

**IN THE MATTER OF
JOHNS HOPKINS BAYVIEW
MEDICAL CENTER**

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

Docket No.: 19-24-CP011

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

June 18, 2020

I. INTRODUCTION

A. Background

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

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

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

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

The Cardiac Surgery Chapter contains standards for evaluating the performance of established PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or both primary and

elective (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

Johns Hopkins Bayview Medical Center

Johns Hopkins Bayview Medical Center (JHBMC) is a 350-bed general hospital located in Baltimore (Baltimore City). JHBMC is part of the Johns Hopkins Hospital System and does not have a cardiac surgery program on site.

JHBMC began providing primary PCI services under a research waiver in 1996 through participation in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials. Subsequently, the hospital was authorized to provide primary PCI on a regular basis, subject to ongoing performance requirements and periodic waiver renewal. JHBMC last applied for a primary PCI waiver in September 2013 and the two-year waiver was issued on December 17, 2013. On June 18, 2009, the Commission granted a two-year research waiver to JHBMC to participate in the Atlantic Cardiovascular Patient Outcomes Research Team Trial: Elective Angioplasty Study (C-PORT E). The C-PORT E study concluded enrollment on March 31, 2011 and on April 1, 2011, MHCC released applications in April 2011 for hospitals with existing C-PORT E research waivers to seek continuation through participation in a follow-on elective PCI registry. JHBMC filed its application on April 25, 2011 and the waiver was approved on November 2011. This authorization, based on the 2012 legislation outlined above, allows JHBMC to provide PCI services subject to periodic review of its ongoing performance. This report and recommendation is the first ongoing performance review of this PCI program.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. JHBMC is located in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Baltimore City, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, Talbot Counties. 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.

C. Staff Recommendation

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

II. PRODEDURAL HISTORY

JHBMC filed a Certificate of Ongoing Performance application on March 22, 2019. MHCC staff reviewed the application and requested additional information on February 13, 2020, April 6, 2020, June 1, 2020, June 4, 2020, and June 8, 2020. JHBMC submitted additional information on March 5, 2020, April 13, 2020, June 1, 2020, June 4, 2020, and June 8, 2020

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

JHBMC's application stated that there were no deficiencies in data collection. The hospital's data coordinator collects and submits data to the ACC-NCDR CathPCI registry daily. Quarterly, she also submits data to the MHCC Quality Reports website.

Staff Analysis and Conclusion

JHBMC has complied with the requirement to submit data to the ACC-NCDR CathPCI registry 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 JHBMC's data reported during the audit period.

MHCC staff concludes that JHBMC 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.

JHBMC states that there is a cardiac catheterization laboratory (CCL) and an electrophysiology laboratory (EPL) capable of facilitating cardiac catheterization procedures. When the cardiac catheterization laboratory is undergoing maintenance or equipment repair, all acute myocardial infarction cases are rerouted to the electrophysiology laboratory for emergency procedures. JHBMC also stated that at no time has a case been diverted because a laboratory was not available.

Table 1A: JHBMC CCL Closures

| Location | Date* | Hours Closed | Reason/Explanation |
|-----------------|--------------|---------------------|--|
| CCL | 4/23/15 | 2:30 | Microphone not working |
| CCL | 4/30/15 | 4:00 | Preventive maintenance |
| CCL | 6/11/15 | 7:00 | Preventive maintenance |
| CCL | 7/6/15 | 7:15 | HeartLab not getting images |
| CCL | 12/31/15 | 2:00 | Time needs to be corrected |
| CCL | 3/3/16 | 2:30 | Blood on foot pedal of xray machine |
| CCL | 3/3/16 | 6:00 | Preventive maintenance |
| CCL | 5/24/16 | 4:30 | Preventive maintenance |
| CCL | 6/2/16 | 4:00 | Preventive maintenance |
| CCL | 10/5/16 | 4:00 | Loud noise at the tube when booting up |
| CCL | 10/7/16 | 2:00 | Loud sound when table lowered |
| CCL | 10/17/16 | 3:30 | Images failed to transfer to HeartLab |
| CCL | 10/19/16 | 3:00 | Noise when system shuts down |
| CCL | 10/19/16 | 7:00 | Distorted image on lateral tube |
| CCL | 10/27/16 | 1:00 | Machine making a noise |
| CCL | 11/7/16 | 1:00 | Time needs to be corrected |
| CCL | 11/8/16 | 1:00 | Loud noise at tube |
| CCL | 12/6/16 | 6:00 | Preventive maintenance |
| CCL | 12/22/16 | 4:00 | Problem following power outage |
| CCL | 12/27/16 | 3:00 | Issue when patient on table |
| CCL | 1/3/17 | 1:00 | Error |
| CCL | 1/6/17 | 5:00 | Issue with lining tube to table |
| CCL | 2/3/17 | 1:30 | Error message in x-ray machine |
| CCL | 4/20/17 | 6:00 | Preventive maintenance |
| CCL | 3/22/17 | 2:00 | Monitors causing noise to control room |
| CCL | 4/19/17 | 1:00 | Preventive maintenance |
| CCL | 8/21/17 | 5:00 | Preventive maintenance |
| CCL | 9/7/17 | 1:00 | Keyboard not working in control room |
| CCL | 9/22/17 | 6:30 | Preventive maintenance |
| CCL | 1/3/18 | 1:00 | Speaker on x-ray is too loud |
| CCL | 1/12/18 | 4:00 | Preventive maintenance |
| CCL | 4/5/18 | 3:30 | Images are dark and grainy |
| CCL | 6/21/18 | 4:00 | Preventive maintenance |
| CCL | 10/10/18 | 5:30 | Preventive maintenance |
| CCL | 12/5/18 | 5:00 | Monitor cannot be turned on |

*Completed date for preventive maintenance; reported date for all other work completed

Source: JHBMC response to MHCC questions, March 5, 2020.

Table 1B: JHBMC EPL Closures

| Location | Date* | Hours Closed | Reason/Explanation |
|-----------------|--------------|---------------------|---|
| EPL | 1/9/15 | 6:00 | Overheat message |
| EPL | 2/4/15 | 1:00 | Tube is rotating very slow, error message |
| EPL | 2/19/15 | 1:00 | X-ray tube not functioning |
| EPL | 4/21/15 | 1:00 | Blood pressure cuff not working |
| EPL | 6/25/15 | 1:15 | C-arm moving slowly |
| EPL | 7/29/15 | 1:00 | Cable hanging out of ceiling |
| EPL | 8/4/15 | 3:45 | Cracked/damaged components |
| EPL | 8/14/15 | 0:30 | Preventive maintenance |
| EPL | 10/8/15 | 5:30 | Preventive maintenance |
| EPL | 12/4/15 | 1:00 | EKG errors in the log |
| EPL | 3/3/16 | 1:00 | Monitor color issues |
| EPL | 5/23/16 | 7:45 | X-ray error message |
| EPL | 9/6/16 | 1:00 | AP detector coolant low |
| EPL | 11/1/16 | 0:30 | Preventive maintenance |
| EPL | 11/9/16 | 2:30 | Issue with cooling system |
| EPL | 2/13/17 | 2:00 | Test of lateral tube, collimator off |
| EPL | 2/17/17 | 0:00 | Collimator blades in view |
| EPL | 3/21/17 | 4:00 | Not sending images |
| EPL | 8/14/17 | 1:00 | Unable to access menu, frozen |
| EPL | 10/12/17 | 1:30 | Preventive maintenance |
| EPL | 10/27/17 | 2:00 | X-ray disabled |
| EPL | 11/20/17 | 1:00 | Preventive maintenance |
| EPL | 12/18/17 | 1:00 | Fluid needs removal, missing barcode |
| EPL | 2/12/18 | 1:30 | Frontal detector fluid low error message |
| EPL | 2/20/18 | 2:30 | Suspect incorrect dose delivered |
| EPL | 2/26/18 | 1:00 | Failure to boot properly |
| EPL | 2/27/18 | 5:30 | Boot sector failure |
| EPL | 3/7/18 | 5:00 | Preventive maintenance |
| EPL | 5/17/18 | 4:00 | Tube not working |
| EPL | 6/18/18 | 2:00 | Rebooted due to memory dump error |
| EPL | 9/24/18 | 2:00 | Lateral tube image not showing full field |
| EPL | 10/10/18 | 6:00 | Preventive maintenance |
| EPL | 11/1/18 | 2:00 | Beeping sound in equipment room |

*Completed date for preventive maintenance; reported date for all other work completed
 Source: JHBMC response to MHCC questions, March 5, 2020.

Staff Analysis and Conclusion

MHCC staff concludes that JHBMC 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.

JHBMC provided a signed statement from Richard G. Bennett, M.D., the hospital President, stating that JHBMC will provide primary PCI services and not exceed 90 minutes from patient arrival at the hospital, excluding transfer patients, for at least 75 percent of appropriate patients. Dr. Bennett also stated that the program will continue to track door-to-balloon times for all cases and evaluate areas for improvement through its PCI committee. Additionally, JHBMC provided a table of the percentages of door-to-balloon (DTB) times of 90 minutes or less for the period between January 2015 to and June 2019. JHBMC also reported that the hospital has not received any transfer PCI cases over this period.

Table 2: JHBMC Reported Compliance With DTB Benchmark and Median DTB

| Quarter | Non-Transfer Cases | |
|-----------|---|----------------------|
| | Percentage of Cases With DTB 90 Minutes or Less | Median DTB (Minutes) |
| CY2015 Q1 | 100% | 70 |
| CY2015 Q2 | 86.67% | 62 |
| CY2015 Q3 | 100% | 59 |
| CY2015 Q4 | 100% | 64 |
| CY2016 Q1 | 94.44% | 64 |
| CY2016 Q2 | 93.33% | 72 |
| CY2016 Q3 | 88.24% | 67 |
| CY2016 Q4 | 100% | 66 |
| CY2017 Q1 | 93.33% | 61 |
| CY2017 Q2 | 88.89% | 62 |
| CY2017 Q3 | 81.25% | 64 |
| CY2017 Q4 | 100% | 63 |
| CY2018 Q1 | 92.86% | 72 |
| CY2018 Q2 | 92.86% | 61 |
| CY2018 Q3 | 81.25% | 66 |
| CY2018 Q4 | 90% | 67 |
| CY2019 Q1 | 91.67% | 75 |
| CY2019 Q2 | 83.3% | 61 |

Source: JHBMC application and response to MHCC questions March 5, 2020.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR data and found that JHBMC met the door-to-balloon time standard in all but two quarters, as shown in Table 3. MHCC staff's analysis differs from the information provided by the hospital because the ACC-NCDR reports exclude certain

cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, JHBMC complied with this standard, with between 78% and 84% of PCI cases meeting the door-to-balloon time standard, as shown in Table 3.

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

| Time Period | Quarter | | | Rolling 8-Quarters | | |
|-------------|--------------------------|-----------------------------|--|--------------------------|-----------------------------|--|
| | Total Primary PCI Volume | Cases With DTB <=90 Minutes | Percent of Cases With DTB <=90 Minutes | Total Primary PCI Volume | Cases With DTB <=90 Minutes | Percent of Cases With DTB <=90 Minutes |
| 2015 Q1 | 21 | 21 | 100% | | | |
| 2015 Q2 | 14 | 11 | 79% | | | |
| 2015 Q3 | 11 | 9 | 82% | | | |
| 2015 Q4 | 10 | 9 | 90% | | | |
| 2016 Q1 | 17 | 16 | 94% | | | |
| 2016 Q2 | 20 | 16 | 80% | | | |
| 2016 Q3 | 22 | 15 | 68% | | | |
| 2016 Q4 | 10 | 8 | 80% | 105 | 125 | 84% |
| 2017 Q1 | 16 | 14 | 88% | 98 | 120 | 82% |
| 2017 Q2 | 11 | 8 | 73% | 95 | 117 | 81% |
| 2017 Q3 | 17 | 13 | 76% | 99 | 123 | 80% |
| 2017 Q4 | 9 | 7 | 78% | 97 | 122 | 80% |
| 2018 Q1 | 15 | 13 | 87% | 94 | 120 | 78% |
| 2018 Q2 | 14 | 12 | 86% | 90 | 114 | 79% |
| 2018 Q3 | 14 | 11 | 79% | 86 | 106 | 81% |
| 2018 Q4 | 8 | 7 | 88% | 85 | 104 | 82% |

Source: MHCC staff analysis of ACC-NCDR CathPCI Data, CY 2015- CY 2018.

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

MHCC staff concludes that JHBMC meets 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.

JHBMC provided the number of physicians, nurses, and technicians who are able to provide cardiac catheterization services to acute myocardial infarction patients as of one week before the due date of the application, as shown in Table 4A. JHBMC also stated that at the time of submission of the application, the hospital had one open nursing position; this position has since been filled.

Table 4A: Total Number or Full-Time Equivalent (FTE) Cardiac Catheterization Laboratory, Physician, Nursing, and Technical Staff

| Staff Category | Number/FTEs | Cross Training |
|------------------------------|--------------------------------------|--|
| Physician | 10 | |
| Nurse | 4 (1.0 FTE), 2 (0.5 FTE), 1 (PRN) | 3 monitor; all circulate |
| Special Procedure Technician | 1 (0.8 FTE), 3 (1.0 FTE); 1 (PRN) | All scrub, monitor, and serve as radiologic technologist |
| Cardiovascular Technologist | 2 (1 FTE) | All monitor |

Source: JHBMC Application, Q6a

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by JHBMC to information reported in JHBMC's primary PCI waiver application in 2013. In 2013, JHBMC reported eight physicians, three fellows, four FTE nurses, three FTE cardiovascular technologists, and four FTE special procedure technicians. Staff also compared the staffing levels reported by JHBMC to the staffing levels for two other hospitals, as reported in each hospital's application for a Certificate of Ongoing Performance for Elective and Primary PCI services. As shown in Table 4B, the nurse FTEs and technician FTEs at JHBMC were similar to those of AHC Shady Grove.

Table 4B: CCL Staffing, JHBMC and Selected Other PCI Programs, 2019

| Program | Total PCI Case Volume in Prior Year | Number (N) or FTE Interventionalists | Nurse FTEs | Technician FTEs |
|--|-------------------------------------|--------------------------------------|------------|-----------------|
| JHBMC | 207 | N = 10 | 5.0 | 5.8 |
| University of Maryland Prince George's Hospital Center | 247 | N = 5 | 10.0 | 6.0 |
| AHC Shady Grove | 269 | N = 5 | 6.0 | 5.0 |

Sources: JHBMC 2019 PCI Certificate of Ongoing Performance Application, University of Maryland Prince George's Hospital Center 2019 PCI Certificate of Ongoing Performance Application, AHC Shady Grove 2019 PCI Certificate of Ongoing Performance Application

MHCC staff concludes that is adequate nursing and technical staff to provide services; therefore, JHBMC meets 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.

JHBMC provided a signed letter of commitment from Richard G. Bennett, M.D., President, acknowledging that JHBMC 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 JHBMC 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.

JHBMC provided a description of the staff involved with these functions. Specifically, one nurse is a full-time outcomes data coordinator who submits all data to the ACC-NCDR CathPCI data registry as well as the MHCC Quality Reports website. This nurse coordinates the PCI Committee meetings and reviews all PCI data, adverse events, and issues with any PCI patients or concerns with the cardiac catheterization laboratory. This nurse is also part of the JHBMC Clinical Practice Committee and reports outcomes of reviews from the external review organizations.

Staff Analysis and Conclusion

MHCC staff concludes that JHBMC is compliant with this standard.

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

Dr. Jeffery C. Trost serves as the Director of Invasive and Interventional Cardiology at JHBMC. He was named the Director in 2007. As Director, he is the physician contact for all clinical, research, and administrative issues related to interventional cardiology procedures. JHBMC submitted a form with a list of the Director's responsibilities.

Staff Analysis and Conclusion

MHCC staff concludes that JHBMC is compliant with this standard.

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

JHBMC provided a lists of educational activities for staff in the cardiac catheterization laboratory and cardiac intensive care unit for the period of January 2015 through December 2018. JHBMC also clarified that while no specific number of continuing education units are required, JHBMC requires annual testing for competency for all staff on equipment such as Avoximeter, glucometer, and intra-aortic balloon pump (IABP). The hospital has mandatory annual online training for safety and infection control. JHBMC also reported that staff are required to be certified in Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS). There is also occasional in-service training from vendors.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that JHBMC 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.

Richard Bennett, M.D., President, JHBMC and Redonda Miller, M.D., President, Johns Hopkins Hospital (JHH), signed and dated a letter of agreement expressing the full commitment of JHH as the Tertiary Care Center in support the non-primary PCI program at JHBMC. The agreement states that JHH unconditionally accepts the transfer of PCI patients from JHBMC for any required additional care, including emergent or elective cardiac surgery or PCI. JHBMC also submitted a patient transfer agreement with JHH for PCI patients. This patient transfer agreement states that JHH will unconditionally accept the transfer of JHBMC patients receiving primary PCI or non-primary PCI for any required additional care, including emergent or elective cardiac surgery or PCI.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of agreement and the patient transfer agreement submitted and concludes that JHBMC 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.

JHBMC submitted a signed letter of agreement between Richard Bennett, M.D., President, JHBMC, Redonda G. Miller, M.D., President, JHH, and James Scheulen, P.A., M.B.A., President, JHEMS, expressing the full commitment of the Johns Hopkins Lifeline, ground, and air medical transportation services to the non-primary PCI program at JHBMC. The agreement states that patients are transported by air or ground from JHBMC and arrive at the JHH within 30 minutes of a request from JHBMC. JHBMC also submitted a letter of agreement signed by Richard G. Bennett, M.D., President, JHBMC, and Arjun Chanmugam, M.D., Chair, Emergency Medicine, JHBMC, stating that JHBMC uses a dedicated alert line for patients with acute coronary syndromes. The agreement states that, when clinically necessary, the Hopkins Access Line (HAL) guarantees the arrival of the ground ambulance at JHBMC within 30 minutes to transport the patient to a tertiary care center.

Staff Analysis and Conclusion

MHCC staff reviewed the agreements submitted by JHBMC. Mr. Scheulen serves as the director of HAL and Johns Hopkins Lifeline. Staff conclude that JHBMC meets 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.

JHBMC submitted attendance records for staff meetings and case review meetings from 2015 through 2018. JHBMC stated that the medical director of the cardiac catheterization laboratory and the interventional cardiologists are present for reviews.

Staff Analysis and Conclusion

Staff reviewed attendance records submitted for ten staff meetings in 2015, ten staff meetings and one case review meeting in 2016, three staff meetings and five case review meetings in 2017, and seven case review meetings in 2018.

MHCC staff concludes that JHBMC 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.

JHBMC provided a list of meeting dates and a list of participants for the PCI Committee meetings. JHBMC also reported that PCI program staff often communicate with each other in person, phone, or via email on any issue that arises, and they do not always wait for monthly meetings to discuss concerns or begin improvement.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation provided and discovered that several monthly meeting attendance records were missing or that meetings had been cancelled. In 2015, JHBMC stated that three monthly meetings had been cancelled for reasons that include a lack of staff available to meet, EPIC training, and the EPIC system start. JHBMC could not verify if meetings had occurred for two other months. In 2016, JHBMC stated that four meetings were cancelled due to lack of staff availability to meet, and a meeting took place in another month, but the attendance record and meeting minutes could not be located. In 2017, JHBMC reported that three meetings were cancelled due to lack of staff availability. In 2018, JHBMC reported that meetings took place monthly without cancellations. In total, between seven and nine meetings were held in 2015, eight meetings were held in 2016, nine meetings were held in 2017, and 12 meetings were held in 2018.

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.

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

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 4. Although only 5% of cases are required to be reviewed, beginning in the second half of 2015, a minimum number of cases to be reviewed for each interventionalist was specified in COMAR 10.24.17, which results in a much higher percentage of cases reviewed for many hospitals, including JHBMC. As shown in Table 4, between 21% and 31% of cases were reviewed. Previously, there was no minimum number of cases to be reviewed.

Table 4: JHBMC External Review, CY 2015- CY 2019

| Time Period | Elective PCI Volume | Number of Cases Reviewed | Percentage of Cases Reviewed | Meets Standard* |
|--------------------|----------------------------|---------------------------------|-------------------------------------|------------------------|
| CY 2015 | 155 | 41 | 26% | Partially |
| 2016 Q1Q2 | 58 | 18 | 31% | Yes |
| 2016 Q3Q4 | 73 | 16 | 22% | Yes |
| 2017 Q1Q2 | 69 | 15 | 22% | Yes |
| 2017 Q3Q4 | 85 | 15 | 22% | Yes |
| 2018 Q1Q2 | 56 | 15 | 27% | Yes |
| 2018 Q3Q4 | 56 | 13 | 23% | Yes |
| 2019 Q1Q2 | 85 | 18 | 21% | Yes |

Source: MHCC Analysis, JHBMC Application updated Q15 and MACPAQ Reports

*Each semiannual review must include three cases per physician or all cases if an interventionalist performed fewer than three cases during the review period

Due to the lack of specificity in the requirements for external review in COMAR 10.24.17 prior to the update in November 2015, many hospitals delayed conducting the external review. In a bulletin issued in October 2015, MHCC staff advised hospitals to conduct an external review for all cases performed in CY 2015, and if the hospital had not conducted semiannual reviews on schedule, then the hospital should still review cases late, rather than not reviewing at all. Hospitals were advised that if the review cycle period ended after the effective date of the updated COMAR regulations, then the new standards for external review should be followed, and this approach was taken by JHBMC for CY 2015. JHBMC should have conducted semiannual reviews in CY 2015, which is why JHBMC only partially meets the standard for external review for this period. For the period between January 2015 and December 2018, MHCC staff verified that if fewer than three

cases had been performed by an interventionalist, then all cases were reviewed by MACPAQ, as required.

JHBMC 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)I, 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, JHBMC described that the CCL Medical Director conducts a full angiographic and medical record review of every primary PCI and all elective PCI cases in which a significant life-threatening complication occurred (i.e. patient death, heart attack, or stroke). This internal review comprises roughly one-third of all PCIs performed at JHBMC in a calendar year among all individual operators combined. For cases where the CCL Medical Director is the operator, the Johns Hopkins Hospital CCL Medical Director performs the reviews. Feedback from the review is provided either by privileged peer-to-peer communication or group discussion during weekly joint interventional cardiology/CLL conferences.

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 When an individual interventionalist has performed fewer than three cases for a review cycle, then all cases are to be reviewed.

The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records. MHCC staff validated that the minimum number of cases were included in the external review through analysis

¹https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

of the ACC-NCDR CathPCI data submitted for the period January 2015 through December 2018. In almost all review cycles, the minimum number of cases reviewed exceeded 10% of the volume performed by the interventionalists. However, for one interventionalist, one additional case should have been reviewed in three review cycles, and two additional cases in one review cycle.

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

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

JHBMC submitted a statement from Richard G. Bennett, M.D. President, stating that JHBMC is committed to the continuous improvement of quality, its monitoring methods and the day-to-day application of such methods. Specifically, JHBMC participated in the ACC-NCDR CathPCI registry for benchmarking and quality monitoring. Dr. Bennett also stated that JHBMC will provide primary PCI services in accordance with the requirements established by MHCC.

Staff Analysis and Conclusion

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

The JHBMC PCI Committee is the primary operational committee to review and implement all quality initiatives involved in PCI patient care. The PCI Committee considers all aspects of care from first point of contact with the emergency medical system (EMS) to discharge. JHBMC provided examples of elements discussed by the PCI Committee. These include the proportion of EMS patients who receive field electrocardiograms (EKGs); the proportion of walk-

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

in patients who receive timely EKGs and activation of the Heart Attack Team; and the time for patient transport to the CCL upon Heart Attack Team activation.

JHBMC explained that MACPAQ reports are reviewed at the Clinical Practice Committee. Dr. Trost also reviews MACPAQ reports and all primary cases performed at JHBMC. All interventional cardiologists who perform procedures at JHBMC or JHH participate in a weekly joint interventional morbidity and mortality conference to review cases. Quality data from the ACC-NDCR CathPCI registry are presented to cardiology administration and faculty via Program Leadership and Development Conferences.

The CCL nurse manager reports quality measures to the Joint Practice Council and the Intensive Care Joint Practice Council, which meet quarterly to provide input on quality improvement initiatives. The CCL nurse manager also performs a follow-up call or visit for all patients post procedurally and records patient comfort during the procedure, any complications, and pain. The feedback is used to improve patient comfort and for patient education. The CCL team also collects data for improvement of charting accuracy and in-room procedure start time; all charts are audited on a monthly basis. JHBMC submitted meeting minutes for PCI Committee Meetings between 2015 through 2018 and several Outcomes Coordinator Meetings and Clinical Practice Committee meetings during the review period.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that JHBMC complies with this standard.

Patient Outcome Measures

10.24.17.07C(5)

- (a) An elective PCI program shall meet all performance standards established in statute or in State regulations.***
- (b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.***
- (c) A hospital shall be subject to a focused review if it has a risk-adjusted mortality rate for non-STEMI PCI cases that exceeds an established benchmark beyond the 95 percent confidence interval calculated for the hospital's all-cause in-hospital risk-adjusted rate for non-STEMI PCI cases.***
 - (i) The primary benchmark is the national median in-hospital risk-adjusted mortality rate for non-STEMI PCI cases, calculated from the CathPCI Registry data; and***
 - (ii) If the statewide median risk-adjusted mortality rate for elective PCI cases is obtained by the Commission within twelve months of the end of the reporting***

period, then the statewide median in-hospital risk-adjusted mortality rate for elective PCI cases will be used as a second benchmark.

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*

JHBMC submitted adjusted mortality by rolling 12-month reporting periods for 2015 Q1 through 2019 Q2, when available, as shown in Table 5. 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 5: JHBMC Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period
and Performance on MHCC Standards for PCI Programs**

| Reporting Period | STEMI | | | | NONSTEMI | | | |
|------------------|--|---------------|--------------|---------------------|--------------|---------------|--------------|---------------------|
| | Hospital AMR | 95% CI | National AMR | Meets MHCC Standard | Hospital AMR | 95% CI | National AMR | Meets MHCC Standard |
| 2018q3-2019q2 | 10.15 | [4.54, 18.56] | 6.38 | Yes | 1.20 | [0.03, 6.56] | 1.0 | Yes |
| 2018q2-2019q1 | 9.55 | [3.61, 19.38] | 6.13 | Yes | 2.85 | [0.35, 10.05] | 0.99 | Yes |
| 2018q1-2018q4 | 11.35 | [3.78, 24.8] | 6.00 | Yes | 4.21 | [0.51, 14.84] | 1.00 | Yes |
| 2017q4-2018q3 | 12.39 | [4.11, 27.19] | 6.54 | Yes | 2.10 | [0.05, 11.46] | 0.98 | Yes |
| 2017q3-2018q2 | Not available for any hospitals participating in the ACC CathPCI Data Registry | | | | | | | |
| 2017q2-2018q1 | 8.65 | [2.4, 20.81] | 6.91 | Yes | NR | [0, 3.8] | 1.03 | Yes |
| 2017q1-2017q4 | 4.68 | [0.57, 16.1] | 6.86 | Yes | NR | [0, 5.3] | 0.99 | Yes |
| 2016q4-2017q3 | 6.22 | [1.3, 17.18] | 6.75 | Yes | 1.30 | [0.03, 7.13] | 0.98 | Yes |
| 2016q3-2017q2 | 5.00 | [0.61, 17.27] | 6.64 | Yes | 0.95 | [0.02, 5.19] | 0.95 | Yes |
| 2016q2-2017q3 | 8.60 | [1.79, 24.0] | 6.77 | Yes | 1.07 | [0.03, 5.83] | 0.97 | Yes |
| 2016q1-2017q4 | 7.82 | [2.16, 19.05] | 6.82 | Yes | 1.09 | [0.03, 5.92] | 0.95 | Yes |
| 2015q4-2016q3 | 7.21 | [1.5, 20.15] | 6.71 | Yes | NR | [0, 4.07] | 0.95 | Yes |
| 2015q3-2016q2 | 7.46 | [1.56, 20.69] | 6.66 | Yes | NR | [0, 7.97] | 0.93 | Yes |
| 2015q2-2016q1 | 2.46 | [0.06, 13.13] | 6.45 | Yes | 2.53 | [0.31, 8.96] | 0.90 | Yes |
| 2015q1-2015q4 | NR | [0, 11.45] | 6.26 | Yes | 2.93 | [0.61, 8.39] | 0.90 | Yes |

Source: MHCC Staff compilation of results from the hospital's quarterly reports from the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between January 2015 and March 2018

Notes: "NR" means not reported. When a hospital has zero deaths for a reporting period, the hospital's AMR is labeled NR. A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) included the National AMR or indicated statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or Non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI or non-STEMI cases, as applicable

Staff Analysis and Conclusion

This standard is not applicable for the majority of the review period for JHBMC's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar standard that was adopted previously referenced a statewide average as the benchmark, and MHCC staff were not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. However, MHCC staff has provided information in Table 5 on how JHBMC performed over the period between January 2015 and June 2019.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for both STEMI and non-STEMI 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 JHBMC for all 12-month reporting periods between 2015 Q1 and 2019 Q2. MHCC staff concludes that JHBMC would have met this standard, if it were applicable for the period reviewed. A report for the hospital's performance for the period ending December 2019, the first period for which the current standard applies, is not yet available.

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.

For each physician who performs PCI at JHBMC, JHBMC submitted the volume of primary PCI cases at JHBMC as well as primary and elective cases at other hospitals by quarter from 2015 through the end of 2018. Drs. Trost, Johnson, Williams, Miller, Hasan, Brinker, Hwang, Chacko, Resar, and Czarny each signed and dated an affidavit affirming under penalties of perjury that the information contained in the table on the doctor's individual form is true and correct to the best of the doctor's knowledge, information, and belief.

Staff Analysis and Conclusion

MHCC staff analyzed data from the ACC-NCDR CathPCI registry to validate that interventionalists who performed primary PCI between January 2015 and December 2018 performed an average of at least 50 cases annually over 24-month periods. All of the interventionalists met the standard.

JHBMC 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.

JHBMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to JHBMC. While JHBMC does not have on-site cardiac surgery, each physician performing primary PCI performed over 50 PCI procedures annually on average over each of the two 24-month periods between January 2015 and December 2018.

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.***

JHBMC responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to JHBMC. While JHBMC does not have on-site cardiac surgery, each physician performing primary PCI performed over 50 PCI procedures annually averaged over each of two 24-month periods between January 2015 and December 2018.

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.

JHBMC submitted a signed and dated statement from Jeffrey C. Trost, M.D., director of the cardiac catheterization laboratory, acknowledging that all physicians performing primary PCI services at JHBMC are board certified in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff concludes that JHBMC meets the standards for board certification.

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.

JHBMC submitted signed and dated attestations from Drs. Trost, Johnston, Williams, Miller, Hasan, Czarny, Hwang, Chacko, and Resar stating each physician completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years. JHBMC did not include a statement for Dr. Thiemann.

Staff Analysis and Conclusion

Although the application from JHBMC did not include an attestation for Dr. Thiemann, a statement from him was submitted by Howard County General Hospital in its 2019 PCI Certificate of Ongoing Performance application.

MHCC staff reviewed the attestations provided and concludes that JHBMC meets this standard.

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

JHBMC submitted a signed statement from the Medical Director of the Cardiac Catheterization Laboratory, Dr. Jeffrey C. Trost, acknowledging that each physician who has performed primary PCI services during the performance period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. JHBMC also submitted a copy of the on-call schedule for March 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for March 2019 and observed that Drs. Thiemann, Johnston, Chacko, Hasan, Czarny, Resar, Trost, and Miller were all scheduled to be on-call at different times during the month. Dr. Stephen Williams was not scheduled during March 2019 at JHBMC. Staff requested additional information about Dr. Williams and JHBMC responded that Dr. Williams participates in the primary PCI on-call schedule at other facilities. Staff notes that its analysis of the data in the ACC-NCDR CathPCI registry indicates that Dr. Williams performed only one primary PCI case at JHBMC in 2017, over the period January 2015 to December 2018.

MHCC staff concludes that JHBMC meets this standard.

Volume

10.24.17.07C(7)(a) The target volume for an existing program with both primary and non-

primary PCI services is 200 cases annually.

(b) A PCI program that provides both primary and elective PCI that fails to reach the target volume of 200 cases annually may be subject to a focused review.

JHBMC provided a table identifying the number PCI cases for fiscal years 2015 to 2019.

Table 6: JHBMC PCI Volume, FY 2015- FY 2019

| Fiscal Year | Total PCI |
|-------------|-----------|
| 2015 | 236 |
| 2016 | 195 |
| 2017 | 210 |
| 2018 | 200 |
| 2019 | 207 |

Source: MHCC analysis of JHBMC application, Q28, Updated Q28.

Staff Analysis and Conclusion

MHCC staff reviewed the table submitted by JHBMC. This data shows that JHBMC met or exceeded the target volume for PCI cases in four of five years, and performed just slightly under the standard for FY 2016, with 195 PCI cases reported.

MHCC staff concludes that JHBMC meets this standard.

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

JHBMC responded that this regulation is not applicable. As shown in Table 7, JHBMC also provided the primary PCI volume by calendar year to demonstrate that the primary PCI volume exceeded the threshold in the standard for triggering a focused review.

Table 7: JHBMC Primary PCI Volume, CY 2015- CY 2018

| Year | Number of Cases |
|---------|-----------------|
| CY 2015 | 60 |
| CY 2016 | 71 |
| CY 2017 | 60 |
| CY 2018 | 58 |

Source: JHBMC response to MHCC questions, June 1, 2020.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2018. This analysis is consistent with the volume reported by JHBMC,

and it confirms that JHBMC exceeded the threshold of 49 cases annually referenced in the standard.

MHCC staff concludes that the standard is not applicable to JHBMC.

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

JHBMC provided the number of primary PCI cases by interventionalist on a quarterly basis for the period from January 2015 to December 2018, except for Dr. Thiemann.

Staff Analysis and Conclusion

MHCC staff reviewed the tables submitted by JHBMC. While JHBMC did not submit volume information for Dr. Thiemann, staff was able to evaluate his annual primary case volume by using the Form A that was submitted by Howard County General Hospital for its 2019 PCI Certificate of Ongoing Performance application. Staff analyzed the data in the ACC-NCDR CathPCI registry for CY 2015- CY 2018 and concluded that each interventionalist met the target of 11 or more primary PCI cases annually.

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.***

JHBMC responded that external review identified one patient who may have received inappropriate PCI based on angiographic results. However, an internal review, which incorporated a more extensive evaluation of the clinical characteristics of the patient, concluded that the PCI was reasonable treatment for the patient. Following the initial submission of JHBMC's application, JHBMC submitted additional newly available results from the external reviews of elective PCI cases in two additional review cycles.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports from 2015 through June 2019 and determined that there was one case during this period that was determined to be "rarely

appropriate” with respect to more than one criteria. JHBMC responded that this case was reviewed by the medical director and communicated to the interventionalist via secure and confidential email, with a request to acknowledge receipt and review of the comments. As a result of the interventionalist’s longstanding track record of performing appropriate PCI procedures, as indicated by other reports from MACPAQ and internal review of cases, no further action was taken by the medical director. In a different review cycle, another case was deemed by the external reviewer to be rarely appropriate based on angiographic criteria, and JHBMC followed-up on further review of this case, and concluded that the case was clinically appropriate.

MHCC staff concludes that JHBMC 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.***

JHBMC responded that no patients received primary PCI services inappropriately, according to internal review. JHBMC responded that one patient received thrombolytic therapy during the review period while the PCI team was in route to the CCL.

Staff Analysis and Conclusion

MHCC concludes that JHBMC complies with this standard.

RECOMMENDATION

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