

**IN THE MATTER OF
UNIVERSITY OF MARYLAND
SAINT JOSEPH
MEDICAL CENTER**

*
*
*
*
*
*
*
*

**BEFORE THE
MARYLAND HEALTH
CARE COMMISSION**

Docket No.: 19-03-CP023

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

December 17, 2020

I. INTRODUCTION

A. Background

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

For many years, only Maryland hospitals with on-site cardiac surgery services could provide PCI. However, in the 1990s, Maryland began allowing some hospitals to perform primary PCI services without cardiac surgery on-site, first as part of research trials evaluating the safety of providing primary PCI at such hospitals and, later, as a regular clinical service, based on the research findings. The Commission issued waivers to hospitals in order 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 (nonprimary) PCI services, for a period of time specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must demonstrate that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide PCI services.

B. Applicant

University of Maryland Saint Joseph Medical Center

University of Maryland Saint Joseph Medical Center (UMSJMC) is a 219-bed general hospital located in Towson (Baltimore County). UMSJMC 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. UMSJMC is located in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties, and Baltimore City. Fourteen hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; all of the other programs provide both primary and elective PCI services. Five of the fourteen hospitals also provide cardiac surgery services, and one additional hospital in this region has a Certificate of Need to establish a cardiac surgery program and is expected to begin operating in December 2020.

C. Staff Recommendation

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

II. PRODEDURAL HISTORY

UMSJMC filed a Certificate of Ongoing Performance application on June 19, 2019. MHCC staff reviewed the application and requested additional information on May 2, 2020, September 30, 2020, and October 28, 2020. MHCC received additional information on May 13, 2020, October 14, 2020, and November 2, 2020.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF-NCDR (American College of Cardiology-National Cardiovascular Data 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.

UMSJMC responded that all of the hospital’s ACC-NCDR CathPCI registry data has been submitted on time to both the ACC-NCDR CathPCI registry and MHCC. There have not been any deficiencies noted.

Staff Analysis and Conclusion

UMSJMC 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 ACC-NCDR CathPCI data to validate that hospitals submitted accurate and complete information. Advanta Government Services, MHCC’s contractor for the audit, did not identify any concerns regarding the accuracy or completeness of UMSJMC’s data reported during the audit period.

MHCC staff received duplicate data as required and concludes that UMSJMC 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.

UMSJMC has three cardiac catheterization laboratories (CCLs), one interventional radiology room, and one hybrid operating room. Two of the CCLs are used for diagnostic and interventional cardiac catheterization procedures. The third CCL is used for electrophysiology procedures. UMSJMC can use the third CCL, the interventional room, or the hybrid operating room if either of the two CCLs routinely used for PCI services are down. The hospital stated that no downtime occurred due to required equipment maintenance or unforeseen circumstances for the period of January 2015 through June 19, 2019, the submission date of the application.

UMSJMC reported that there was one primary PCI patient who needed to be moved from one CCL to another because the equipment failed on January 7, 2018. The hospital also installed new imaging equipment in the two CCLs routinely used for PCI in March 2018. UMSJMC submitted a log of service requests for these two CCLs for the period January 1, 2015 through May 5, 2020. See Table 1, below.

Table 1: Number of Separate Instances of Downtime Reported by UMSJMC for CCLs Routinely Used for PCI, by Time Period

| Time Period | Room 3 | Room 5 | Simultaneous Downtime |
|------------------------|---------------|---------------|------------------------------|
| CY 2015 | 15 | 9 | No |
| CY 2016 | 16 | 11 | No |
| CY 2017 | 13 | 15 | No |
| CY 2018 | 16 | 11 | No |
| CY 2019 | 5 | 3 | No |
| January 1- May 5, 2020 | 3 | 6 | No |

Source: UMSJMC application and updated response to Q2.

Staff Analysis and Conclusion

MHCC staff reviewed the tables of CCL downtime and information submitted by UMSJMC. The hospital stated that there are three other rooms that can be employed PCI services if both CCLs routinely used for PCI services are unavailable.

MHCC staff concludes that UMSJMC complies with this standard.

10.24.17.07D(4)(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

UMSJMC provided a signed statement from Thomas B. Smyth, M.D., President and Chief Executive Officer of UMSJMC, 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 for at least 75% of cases. The statement also affirms that UMSJMC commits to tracking and improving door-to-balloon (DTB) times for transfer cases. As shown in Table 2A, UMSJMC provided quarterly information on compliance with the DTB time standard for the period from January 2015 through December 2019. The reported information shows that the hospital met the DTB time standard throughout this period.

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

| Quarter | Total Primary PCI Case Volume | Cases with DTB <= 90 minutes | Percent of Total Primary PCI Cases with DTB <=90 Minutes |
|-----------|-------------------------------|------------------------------|--|
| CY2015 Q1 | 21 | 21 | 100.0% |
| CY2015 Q2 | 26 | 24 | 92.3% |
| CY2015 Q3 | 16 | 15 | 93.8% |
| CY2015 Q4 | 30 | 30 | 100.0% |
| CY2016 Q1 | 26 | 26 | 100.0% |
| CY2016 Q2 | 22 | 21 | 95.5% |
| CY2016 Q3 | 16 | 16 | 100.0% |
| CY2016 Q4 | 21 | 21 | 100.0% |
| CY2017 Q1 | 20 | 20 | 100.0% |
| CY2017 Q2 | 16 | 16 | 100.0% |
| CY2017 Q3 | 17 | 17 | 100.0% |
| CY2017 Q4 | 18 | 18 | 100.0% |
| CY2018 Q1 | 20 | 20 | 100.0% |
| CY2018 Q2 | 15 | 14 | 93.3% |
| CY2018 Q3 | 17 | 17 | 100.0% |
| CY2018 Q4 | 25 | 24 | 96.0% |
| CY2019 Q1 | 17 | 17 | 100.0% |
| CY2019 Q2 | 18 | 16 | 88.9% |
| CY2019 Q3 | 11 | 10 | 90.9% |
| CY2019 Q4 | 18 | 16 | 88.9% |

Source: UMSJMC application, Q4, updated Q4.

UMSJMC also provided DTB information for primary PCI transfer cases. Between January 2015 and June 2019, UMSJMC received 80 primary PCI transfer cases, and all of the transfer cases in this timeframe had a DTB of 120 minutes or less except for two cases in CY2019 Q3.

UMSJMC explained its approach to improving transfer times for patients who require primary PCI. The Cardiac Interventional Center Quality Assurance Medical Review Committee, which meets once a month, is dedicated to reviewing clinical performance and practice patterns. The data from multiple registries are reviewed at these meetings, including the ACC-NCDR ACTION and CathPCI Registries and the American Heart Association Mission Lifeline Registry. UMSJMC reviews key time intervals and quality metrics relevant to emergency medical services, the emergency department, the CCL, and ST-segment elevation myocardial infarction (STEMI)¹ referral centers. Any deviations from quality metrics are analyzed to identify opportunities for performance improvement.

UMSJMC also explained that it has a transfer agreement with Greater Baltimore Medical Center (GBMC) and includes representatives from GBMC in meetings of the Cardiac Interventional Center Quality Assurance Medical Review Committee. UMSJMC coordinates discussion of changes to standards of care for STEMI patients, as needed.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases, as shown in Table 2B. MHCC staff found that the quarterly percentage of patients with a DTB time of 90 minutes or less ranged from 88.9% to 100.0%. 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, whereas MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer time periods. Over rolling eight quarter periods, UMSJMC complied with this standard, with between 97.7% to 99.4% of primary PCI cases met the DTB time standard, as shown in Table 2B.

¹ "ST-segment elevation myocardial infarction, or STEMI, means a heart attack in which there is cardiac muscle damage resulting from an acute interruption of blood supply to a part of the heart and can be demonstrated by a change of ST-segment elevation on an electrocardiogram. Primary PCI is the standard of care for STEMI.

Table 2B: UMSJMC Primary PCI Case Volume and Percentage of Cases With DTB Time Less Than or Equal to 90 Minutes, by Time Period

| Time Period | Quarter | | | Rolling Eight-Quarter Periods | | |
|-------------|--------------------------|----------------------------|--|-------------------------------|----------------------------|--|
| | 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 | 21 | 21 | 100.0% | | | |
| 2015q2 | 26 | 24 | 92.3% | | | |
| 2015q3 | 16 | 15 | 93.8% | | | |
| 2015q4 | 30 | 30 | 100.0% | | | |
| 2016q1 | 26 | 26 | 100.0% | | | |
| 2016q2 | 22 | 21 | 95.5% | | | |
| 2016q3 | 16 | 16 | 100.0% | | | |
| 2016q4 | 21 | 21 | 100.0% | 178 | 174 | 97.8% |
| 2017q1 | 20 | 20 | 100.0% | 177 | 173 | 97.7% |
| 2017q2 | 16 | 16 | 100.0% | 167 | 165 | 98.8% |
| 2017q3 | 17 | 17 | 100.0% | 168 | 167 | 99.4% |
| 2017q4 | 18 | 18 | 100.0% | 156 | 155 | 99.4% |
| 2018q1 | 20 | 20 | 100.0% | 150 | 149 | 99.3% |
| 2018q2 | 15 | 14 | 93.3% | 143 | 142 | 99.3% |
| 2018q3 | 17 | 17 | 100.0% | 144 | 143 | 99.3% |
| 2018q4 | 25 | 24 | 96.0% | 148 | 146 | 98.6% |
| 2019q1 | 17 | 17 | 100.0% | 145 | 143 | 98.6% |
| 2019q2 | 18 | 16 | 88.9% | 147 | 143 | 97.3% |
| 2019q3 | 11 | 10 | 90.9% | 141 | 136 | 96.5% |
| 2019q4 | 18 | 16 | 88.9% | 141 | 134 | 95.0% |

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

Note: Calculations for each quarter are based on the procedure date.

MHCC staff concludes that UMSJMC complies with this standard.

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

At the time of its original application UMSJMC provided the number of physicians, nurses, and technicians who are able to provide cardiac catheterization services to acute myocardial infarction patients, shown in Table 3A. The hospital also stated that staffing is evaluated on an ongoing basis through a collaborative review by the Director, Nurse Manager, and Charge Nurse. The workload is based upon routine daily unit operations, patient census, and patient acuity.

UMSJMC also provided updated information that, as of October 14, 2020, staffing includes one additional nurse full-time equivalent (FTE) and that two PRN² technicians are also available.

Table 3A: Total Number of CCL Physician, Nursing, and Technical Staff

| Category | Number/FTEs | Cross Training (S/C/M)* |
|------------|-------------|-------------------------------------|
| Physician | N = 2** | |
| Nurse | 10.3 | C, M = 7.3 FTE S, C, M = 3.0 FTE |
| Technician | 4.0 | S, C, M |

Source: UMSJMC application, Q6a.

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

**Note: One additional interventionalist available, as needed.

Staff Analysis and Conclusion

MHCC staff compared UMSJMC’s reported staffing levels to the levels reported by three other hospitals with primary and elective PCI programs and similar PCI case volumes. As shown in Table 3B, below, UMSJMC’s 2018 PCI case volume was greater than the volume reported by Sinai Hospital of Baltimore (Sinai), Johns Hopkins Hospital (JHH), and TidalHealth Peninsula Regional (THPR) and closest to the volume for THPR. UMSJMC reported that its PCI program had two interventionalists, which is less than reported by all three of the other programs. However, UMSJMC also reported that one additional interventionalist is available, as needed. The number of full-time equivalent (FTE) nurses reported by UMSJMC was less than the FTEs reported by JHH and THPR but greater than the number reported by Sinai. The number of technician FTEs reported by UMSJMC is much less than the FTEs reported by all three of the other programs. Although UMSJMC stated that two additional technicians are also available as needed, the number of technician FTEs is much lower than that reported for the other programs, even when these two additional technicians are included.

Table 3B: CCL Staffing, UMSJMC and Selected Other PCI Programs

| Program & Year Reported | 2018 Total PCI Volume* | Number (N) of Interventionalists or FTEs | Nurse FTEs | Technician FTEs |
|-------------------------|------------------------|--|------------|-----------------|
| UMSJMC 2019 | 741 | N = 2 | 11.3 | 4.0 |
| Sinai 2019 | 632 | N = 13 | 7.0 | 10.0 |
| JHH 2019 | 559 | N = 9 | 20.25 | 14.2 |
| THPR 2019 | 695 | N = 10 | 13.45 | 10.7 |

Sources: UMSJMC 2019 PCI Certificate of Ongoing Performance application, Sinai 2019 PCI Certificate of Ongoing Performance application, JHH 2019 PCI Certificate of Ongoing Performance application, and THPR 2019 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.

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.

² “Pro re nata,” when used in the context of personnel, means “as needed.”

UMSJMC provided a signed letter of commitment from Dr. Smyth acknowledging that UMSJMC 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 UMSJMC 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.

UMSJMC stated that data entry and analysis for PCI services are staffed under the Director of Cardiac and Vascular Services (1.0 FTE) who has assigned a qualified Registry Site Manager (1.0 FTE) and a Physician Medical Director (1.0 FTE). The Registry Site Manager is the primary point of contact for these registries, supervises data collection and submission, confirms the accuracy of data, receives quarterly outcomes reports, and acts as the direct liaison with NCDR and ACC. Data collection is performed by registered nurse abstractors who have experience in cardiovascular disease (1.5 FTEs).

Staff Analysis and Conclusion

MHCC staff concludes that UMSJMC 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.

Interventional cardiology services are under the direction of the acting Chief of Cardiology and Chief of Medicine, Dr. Jason Marx. Shumile Zaidi, M.D. and Henry Sun, M.D. are the CCL Co-Directors. Drs. Zaidi and Sun were appointed in January 2018. Additionally, Jennifer Young, R.N., and David Zimrin, M.D., Chief of Cardiology at University of Maryland Medical Center, coordinate peer review services.³ Prior to Drs. Zaidi and Sun, David Zimrin, M.D. was the Medical Director of the CCL, during 2015 through January 2016, and Frank Morris, M.D. was the Medical Director of the CCL from January 2016 to January 2018.

UMSJMC provided a list of responsibilities for the Medical Director of the CCL. This list included administrative duties such as resolving personnel issues, attending staff meetings, and coordinating the physician call schedule. The Medical Director is also involved with quality and performance improvement, including the oversight and coordination of submission of data to the

³ Dr. Zimrin retired in March 2020, and Anoop Patel, M.D. currently coordinates peer review of cases.

NCDR and CathPCI databases, leading morbidity and mortality meetings, reviewing physician performance, and oversight of the CCL budget.

Staff Analysis and Conclusion

MHCC staff concludes that UMSJMC 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.

UMSJMC submitted a list of continuing educational programs and activities in which staff in the CCL and the coronary care unit participated over the review period. UMSJMC does not require a minimum number of continuing education credits. There are continuing education credits required for specific staff licenses and certifications that are tracked by the human resources department. Managers are notified of delinquent employees, and these employees are not allowed to practice until compliant.

Additionally, each staff member is required to maintain advanced cardiovascular life support and basic life support certification as well as an active license or certification, as applicable. All employees complete mandatory online compliance modules that consist of continuous compliance, environment of care, and regulatory compliance, including mission and values, falls, and fire safety. All staff also participate in annual competencies including components in critical thinking, communication, radiation safety, procedural fire and electrocautery safety, and two to three high risk or low volume procedural competencies.

Staff Analysis and Conclusion

MHCC staff reviewed the information submitted and concludes that UMSJMC 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.

UMSJMC provides the full spectrum of cardiac care, including cardiac surgery. This standard is not applicable to UMSJMC.

Staff Analysis and Conclusion

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

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.

UMSJMC provides the full spectrum of cardiac care, including cardiac surgery; this standard is not applicable to UMSJMC.

Staff Analysis and Conclusion

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

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.

UMSJMC submitted attendance records for the clinical conferences held between October 2016 and March 2020. These conferences included Cardiovascular Medicine and Surgery Conferences, Morbidity and Mortality Reviews, Cardiac Catheterization Conferences, Cardiology Grand Rounds, and peer review meetings. UMSJMC also separately identified attendees who are technicians because attendance records usually did not capture this information. The hospital reported that while meetings were held prior to October 2016, the attendance records cannot be located.

Staff Analysis and Conclusion

MHCC staff reviewed attendance records and meeting minutes submitted and determined that UMSJMC holds several types of meetings that include interventional case review. The frequency of these meetings was greater than once every two months for the entire review period. Records show that between October 2016 and March 2020, twenty-five meetings were held. Interventional case review meetings include physicians, nurses, and technicians who care for primary PCI patients, as required.

MHCC staff concludes that UMSJMC 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.

UMSJMC submitted meeting attendance records and dates for Cardiac Interventional Center Quality Assurance Medical Review Committee meetings held between January 2015 and May 2019. UMSJMC provided details regarding the attendees' work locations and stated that every attempt is made to have representatives from the emergency department, medical surgical intensive care unit, CCL, Greater Baltimore Medical Center, and emergency medical services represented at monthly meetings. Nursing leadership and physicians are invited, and data spreadsheets are emailed to the core group of the committee several days prior. Should a member

be unable to attend the meeting in person, the member has the opportunity to review the data and provide comments to be shared at the meeting.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for UMSJMC’s Cardiac Interventional Center Quality Assurance Medical Review Committee meetings. Eleven meetings were held in 2015, 2016, and 2017, and ten meetings were held in 2018. UMSJMC reported meeting cancellations due to a conflict with another meeting and expected low attendance, low number of cases in the prior month, committee members unavailable, and a conflict with the meeting of the Joint Commission Survey’s debrief.

MHCC staff concludes that UMSJMC 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.

UMSJMC submitted reports for the external reviews of PCI cases performed between January 2016 and June 2019. UMSJMC also stated that if fewer than three cases were performed by an interventionalist for a review period, then all cases were reviewed by the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), the hospital’s contracted external review organization, as required.

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 4. Although only 5% of cases are required to be reviewed, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. As shown in Table 4, between 6.8% and 7.8% of cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed. UMSJMC participated in external review in calendar year 2015 as part of compliance with a consent decree, expected to be at least equivalent to the standards included in MHCC’s regulations. MHCC staff did not review the report from that external review.

Table 4: UMSJMC External Review of PCI Cases by Time Period, January 1, 2016- June 2019

| Time Period | Elective PCI Volume | Number of Cases Reviewed | Percentage of Cases Reviewed | Frequency of Reviews | Meets Standard* |
|--------------------|----------------------------|---------------------------------|-------------------------------------|-----------------------------|------------------------|
| CY 2016 | 716 | 56 | 7.8% | Semiannual | Yes |
| CY 2017 | 704 | 53 | 7.5% | Semiannual | Yes |
| CY 2018 | 651 | 46 | 7.1% | Semiannual | Yes |
| 2019 Q1Q2 | 296 | 20 | 6.8% | Semiannual | Yes |

Source: MHCC staff analysis of MACPAQ reports.

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

For the period between January 2016 and June 2019, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that at least five percent of elective PCI cases were reviewed. MHCC staff also confirmed that when the external review report indicated that less than three cases were reviewed it was because one or more physicians performed only one or two PCI cases for the review period.

UMSJMC 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 described above, UMSJMC noted that, for the purposes of internal review, cases are randomized. The medical records as well as the coronary angiograms remain blinded during the committee review process to protect the identity of the patient and the interventionalist. UMSJMC submitted minutes from monthly CCL Peer Review meetings between January 2015 and April 2019 that show the number of cases reviewed for individual physicians at each meeting. UMSJMC subsequently provided summary information with the total number of cases reviewed for each interventionalist in CY 2016, CY 2017, CY 2018, and CY 2019.

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).⁴

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

⁴https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

MHCC staff concludes that UMSJMC 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).⁵

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.

UMSJMC submitted an affidavit from Dr. Smyth 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, semi-annual external review, and monthly internal review of individual interventionalists consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that UMSJMC 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.***

UMSJMC provided descriptions of three quality improvement initiatives. The hospital stated that in 2019, there was an increase in acute stent thrombosis noted during Quality Outcomes reviews. Each case was reviewed, and it was determined that the cases were related to pharmacology. UMSJMC detailed the changes made because of the conclusions of this review. For example, before any wire is opened, staff ask the physician if heparin was given, and a minimum standard dose of 70units/kg is given intravenously, per physician order. The second quality improvement initiative described was a protocol for handling STEMI patients that was developed in 2016 in an effort to maximize efficiencies. The hospital explained that this protocol was reviewed in 2019 and discovered that not all staff were following the protocol consistently. UMSJMC re-educated staff and monitored their performance in real-time. The third quality improvement described was an initiative in 2016 by the Interventional Cardiology Council to share

⁵ Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the individual interventionalist review requirements.

best practices. UMSJMC provided information about best practices and data on risk-adjusted acute kidney injury prevalence.

Staff Analysis and Conclusion

MHCC staff reviewed peer review documentation and description of quality assurance practices provided and concludes that UMSJMC complies with this standard.

Patient Outcome Measures

10.24.17.07D(5)(a) A primary PCI program shall meet all performance standards established in statute or in State regulations.

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

(c) A hospital with a risk-adjusted mortality rate for 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.

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 non-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 non-STEMI PCI cases.

(i) The primary benchmark is the national median risk-adjusted in-hospital mortality rate for non-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 elective PCI cases will be used as a second benchmark.

**Table 5: UMSJMC Risk Adjusted Mortality Rates (AMR) for PCI Cases 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 |
| 2019q1-2019q4 | 1.65 | [0.04, 9.93] | 6.01 | Yes | 0.81 | [0.22, 2.07] | 0.95 | Yes |
| 2018q4-2019q3 | 3.60 | [0.44, 12.65] | 6.06 | Yes | 0.45 | [0.09, 1.31] | 0.98 | Yes |
| 2018q3-2019q2 | 1.94 | [0.05, 10.56] | 6.38 | Yes | 0.64 | [0.21, 1.48] | 1.00 | Yes |
| 2018q2-2019q1 | 3.04 | [0.37, 10.68] | 6.13 | Yes | 0.60 | [0.19, 1.39] | 0.99 | Yes |
| 2018q1-2018q4 | 3.78 | [0.79, 10.73] | 6.00 | Yes | 0.59 | [0.19, 1.36] | 1.00 | Yes |
| 2017q4-2018q3 | 2.95 | [0.36, 10.33] | 6.54 | Yes | 1.03 | [0.38, 2.24] | 0.98 | Yes |
| 2017q3-2018q2 | Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry | | | | | | | |
| 2017q2-2018q1 | 2.75 | [0.33, 9.64] | 6.91 | Yes | 0.48 | [0.06, 1.74] | 1.03 | Yes |
| 2017q1-2017q4 | 3.84 | [0.80, 10.86] | 6.86 | Yes | 1.02 | [0.38, 2.21] | 0.99 | Yes |
| 2016q4-2017q3 | 4.51 | [1.48, 10.17] | 6.75 | Yes | 0.59 | [0.16, 1.51] | 0.98 | Yes |
| 2016q3-2017q2 | 5.25 | [1.96, 10.99] | 6.64 | Yes | 0.95 | [0.41, 1.87] | 0.95 | Yes |
| 2016q2-2017q3 | 6.10 | [2.27, 12.80] | 6.77 | Yes | 1.18 | [0.61, 2.04] | 0.97 | Yes |
| 2016q1-2017q4 | 6.53 | [2.87, 12.41] | 6.82 | Yes | 1.39 | [0.72, 2.41] | 0.95 | Yes |
| 2015q4-2016q3 | 9.55 | [4.86, 16.50] | 6.71 | Yes | 1.66 | [0.91, 2.77] | 0.95 | Yes |
| 2015q3-2016q2 | 9.35 | [4.56, 16.63] | 6.66 | Yes | 1.67 | [0.86, 2.89] | 0.93 | Yes |
| 2015q2-2016q1 | 7.63 | [3.72, 13.59] | 6.45 | Yes | 1.43 | [0.62, 2.80] | 0.90 | Yes |
| 2015q1-2015q4 | 5.81 | [2.37, 11.62] | 6.26 | Yes | 0.84 | [0.27, 1.96] | 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 December 2019.

Notes: A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) included 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 the majority of the review period for UMSJMC's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar standard that was adopted previously referenced a statewide average as the benchmark, but 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. However, MHCC staff has provided information below on how UMSJMC performed over the period between January 2015 and December 2019.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period 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 UMSJMC for all 12-month reporting periods between 2015 Q1 and 2019 Q4, including the period ending December 2019, the first period for which the current standard applies. MHCC staff concludes that UMSJMC meets this standard for the period ending December 2019 and would have met this standard, had it been applicable for the rest of the period reviewed.

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.

UMSJMC provides a full spectrum of cardiac care, including cardiac surgery. This standard is not applicable to UMSJMC.

Staff Analysis and Conclusion

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

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.

UMSJMC provides a full spectrum of cardiac care, including cardiac surgery. This standard is not applicable to UMSJMC.

Staff Analysis and Conclusion

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

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.***

UMSJMC is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery; this standard is not applicable to UMSJMC.

Staff Analysis and Conclusion

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

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.

UMSJMC submitted signed and dated statements from Drs. Sun and Zaidi, Co-Directors of the CCL, acknowledging that all physicians performing primary PCI are board certified in interventional cardiology or are exempt from this requirement.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that UMSJMC meets these standards.

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

UMSJMC submitted signed and dated attestations from Drs. Pressel, Sun, and Zaidi stating that each physician 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 UMSJMC meets this standard.

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

UMSJMC submitted a signed statement from the Medical Directors of the CCLs, Drs. Sun and Zaidi, acknowledging that each physician who has performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. UMSJMC also submitted a copy of its on-call schedule for June 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for June 2019 and observed that Drs. Baker, Patel, Sun, Pollock, Chahal, Roberts, Schechter, Plotnick, and Zaidi, were all scheduled to be on-call at different times during the month.

MHCC staff concludes that UMSJMC meets this standard based on the statement provided as well as review of the June 2019 on-call schedule.

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.

UMSJMC provided the number of total PCI cases by year for fiscal year (FY) 2015 through 2019. As shown in Table 6, the annual case volume ranged from 729 to 1,220 cases between FY 2015 and FY 2019.

Table 6: UMSJMC Total PCI Case Volume, FY 2015- FY 2019

| Fiscal Year | Total Number of PCI Cases |
|-------------|---------------------------|
| 2015 | 1,220 |
| 2016 | 944 |
| 2017 | 788 |
| 2018 | 741 |
| 2019 | 729 |

Source: UMSJMC application, question 28, and updated question 28.

Staff Analysis and Conclusion

MHCC staff reviewed the information submitted by UMSJMC and analyzed the ACC-NCDR CathPCI data submitted. Staff determined that at least 200 PCI procedures were completed per calendar year during the review period.

MHCC staff has determined that UMSJMC 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.

UMSJMC submitted information on the volume of primary PCI cases for each quarter between January 1, 2015 and December 31, 2019.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data by calendar year for 2015 through 2019. As shown in Table 7, this analysis shows that primary PCI volume ranged from 94 to 167 cases each calendar year and confirms that UMSJMC, a non-rural provider, exceeded the threshold of 49 cases annually referenced in the standard.

Table 7: UMSJMC Primary PCI Case Volume

| Calendar Year | Primary PCI Cases |
|----------------------|--------------------------|
| 2015 | 161 |
| 2016 | 167 |
| 2017 | 136 |
| 2018 | 146 |
| 2019 | 94 |

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

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

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

UMSJMC stated that all physicians performing PCI at UMSJMC meet the target volume of 11 primary PCI cases annually.

Staff Analysis and Conclusion

MHCC staff notes that 11 primary PCI cases is a target rather than a strict standard. MHCC staff analyzed the ACC-NCDR CathPCI data for physicians who performed primary PCI services at UMSJMC between January 1, 2015 and December 31, 2015. Although in CY 2019 all physicians performed at least 11 primary PCI cases, in prior years there has been a single physician, who performed less than the target volume of 11 primary PCI cases. The single physician who performed less than 11 primary PCI cases differed from year-to-year.

MHCC staff concludes that UMSJMC meets this standard.

Patient Selection

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

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

UMSJMC stated that no patients received elective PCI services inappropriately based on an internal and external review of cases for the review period.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from 2015 through June 2019 and determined that no cases were identified as rarely appropriate across all the clinical, angiographic, and ACC/AHA criteria. Five cases were determined to be rarely appropriate by one or two criteria. The hospital stated that in all of these cases, Dr. Zimrin or physician leadership reviewed the external reports and shared the conclusions with the physician responsible for the case, if the physician was still performing PCI services at UMSJMC. In all cases, no additional follow-up was needed. UMSJMC stated that all external review reports will continue to be reviewed by physician leadership and the internal peer review committee.

MHCC staff concludes that UMSJMC 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.

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

Staff Analysis and Conclusion

MHCC staff determines that UMSJMC complies with the standard.

RECOMMENDATION

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