enabled SGMC to improve the accuracy of metrics reported for door to balloon times.

Staff Analysis and Conclusion

MHCC staff reviewed SGMC's description of quality assurance practices and concludes that SGMC complies with this standard.

<u>Patient Outcome Measures</u>

10.24.17.07D(6)(a) A primary PCI program shall meet all performance standards established in statute or in State regulations.

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

(c) A hospital with a risk-adjusted mortality rate for STEMI PCI cases that exceeds the

established benchmark beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause in-hospital risk-adjusted mortality rate for STEMI PCI cases.

(i) The primary benchmark is the national median risk-adjusted in-hospital mortality rate for STEMI PCI cases; and

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

SGMC submitted adjusted mortality by rolling 12-month reporting period 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: Adventist Healthcare Shady Grove Medical Center's Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI				Non-STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2019q4-2020q3	7.24	[3.69,12.48]	6.37	Yes	NR	[0.00, 2.68]	0.95	Yes
2019q3-2020q2	4.48	[1.83, 8.96]	6.06	Yes	NR	[0.00, 2.79]	0.95	Yes
2019q2-2020q1	3.83	[1.42, 8.09]	5.99	Yes	NR	[0.00, 2.54]	0.95	Yes
2019q1-2019q4	5.27	[2.15, 10.51]	6.01	Yes	NR	[0.00, 3.90]	0.95	Yes
2018q4-2019q3	4.68	[1.74, 9.88]	6.32	Yes	NR	[0.00,3.49]	0.99	Yes
2018q3-2019q2	6.55	[2.43, 13.81]	6.38	Yes	NR	[0.00, 3.63]	1.00	Yes
2018q2-2019q1	5.71	[2.33, 11.38]	6.13	Yes	NR	[0.00, 4.12]	0.99	Yes
2018q1-2018q4	5.34	[2.34, 10.19]	6.00	Yes	NR	[0.00, 3.96]	1.00	Yes
2017q4-2018q3	5.78	[2.53, 11.04]	6.54	Yes	1.31	[0.03, 7.18]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	4.94	[1.62, 11.22]	6.91	Yes	2.57	[0.71, 6.45]	1.03	Yes
2017q1-2017q4	5.94	[2.21, 12.54]	6.86	Yes	2.23	[0.61, 5.58]	0.99	Yes
2016q4-2017q3	6.07	[1.99, 13.75]	6.75	Yes	2.16	[0.59, 5.42]	0.98	Yes
2016q3-2017q2	4.88	[1.6, 11.07]	6.64	Yes	1.11	[0.13, 3.93]	0.95	Yes
2016q2-2017q1	7.22	[3.15, 13.85]	6.77	Yes	0.95	[0.02, 5.19]	0.97	Yes
2016q1-2016q4	6.32	[2.57, 12.69]	6.82	Yes	1.07	[0.13, 3.78]	0.95	Yes
2015q4-2016q3	5.13	[1.9, 10.88]	6.71	Yes	0.5	[0.01, 2.77]	0.95	Yes
2015q3-2016q2	7.54	[3.67, 13.45]	6.66	Yes	1.3	[0.27, 3.73]	0.93	Yes
2015q2-2016q1	6.06	[3.08, 10.46]	6.45	Yes	1.67	[0.46, 4.19]	0.90	Yes
2015q1-2015q4	5.27	[2.57, 9.39]	6.26	Yes	2.22	[0.46, 6.35]	0.90	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports form the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and September 2020.

Notes: NR means a value was not reported. When a hospital has zero deaths, then no value is reported for a hospital's adjusted mortality rate. 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 STEMI 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 SGMC'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. 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 SGMC's performance relative to the current standard over the period between January 2015 and September 2020.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for SGMC for all 12-month reporting periods between January 2015 and September 2020, when an adjusted mortality rate was reported. MHCC staff concludes that SGMC would have met this standard if it had been applicable for the period January 2015 through September 2020. The hospital meets the benchmark for both STEMI and non-STEMI cases for the periods ending December 2019, March 2020, June 2020, and September 2020. Notably, the hospital had no deaths among the non-STEMI patients for the most recent reporting periods shown in Table 6.

MHCC staff concludes that SGMC complies with this standard.

<u>Physician Resources</u>

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

SGMC submitted information on the volume of primary and elective PCI cases at SGMC and other hospitals, by physician and quarter, for the period for January through December 2019 for Drs. Friedman, Fisher, Chen, Wang, Patel and Trujillo. Dr. Friedman signed and dated an affidavit affirming under penalty of perjury that the information provided is true and correct to the best of his knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed the reported physician volumes for the interventionalists who performed primary PCI services at SGMC in 2015, 2016, 2017, 2018 and 2019 and determined that each interventionalist performed at least 50 PCI procedures annually on average over the following 24-month periods: January 2015 through December 2016, January 2017 through December 2018, and January 2018 through December 2019. One physician did not start performing PCI cases until 2019 Q4, but this physician was meeting the standard prior to being added to the roster, based on documentation provided to staff in October 2019.

MHCC staff concludes that SGMC 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.

SGMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to SGMC because each physician performing primary PCI procedures at SGMC performed 50 PCI procedures annually on average 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.

SGMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

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

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.

SGMC submitted a signed and dated statement from Dr. Friedman, Medical Director for Cardiovascular Services and Research, acknowledging that all physicians performing primary PCI services at SGMC are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that SGMC 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.

SGMC submitted signed and dated attestations from Drs. Friedman, Fisher, Chen, Wang, Patel, and Trujillo stating that each has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

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

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

SGMC submitted a signed statement from Dr. Friedman, 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. SGMC also submitted a copy of its on-call schedule for September 2019. SGMC later reported that since the renewal application was submitted in 2019, one physician retired and is no longer participating in the on-call schedule or performing PCI services. SGMC also reported that Dr. Wang participates in the on-call rotation, but on a limited basis as he is primarily on-call for primary PCI at another facility.

Staff Analysis and Conclusion

Staff examined the on-call schedule for May 2021 and observed that Drs. Friedman, Chen, Wang, Patel, and Trujillo were all scheduled to be on-call at different times during the month.

MHCC staff concludes that SGMC 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.

SGMC provided PCI volume information by fiscal year 2015 through 2019, as shown in Table 7. This information shows that SGMC performed between 263 and 302 cases annually.

Table 7: SGMC Total PCI Volume, FY 2015- FY 2019

Fiscal Year	Number of PCI Cases
2015	283
2016	302
2017	292
2018	269
2019	263

Source: SGMC application, question 28, and updated question 28 provided March 23, 2021.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI volume information submitted by SGMC and analyzed the ACC-NCDR CathPCI data submitted. Staff determined at least 200 PCI procedures were completed per calendar year in 2015, 2016, 2017, 2018 and 2019. For CY 2019, MHCC staff's analysis of the ACC-NCDR CathPCI data indicates a total of 263 PCI cases were performed.

MHCC staff concludes that SGMC complies with this standard.

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

SGMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI case volume for CY 2015 through CY 2019, as shown in Table 8. This analysis shows primary PCI volume ranged from 142 to 165 cases each calendar year and confirms that SGMC exceeded the threshold of 49 cases annually referenced in the standard.

Table 8: SGMC Primary PCI Volume
CY 2015- CY 2019

Calendar Year	Number of Primary PCI Cases
2015	154
2016	165
2017	144
2018	147
2019	142

Source: MHCC staff analysis of CathPCI data CY 2015- CY 2019

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

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

SGMC provided the number of primary PCI cases by interventionalist for the period of January 2015 through December 2019 by quarter, both at SGMC and at other Maryland hospitals. Between 2015 Q1 and 2019 Q4, at least 11 primary PCI procedures were completed per year, for practicing interventionalists at the time of application, with two exceptions. One physician retired in 2019 and completed only nine cases in 2019, and another physician also performed only nine cases in 2019.

Staff Analysis and Conclusion

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

MHCC staff concludes that SGMC meets this standard.

<u>Patient Selection</u>

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.

SGMC stated that all cases in CathPCI Registry PCI Appropriate Use Criteria (AUC) Metric reports from October 2014 through March 2019 were reviewed, and these cases meet Appropriate Use Criteria based on the ACCF/AHA/SCAI Guidelines. SGMC also noted that external review did not identify any inappropriate PCI cases and submitted results from external reviews from April 2019 through September 2020.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports from October 2014 through September 2020 and determined that no cases between October 2014 and September 2020 were deemed to be "rarely appropriate" with respect to one or more of the following: clinical criteria; angiographic criteria; and ACC/AHA appropriateness criteria.

MHCC staff concludes that SGMC 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.

In its application, SGMC initially stated that all cases in ACC-NCDR CathPCI Registry PCI Appropriate Use Criteria Metric reports from October 2014 through March 2019 were reviewed, and these cases meet Appropriate Use Criteria based on the ACCF/AHA/SCAI Guidelines. SGMC also stated that external review did not identify any inappropriate PCI cases and submitted results from external reviews from April 2019 through September 2020. When asked about the number of PCI patients who received thrombolytic therapy that subsequently failed during the review period, SGMC reported that only one patient received thrombolytic therapy that subsequently failed.

Staff Analysis and Conclusion

MHCC staff concludes that SGMC complies with the standard.

RECOMMENDATION

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