IN THE MATTER OF	*	**BEFORE THE**
CARROLL HOSPITAL	*	**MARYLAND**
CENTER, INC.	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 24-24-CP053	*	

*** ***

STAFF REPORT AND RECOMMENDATION

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

November 21, 2024

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 Maryland Health Care Commission (MHCC or Commission) issued waivers to hospitals to exempt these hospitals from the requirement for co-location of primary 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 Services Chapter) of the State Health Plan for Facilities and Services (State Health Plan) was replaced, effective August 2014. The Cardiac Services Chapter was subsequently revised in November 2015 and again in January 2019.

The Cardiac Services Chapter contains standards for evaluating the performance of established cardiac surgery and PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or both primary and elective (non-primary) PCI services, for a time specified by the Commission that cannot exceed five years, unless an extension is granted by the Executive Director. At the end of the period, the hospital must demonstrate that it continues to meet the requirements in the Cardiac Services Chapter in order for the Commission to renew the hospital's authorization for a Certificate of Ongoing Performance.

In between renewals for a Certificate of Ongoing Performance, if a hospital is not in compliance with certain standards, a focused review shall be conducted. The regulations authorize Commission staff to conduct a focused review based on reported patient safety concerns, aberrations in data, or failure to meet quality standards established in State and federal regulations.[1] A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance must receive a detailed list of deficiencies from Commission staff and submit a plan of correction within 30 days of receipt of the list of deficiencies.[2] If a hospital does not submit a plan of correction that addresses the deficiencies cited or successfully complete a plan of correction, the hospital shall, upon notice of the Executive Director of the Commission, voluntarily relinquish its authority to perform cardiac surgery or emergency or elective PCI services, as applicable.[3]

B. Applicant

Carroll Hospital Center, Inc.

Carroll Hospital Center, Inc. (CHC) is a 164-bed acute care general hospital located in Westminster, Maryland (Carroll County). It is part of the LifeBridge Health System. The hospital does not have a cardiac surgery program.

CHC initiated primary PCI services on October 8, 2008, and has continued performing primary PCI without cardiac surgery on-site through waivers issued in 2009, 2011, and 2013. A Certificate of Conformance allowing the hospital to provide elective PCI services was approved in December 2014. The hospital's first Certificate of Ongoing Performance for primary and elective PCI services was approved on September 17, 2020, for four years. In September 2024, a six-month extension was granted by the Executive Director of the Commission, to allow MHCC staff to complete a thorough review of CHC's current application for a Certificate of Ongoing Performance. This is CHC's first renewal of its Certificate of Ongoing Performance for primary and elective PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in the Cardiac Services Chapter. CHC is in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot counties, and Baltimore City. Fourteen hospitals in this health planning region provide PCI services. Six of these hospitals also provide cardiac surgery services. Eight hospitals provide only PCI services.

C. Staff Recommendation

MHCC staff recommends that the Commission approve CHC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services for four years

[1] COMAR 10.24.17.07B(2)(a), .07C(2)(a), and .07D(2)(a).
[2] COMAR 10.24.17.07B(2)(c), .07C(2)(c), and .07D(2)(c).
[3] COMAR 10.24.17.07B(2)(e), .07C(2)(e), and .07D(2)(e).

with one condition. A description of CHC's documentation of its performance and MHCC staff's analysis follows.

II. PROCEDURAL HISTORY

On April 4, 2024, CHC filed its application for a Certificate of Ongoing Performance for primary and elective PCI services. Additional information was requested by MHCC staff on July 22, 2024, September 27, 2024, November 1, 2024, and November 6, 2024. Additional information was provided by CHC on August 23, 2024, October 17, 2024, November 4, 2024, and November 8, 2024.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07C(3) and .07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACC-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.

The hospital has submitted the data and reports required by MHCC. In its application, CHC reported that there are currently no deficiencies in data collection or reporting.

Staff Analysis and Conclusion

CHC has complied with the submission of data to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI, with duplicate data submitted to MHCC in accordance with the established schedule. There are no reporting periods when the hospital's performance on mortality metrics or other key quality metrics cannot be determined.

MHCC staff concludes that CHC 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.

CHC reported that the hospital has a total of three cardiac catheterization laboratories (CCLs) that are capable of cardiac angiography and PCI services. Despite one CCL being down for four months while a replacement CCL was constructed, the hospital states that there was never a time that a patient was deferred, diverted, or treated differently due to equipment or room concerns. CHC submitted a log of work orders for the three CCLs. The number of downtime occurrences for each CCL is reported in Table 1 below. A detailed description of the downtime for each CCL is shown in Appendix 1.

Table 1. CHC's Reported CCL Downtime Occurrences by Room, CY 2019 – CY 2023

Year	Lab 1	Lab 2	Lab 3	Overlapping Downtime*
CY 2019	N/A	11	4	No
CY 2020	N/A	10	11	No
CY 2021	2	3	0	No
CY 2022	10	2	0	No
CY 2023	7	6	1	No

Source: CHC's application for a Certificate of Ongoing Performance 2024, p. 3, and supplemental information received on August 23, 2024, and October 17, 2024.
*Overlapping downtime refers to instances when all three CCLs are not in service.
Notes: Installation of Lab 1 was completed on September 22, 2021, and renovation of Lab 3 was completed between January 5, 2023, and May 11, 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided on CCL room closures submitted by CHC and determined that none of the maintenance or repairs completed left the hospital without a functional CCL from CY 2019 to CY 2023. At least one CCL was always available for primary PCI services 24 hours per day, seven days per week during the period reviewed.

MHCC staff concludes that CHC 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 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

CHC provided a signed statement from Garrett Hoover, MA, MHA, FACHE, President and Chief Operating Officer (COO) of Carroll Hospital and Senior Vice President of LifeBridge Health, attesting that the hospital will provide primary PCI services as soon as possible and not to exceed 90 minutes from the time when patients arrive at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital reported that it does not accept transfer PCI cases. Additionally, CHC provided the number and percentage of non-transfer primary PCI patients with a DTB time less than 90 minutes, for the period between January 2020 through December 2023, as shown in Table 2. During this period, the hospital stated that 83.3 to 100 percent of cases met this standard.

Table 2. CHC's Reported Door-to-Balloon (DTB) Times for Non-Transfer Primary PCI Cases by Quarter, January 2020 – December 2023

Quarter Ending	Number of Non-Transfer Primary PCI Patients	Number of Non-Transfer Patients with DTB Time ≤ 90 Minutes	
		Number	Percentage
CY 2020 Q1	19	18	94.7%
CY 2020 Q2	19	16	84.2%
CY 2020 Q3	12	10	83.3%
CY 2020 Q4	20	18	90.0%
CY 2021 Q1	8	7	87.5%
CY 2021 Q2	14	13	92.8%
CY 2021 Q3	10	9	90.0%
CY 2021 Q4	17	16	94.1%
CY 2022 Q1	11	10	90.9%
CY 2022 Q2	21	19	90.5%
CY 2022 Q3	22	19	86.4%
CY 2022 Q4	9	8	88.9%
CY 2023 Q1	15	15	100.0%
CY 2023 Q2	13	13	100.0%
CY 2023 Q3	12	12	100.0%
CY 2023 Q4	16	16	100.0%

Source: CHC's application for a Certificate of Ongoing Performance 2024, p.4.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI Registry data for non-transfer primary PCI cases for the period from CY 2020 to CY 2023, as shown in Table 3a. Staff determined that CHC met the DTB standard in six of the eight quarters during CY 2022 and CY 2023. While the DTB time standard was not met in five of the eight quarters in CY 2020 and CY 2021, compliance with this standard was waived due to the COVID-19 state of emergency. Between 53.8 and 100 percent of non-transfer primary PCI cases met the DTB standard during the review period from CY 2020 through CY 2023.

CHC provided the reasons for delay for each primary PCI case identified that exceeded a DTB time of 90 minutes for the quarters where the DTB standard was not met. This information indicates that most PCI cases, which exceeded 90 minutes from DTB, had a patient specific, non-system reason for the delay. The reasons for delays included difficulty crossing the lesion, difficult vascular access, intubation, cardiac arrest, and an inability to obtain consent. In addition, during the COVID-19 pandemic, the suspected diagnosis of COVID in patients, time spent waiting for COVID test results, and a COVID surge in January 2022 also contributed to delays in DTB times in a few cases. For Q1 2020, four of the five patients who did not meet the DTB standard had a non-system reason for delay. In Q2 2020, six of eight patients had a non-system reason for delay, and in Q4 2020, six of seven patients had a non-system reason for delay. In the first two quarters of CY 2021, most patients, 13 of 15, had a non-system reason for the delay in DTB time. In the first quarter of CY 2022, four of five patients had a non-system reason for delay and in the last quarter of CY 2022, three of four patients had a non-system reason for delay.

Only a few system reasons contributed to the increase in DTB times. In one case, CHC reported that a fluoro reboot was needed for the CCL to resume normal functionality and the

decision was made to wait for the reboot rather than moving the patient to another room because the patient was already prepped and ready for the PCI. This is reasonable, as transfer of the PCI patient to a different CCL would have resulted in longer wait times for the patient. In another instance, the hospital reported that the Emergency Department (ED) physician waited to speak to the interventionalist, which is outside of standard procedure. In this case, the ED physician was educated to handle the situation differently in the future. In another case, the hospital identified as an opportunity for improvement, having EMS transmit the EKG and activate a STEMI alert with CHC prior to arrival of the patient in the ED. According to the hospital, the opportunity for improvement was communicated with the EMS provider involved. Only two PCI cases had no delay reason identified.

Table 3a. CHC's Compliance with DTB Benchmark by Quarter, CY 2020 - CY 2023

Quarter	Non-Transfer Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <= 90 Minutes
CY 2020 Q1	23	17	**73.9%**
CY 2020 Q2	25	17	**68.0%**
CY 2020 Q3	12	9	75.0%
CY 2020 Q4	26	19	**73.1%**
CY 2021 Q1	13	7	**53.8%**
CY 2021 Q2	22	13	**59.1%**
CY 2021 Q3	12	10	83.3%
CY 2021 Q4	19	15	78.9%
CY 2022 Q1	16	11	**68.8%**
CY 2022 Q2	21	17	81.0%
CY 2022 Q3	25	19	76.0%
CY 2022 Q4	13	9	**69.2%**
CY 2023 Q1	15	12	80.0%
CY 2023 Q2	16	14	87.5%
CY 2023 Q3	10	10	100.0%
CY 2023 Q4	17	16	94.1%

Source: MHCC staff's analysis of ACC-NCDR CathPCI data for CY 2020 – CY 2023.

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 the delay, and MHCC includes all cases in reviewing compliance with this standard. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers the hospital's performance over rolling eight-quarter periods, as shown in Table 3b.

Table 3b. CHC's Non-Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period

Quarter				Rolling Eight-Quarters		
Time Period	Total Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <= 90 Minutes	Total Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <=90 Minutes
CY 2020 Q1	23	17	**73.9%**			
CY 2020 Q2	25	17	**68.0%**			
CY 2020 Q3	12	9	75.0%			
CY 2020 Q4	26	19	**73.1%**			
CY 2021 Q1	13	7	**53.8%**			
CY 2021 Q2	22	13	**59.1%**			
CY 2021 Q3	12	10	83.3%			
CY 2021 Q4	19	15	78.9%	152	107	**70.4%**
CY 2022 Q1	16	11	**68.8%**	145	101	**69.7%**
CY 2022 Q2	21	17	81.0%	141	101	**71.6%**
CY 2022 Q3	25	19	76.0%	154	111	**72.1%**
CY 2022 Q4	13	9	**69.2%**	140	100	**71.4%**
CY 2023 Q1	15	12	80.0%	143	106	**74.1%**
CY 2023 Q2	16	14	87.5%	137	107	78.1%
CY 2023 Q3	10	10	100.0%	135	107	79.3%
CY 2023 Q4	17	16	94.1%	133	108	81.2%

Source: MHCC staff analysis of ACC-NCDR CathPCI data for CY 2020 – CY 2023.
Notes: Calculations for each quarter are based on the procedure date.

As shown in Table 3b, over rolling eight-quarter periods, between 69.7 and 81.2 percent of primary PCI cases met the DTB time standard. The hospital did not meet the DTB standard for six of the nine rolling eight-quarter periods that ended between Q4 2021 and Q4 2023. However, the hospital's performance was likely negatively affected by the COVID-19 pandemic in CY 2020 and CY 2021. Additionally, the hospital has met the DTB standard for all quarters in CY 2023, resulting in an adequate percentage of cases meeting the DTB time standard over rolling eight-quarters ending between Q2 and Q4 of 2023.

While no specific initiatives were undertaken by the hospital to improve DTB times during the review period, staff observed that many delays were due to non-system reasons. The hospital also reported that meeting the DTB standard is emphasized to staff and included in the goals for all staff on their annual performance reviews. Because staff receive better performance reviews for lower DTB times, hospital staff are incentivized to ensure that the patient is being taken from the ED to the CCL as soon as possible. In addition, MHCC staff noted that PCI meeting minutes indicate staff frequently review and discuss cases when DTB times exceed 90 minutes to identify any opportunities for improvement.

Because the hospital showed improvement in DTB times, and as this standard was waived for CY 2020 and CY 2021[4], MHCC staff recommends that the Commission find the hospital in

[4] https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/documents/MHCC%20bulletin_20210827.pdf

compliance 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 acute MI patients 24 hours per day, seven days per week.

CHC provided the number of physicians, nurses, and technicians available to provide cardiac catheterization services to acute myocardial infarction patients as of one week before the application was submitted, as shown in Table 4a. As of April 5, 2024, the hospital had two open positions for technicians available; however, a contract employee was helping to fill one of these positions. The positions had also been posted for potential applicants, and a request had been made for another contractual technician.

Table 4a. Total Number of CCL Physician, Nursing, and Technical Staff

Staff Category	Number/FTEs	Cross Training (S/C/M*)
Physician	4	
Nurse	11 (9.8 FTE)	C/M
Technician	4 (4 FTE)	S/M

Source: CHC's application for a Certificate of Ongoing Performance 2024, p. 5.
*Scrub (S), Circulate (C), Monitor (M)

Staff Analysis and Conclusion

MHCC staff compared CHC's staffing levels to information reported by three other existing PCI programs with similar case volumes. A comparison of volume and staffing levels for CHC, University of Maryland Baltimore Washington Medical Center (UM BWMC), Medstar Franklin Square Medical Center (MFSMC), and Johns Hopkins Bayview Medical Center (JHBMC) is shown in Table 4b. MHCC staff observed that CHC and MFSMC performed the same number of PCI cases in 2023 and have a similar number of interventionalists, nurses, and technicians available to provide PCI services to patients. While UM BWMC completed a few more PCI cases than CHC in 2023, the PCI program at UM BWMC operated with fewer interventionalists and nurse full-time equivalents (FTEs) than CHC, but with three more technician FTEs than CHC. Conversely, JHBMC performs almost 100 fewer PCIs annually than CHC, dedicating five more interventionalists and two additional technicians to the PCI program, but almost five fewer nurses.

Table 4b. CCL Staffing for CHC and Other Select PCI Programs

Program and Year Reported	Total PCI Volume	Number of Interventionalists or FTEs	Nurse FTEs	Technicians FTEs
CHC – CY 2023	222	4	9.8	4.0
UM BWMC – CY 2023	258	3	7.4	7.0
MFSMC – FY 2023	222	5	9.0	4.5
JHBMC – CY 2023	129	9	5.0	6.0

Source: CHC's application for Certificate of Ongoing Performance 2024, p. 5, UM BWMC's application for a Certificate of Ongoing Performance 2024, MFSMC's application for a Certificate of Ongoing Performance 2024, and JHBMC's application for a Certificate of Ongoing Performance 2024.

Based on the comparative information available, MHCC staff concludes that the hospital has adequate nursing and technician staff to provide PCI services. Staff concludes that CHC complies with this standard.

10.24.17.07D(4)(d) The hospital president or chief executive officer, as appropriate, shall provide a written commitment stating the hospital administration will support the program.

CHC provided a written letter, signed by President and COO of Carroll Hospital, Garrett Hoover, MA, MHA, FACHE, confirming that the hospital will provide primary PCI services in accordance with the requirements established by the MHCC.

Staff Analysis and Conclusion

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

CHC employs a Quality Reviewer, Veronica Shaffer, RN, BSN, who is responsible for data management, reporting, and coordination. This position is one FTE. CHC reports utilizing Q-Centrix for outside data collection and the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ) for external reviews of select PCI cases.

Staff Analysis and Conclusion

MHCC staff concludes that CHC 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 cardiac 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.

CHC reported that Dr. Calin Maniu was functioning as the medical director at the time of the hospital's last application for a Certificate of Ongoing Performance. He remained the medical director until July 1, 2019, when Dr. Anuj Gupta was named the Interventional Cardiology Services Director. Dr. Mukta Srivastava took over the appointment on July 1, 2021, until May 1, 2023, when primary coverage of the PCI program transitioned to LifeBridge Health. At that time, Dr. Henry Sun transitioned into the role of Director. CHC described his responsibilities as those that include the recruitment and supervision of all physicians with CCL privileges, development and implementation of a quality improvement plan, and daily and on-call scheduling.

Staff Analysis and Conclusion

MHCC staff reviewed the description of job duties for the medical director of the CCL that was provided by the hospital and concludes that CHC complies with this standard.

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

CHC provided a list of educational topics provided to both CCL and Coronary Care Unit (CCU) staff from CY 2018 to CY 2023.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for CCL and CCU staff includes appropriate topics relating to cardiac services, such as intra-aortic balloon pumps (IABP) and fiberoptic balloons, pacemaker insertion and management, radiation safety, and intravascular ultrasounds. MHCC staff concludes that CHC complies with this standard.

10.24.17.07D(4)(h) A hospital that performs primary PCI without on-site cardiac surgery shall have a formal, written agreement with a tertiary institution that provides for unconditional transfer of the hospital's patients for any required additional care, including emergent or elective cardiac surgery or PCI.

CHC submitted a transfer agreement signed in April 2015, by the hospital's president at the time, Leslie Simmons, RN, FACHE, and by Jonathan Ringo, M.D., who was president and COO of Sinai Hospital of Baltimore, Inc. The original agreement was amended on May 18, 2020, and states that in no event shall the transfer of any primary PCI patients who require additional care, including emergent or elective cardiac surgery or PCI, be subject to any conditions, including, without limitation, the availability of beds or any policies or procedures. This amendment was signed by President and COO of Carroll Hospital, Garrett Hoover, MA, MHA, FACHE, and the President of Sinai Hospital of Baltimore, Inc., Daniel Blum.

Staff Analysis and Conclusion

MHCC staff reviewed the transfer agreement and amendment provided by CHC and concludes that the hospital complies with this standard.

10.24.17.07D(4)(i) The hospital shall maintain a formal written 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.

CHC provided an agreement between the hospital and Pulse Medical Transport signed in 2015 by former Vice President of Clinical Integration, Sharon Sanders, and the subsequent amendment in 2018. The amendment was signed by Mark D. Olszyk, M.D., who was vice president of CHC at the time. This amendment guarantees the arrival of an air or ground ambulance

at CHC within 30 minutes of a request from the hospital for the transport of a primary PCI patient to a tertiary care center.

Staff Analysis and Conclusion

MHCC staff reviewed the transport agreement and subsequent amendment provided by CHC. The agreement automatically renews and remains in effect. Staff concludes that the hospital complies with this standard.

Quality

10.24.17.07C(4)(a) and .07D(5)(a) The hospital shall develop a formal process for interventional case review that includes regularly scheduled meetings (at least every other month) with required attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

CHC stated that one combined meeting (PCI Meeting) is held for both interventional case review and multiple care area group meetings. The hospital provided a list of dates and attendees at PCI Meetings held from CY 2019 through CY 2023 and explained the reasons for meeting cancellations. Meetings were cancelled in July 2019 due to an emergency for the CCL manager, in July 2022 because the Joint Commission was onsite, and in December 2019 and 2023 due to proximity to the holidays. Attendees at these PCI Meetings include interventionalists, and other physicians and nurses who care for primary PCI patients. While CHC reported that CCL technicians are invited to attend these meetings, the hospital verified that no technicians have been able to routinely attend. CHC states that pertinent information is communicated to staff in all areas including the CCL, ED, Critical Care, and Cardiology, by the leader of that area who attends the meeting. This communication may be via email, staff meeting, or in-person feedback. Additionally, the hospital states that PCI Meeting minutes are also posted on the CCL team's huddle board so that technicians, or any other staff who are unable to attend the meeting, may see the commentary and look up the cases reviewed for their own learning and benefit.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation submitted by CHC including attendance records, meeting dates, and minutes for PCI meetings. Ten meetings were held in CY 2019, 12 in CY 2020 and CY 2021, and 11 in both CY 2022 and CY 2023, which exceeds the number of times these meetings are required annually. Staff determined that meetings routinely include interventionalists, and other physicians and nurses who care for primary PCI patients. Technicians attended these meetings only once in CY 2019 and CY 2020, twice in CY 2021 and CY 2022, and not at all in CY 2023.

Because technicians rarely attend the PCI meetings and should be attending those meetings, MHCC staff recommends that the Commission find that CHC complies with the standard of holding interventional case review meetings every other month, with the following condition on the Certificate of Ongoing Performance:

CHC shall hold interventional case review meetings at least every other month that include physicians, nurses, and technicians, as required in COMAR 10.24.17.07D(5)(a). CHC shall track the attendance of physicians, nurses, and technicians at each of these meetings. CHC shall submit to Commission staff attendance lists for each of these meetings held between May and October by December 1 of each year and attendance lists for meetings held between November and April by June 1 of each year, beginning with meetings held after November 30, 2024, until at least December 31, 2026, to document compliance with this condition. After this date, the Executive Director may release CHC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

10.24.17.07C(4)(b) and .07D(5)(b) The 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.

CHC provided a list of dates and attendees, as well as meeting minutes for PCI Meetings held from CY 2019 through CY 2023. CHC states that one meeting is conducted each month, that includes both interventional case reviews and multiple care area group agenda items. The hospital reports that holding both meetings at the same time allows for multiple disciplines to receive education and a review of operations at the same time. Attendees include physician and nursing leadership from the CCL, CCU, ED, cardiac rehab, pharmacy, emergency medical services (EMS), nursing education, and quality review. The hospital explained that meetings were cancelled in July 2019 due to an emergency for the CCL manager, in July 2022 because the Joint Commission was on-site, and in December 2019 and 2023 due to proximity to the holidays.

Staff Analysis and Conclusion

The documentation submitted by CHC includes attendance records, meeting dates, and minutes for 10 meetings in CY 2019, 12 in CY 2020 and CY 2021, 11 in CY 2022 and CY 2023. Only four meetings were cancelled in a five-year period, and at least 10 meetings were held each year.

MHCC staff concludes that CHC 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.

CHC submitted copies of external review reports for elective PCI cases performed between January 2019 and December 2022. CHC uses an MHCC approved review organization, MACPAQ, to complete these external reviews according to standards established by the Commission. These reviews include the review of angiographic images, medical test results, and

the patient's medical record and take place on a semi-annual basis.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. As shown in Table 5, between 20.6 and 27.3 percent of cases were reviewed each year, consistent with the requirement that at least five percent of cases be reviewed.

Table 5. CHC's External Review, January 2019 – December 2022

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2019	126	26	20.6%	Semi-annually	Yes
CY 2020	126	30	23.8%	Semi-annually	Yes
CY 2021	128	35	27.3%	Semi-annually	Yes
CY 2022	173	45	26.0%	Semi-annually	Yes

Source: MHCC staff analysis of external review reports, CY 2019 – CY 2022.

For the period between January 2019 and December 2022, MHCC staff analyzed the ACC-NCDR CathPCI Registry data and verified that, in each six-month review period, at least three cases per physician, or all cases were reviewed, if an interventionalist performed fewer than three PCI cases during the review period, with one exception. For the period from July through December 2020, only two PCI cases were reviewed for one interventionalist, and a third diagnostic case without PCI. When asked about this, the hospital reported that a list of 20 cases was sent to MACPAQ for this interventionalist during the review period. For one of the cases reviewed, MACPAQ selected a diagnostic case, and this was not discovered until MHCC questioned CHC about this. While the hospital volunteered to rectify this with external review of another case, the hospital is not responsible for the error. The external review organization selected the cases to be reviewed.

MHCC staff recommends that the Commission find CHC in compliance 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 three cases at the hospital 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 review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraph .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).

10.24.17.07C(4)(e) and .07D(5)(d) The external review of PCI cases and the performance review of an interventionalist referenced in Paragraphs .07C(4)(c) and .07C(4)(d) 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.

CHC reported that both internal and external reviews are conducted, with MACPAQ completing external reviews. For these reviews, the hospital sends a list quarterly to MACPAQ so that a randomly selected case list can be returned to CHC with a unique identifier for each case. CCL staff then collects the pertinent documentation and uploads it through Johns Hopkins Hospital (JHH) ImageShare. The hospital provided the number of cases reviewed for each physician, both internally and externally and reports that a random sampling of cases is reviewed internally, resulting in 10 percent or 10 cases being reviewed in total for each interventionalist, whichever is greater.

CHC also indicates that four to five PCI cases are also chosen for review at the monthly PCI meetings. Cases reviewed include those with DTB times over 90 minutes, outliers including deaths and complications, and staff referrals.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by CHC and analyzed the ACC-NCDR CathPCI Registry data to determine the number of elective PCI cases performed by each interventionalist. Staff calculated the number of cases required to be reviewed for each interventionalist, per calendar year and compared the results of the analysis to the number of PCI cases reviewed internally and externally, per physician according to the hospital. MHCC staff observed that all physicians had ten percent, or ten cases reviewed, whichever was greater, for all reporting periods from CY 2019 to CY 2022, except for one instance. In 2019, for one physician only six were reviewed. Staff notes that the physician only performed PCI cases at CHC for about half of that year and six cases are consistent with the standard on a pro-rated basis. A review of six cases represents over 10 percent of the volume of PCI cases performed by the physician that year.

MACPAQ has been approved by MHCC as a reviewer and their external reviews meet the Cardiac Services Chapter requirements. MACPAQ's review of cases includes angiographic images, medical test results, and patients' medical records.

Because the hospital's documentation shows that the greater of either 10 percent of cases or 10 cases were reviewed for all interventionalists each year, MHCC staff concludes that CHC complies with these standards.

10.24.17.07C(4)(f) and .07D(5)(e) The chief executive officer of the hospital shall certify upon request by Commission staff 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.

CHC submitted an affidavit from the President and COO, Garrett Hoover, MA, MHA, FACHE, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for internal case review, multiple area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist review consistent with the Cardiac Services Chapter.

Staff Analysis and Conclusion

MHCC staff reviewed the affidavit provided and concludes that CHC complies with this standard.

10.24.17.07C(4)(g) and .07D(5)(f) A hospital's application for a Certificate of Ongoing Performance shall demonstrate that it has taken appropriate action in response to each concern identified through its quality assurance processes.

(i) All individually identifiable patient information submitted to the Commission for

the purpose described in this subsection shall remain confidential.

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

CHC provided minutes from PCI Meetings held between CY 2019 and CY 2023, and the results of external reviews of elective PCI cases performed from CY 2019 through CY 2022. The hospital also identified three quality assurance activities that have been initiated by the hospital and that are referenced in meeting minutes. Examples of these activities are described in further detail below.

The hospital identified increasing the percentage of appropriate referrals to cardiac rehabilitation as an opportunity for improvement. In the second quarter of 2022, the percentage of appropriate referrals to cardiac rehabilitation reached an all-time low at 46.7 percent. CHC was able to increase the percentage of appropriate referrals to cardiac rehabilitation by providing information to patients prior to discharge and reminding case management staff and providers of services. The hospital reported that it has succeeded in increasing the percentage of appropriate referrals. In the third quarter of 2023, the percentage of appropriate referrals was 89.7 percent.

In May 2023, CHC assessed whether transporting a patient to the CCL on the ambulance stretcher, rather than transferring the patient to a regular stretcher, would save time. Patients are now being transported to the CCL on the ambulance stretcher after receiving guidance from the interventionalists.

Furthermore, in September 2023, CHC identified inadequate documentation of radial band care as a concern and opportunity for improvement. The hospital decided to address this issue by adding documentation to the charting system to prompt staff to document neurovascular checks, vital signs, and site checks in the same place as the documentation for when and how much air is added or removed from the radial band. The changes to the charting system were implemented in March 2024. Because this is a new project, the hospital reported that feedback from the quality improvement initiative is still being gathered.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by the hospital and, based on the details provided regarding quality assurance initiatives undertaken by the hospital, staff concludes that CHC complies with this standard.

Patient Outcome Measures

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.

10.24.17.07C(5)(a) An elective PCI program shall meet all performance standards established in statute or 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 mortality 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.

CHC submitted risk-adjusted mortality data by rolling 12-month reporting period for Q1 2020 through Q1 2024, as shown in Table 6. The hospital reports that it meets the standard for acceptable risk-adjusted mortality rates each reporting period.

Table 6. CHC's Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI				Non-STEMI			
	Hospital AMR	95% Confidence Interval	National AMR	Meets MHCC Standards	Hospital AMR	95% Confidence Interval	National AMR	Meets MHCC Standards
2023q2-2024q1	0.00	[0.00, 6.27]	0.79	Yes	0.00	[0.00, 4.11]	2.00	Yes
2023q1-2023q4	0.00	[0.00, 8.34]	1.88	Yes	0.00	[0.00, 3.58]	1.99	Yes
2022q4-2023q3	0.00	[0.00, 9.67]	1.91	Yes	0.00	[0.00, 3.72]	2.02	Yes
2022q3-2023q2	0.00	[0.00, 8.47]	1.89	Yes	0.00	[0.00, 2.97]	2.02	Yes
2022q2-2023q1	0.00	[0.00, 3.54]	1.89	Yes	0.44	[0.11, 3.21]	2.05	Yes
2022q1-2022q4	2.07	[0.05, 11.07]	2.00	Yes	0.00	[0.00, 3.61]	2.14	Yes
2021q4-2022q3	2.04	[0.05, 11.00]	2.11	Yes	0.92	[0.02, 5.07]	2.20	Yes
2021q3-2022q2	2.33	[0.06, 12.51]	2.18	Yes	1.42	[0.04, 7.75]	2.26	Yes
2021q2-2022q1	4.85	[0.75, 9.72]	2.82	Yes	1.22	[0.03, 6.66]	1.16	Yes
2021q1-2021q4	3.31	[0.40, 11.35]	2.74	Yes	1.57	[0.04, 8.55]	1.16	Yes
2020q4-2021q3	3.57	[0.75, 9.86]	2.18	Yes	0.00	[0.00, 6.25]	2.23	Yes
2020q3-2021q2	16.88	[6.97, 32.76]	7.51	Yes	0.00	[0.00, 6.16]	1.18	Yes
2020q2-2021q1	13.97	[5.24, 28.83]	7.55	Yes	0.00	[0.00, 7.81]	1.21	Yes
2020q1-2020q4	13.29	[4.97, 27.55]	6.89	Yes	0.00	[0.00, 7.29]	1.13	Yes
2019q4-2020q3	9.60	[2.66, 23.47]	6.37	Yes	0.00	[0.00, 5.16]	1.06	Yes
2019q3-2020q2	12.01	[3.97, 26.68]	6.06	Yes	0.00	[0.00, 3.56]	1.00	Yes
2019q2-2020q1	11.87	[3.29, 28.82]	5.99	Yes	0.00	[0.00, 3.39]	0.95	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 2020 and March 2024.

Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval includes the national benchmark or indicates statistically significantly better performance than the national benchmark for ST-elevated myocardial infarction (STEMI) or non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs 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

As shown in Table 6 above, MHCC staff compiled the results from CHC's quarterly reports from the ACC-NCDR CathPCI Registry for STEMI and non-STEMI PCI cases performed between January 2020 and March 2024. MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's risk-adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period. The national benchmark fell within the 95 percent confidence interval (CI) for CHC for all 12-month reporting periods between January 2020 and March 2024. MHCC staff concludes that CHC meets the benchmark for both STEMI and non-STEMI cases and complies with this standard.

Physician Resources

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

CHC submitted information on the volume of primary and elective PCI cases at CHC and other hospitals, by physician and quarter, for the period from January 2019 through December 2023 for Drs. Harfouch, Vesely, El-Haddad, Chahal, Shkullaku, Gupta, Maniu, Pfeffer, Srivastava, and Sun. Each interventionalist signed and dated an affidavit affirming under penalty of perjury that the information contained in the table on their form is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed the physician volumes reported by CHC and analyzed data from the ACC-NCDR CathPCI Registry. Staff confirmed that each interventionalist who performed primary PCI services at CHC in CYs 2019, 2020, 2021, 2022, and 2023 performed a minimum of 50 procedures annually, averaged over a 24-month period.

MHCC staff concludes that CHC 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 the Commission. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Staff Analysis and Conclusion

MHCC staff's analysis showed that each interventionalist at CHC performed greater than 50 PCI procedures annually, averaged over a 24-month period. This standard is not applicable to the hospital.

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.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to CHC. While CHC does not have on-site cardiac surgery, each physician performing primary PCI at the hospital performed over 50 PCI procedures annually, averaged over 24-month periods between January 2019 and December 2023.

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.

10.24.17.07D(7)(f) Each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

CHC submitted a signed and dated statement from Dr. Henry Sun, FSCAI, Senior Physician Executive of LifeBridge Health Cardiac Service Line and Director of the Cardiovascular Institute, confirming that each physician performing PCI at the hospital is board-certified in interventional cardiology.

Staff Analysis and Conclusion

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

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

practice.

CHC submitted signed and dated attestations from Drs. Vesely, Chahal, El-Haddad, Harfouch, Shkullaku, Gupta, Maniu, Pfeffer, Srivastava, and Sun 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 determined that CHC complies with this standard.

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

CHC submitted a signed statement from the Senior Physician Executive of LifeBridge Health Cardiac Service Line and Director of the Cardiovascular Institute, Dr. Sun, attesting that each physician who has performed primary PCI within the review period has participated in the on-call schedule. The on-call schedule for April 2024 was also provided by the hospital.

Staff Analysis and Conclusion

MHCC staff reviewed the letter provided by Dr. Sun and the on-call schedule for April 2024. All physicians who perform primary PCI at CHC participate in the on-call schedule.

MHCC staff concludes that the hospital complies with 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.

10.24.17.07C(7)(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.

As shown in Table 7 below, CHC provided the total annual PCI case volume for each CY between 2020 and 2023. During this time, the hospital performed between 197 and 245 PCI cases annually.

Table 7. CHC's Reported Total PCI Volume, CY 2019 – CY 2023

Time Period	Total PCI Volume
CY 2020	216
CY 2021	197
CY 2022	245
CY 2023	222

Source: CHC's application for a Certificate of Ongoing Performance 2024, p. 16.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI case volume information submitted by CHC. This data shows that the hospital fell slightly below the target volume of 200 PCI cases in one of four years. CHC met the target case volume in CYs 2020, 2022, and 2023, when the hospital reported more than 200 cases annually. MHCC staff also calculated the volume of PCI cases, using the ACC-NCDR CathPCI Registry data for the period from CY 2020 to CY 2023. This analysis indicates CHC performed 211 cases in CY 2020, 196 cases in CY 2021, 244 cases in CY 2022, and 220 cases in CY 2023. This analysis is consistent with the volumes reported by the hospital, which indicated that the hospital performed less than 200 PCI cases in CY 2021.

Because 200 PCI cases is a target, and the hospital only had one year that fell slightly below the target number for PCI cases during the review period, MHCC staff concludes that CHC 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.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI Registry data to calculate the volume of primary PCI cases performed at CHC from CY 2020 through CY 2023. As shown in Table 8, the primary PCI volume ranged from 60 to 90 cases each year.

Table 8. CHC's Primary and Elective PCI Volume, CY 2019 - CY 2023

Time Period	Primary PCI Volume	Elective PCI Volume	Total PCI Volume
CY 2020	90	121	211
CY 2021	72	124	196
CY 2022	84	160	244
CY 2023	60	160	220

Source: MHCC staff's analysis of the ACC-NCDR CathPCI registry data (CY 2020 – CY 2023).

Because CHC exceeded the threshold of 49 cases annually, during the review period, no focused review is required.

10.24.17.07D(8)(b) The target volume for each physician who performs primary PCI is 11 or more primary cases annually.

CHC provided the number of primary PCI cases, by location and interventionalist, for each quarter from CY 2019 through CY 2023.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume submitted by CHC and analyzed the ACC-NCDR CathPCI Registry data to verify the number of primary PCI cases performed by physicians between CY 2019 and CY 2023. MHCC staff determined that each interventionalist performed at least 11 primary PCI cases annually during the review period.

MHCC staff concludes that the hospital complies with this standard.

Patient Selection

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for appropriate patients, as described in Expert Guidelines for hospitals with and without cardiac surgery on-site.

CHC stated that it is committed to appropriate patient selection and treatment as described in the Society for Cardiovascular Angiography and Interventions (SCAI)/American Heart Association (AHA)/American College of Cardiology (ACC) Expert Consensus document on PCI at hospitals with and without cardiac surgery backup on-site.

Staff Analysis and Conclusion

MHCC staff reviewed the reports from MACPAQ for the hospital's elective PCI procedures. Reports indicate that all cases were either "appropriate" or "maybe appropriate" in terms of angiographic, clinical, and AHA/ACC appropriate use criteria. One case completed between July and December 2019 was found to be "rarely appropriate" in terms of AHA/ACC appropriate use criteria, both reviewers also noted the guidelines were not well suited to the patient's situation. Staff notes that rarely appropriate does not mean inappropriate, and one of the reviewers directly expressed that the patient likely benefited from the procedure. The hospital followed up with the interventionalist for the case and reported that it did not have concerns regarding the care provided or other prior cases performed by the interventionalist.

MHCC staff concludes that CHC complies with this standard because there is not a concerning trend and the hospital followed-up on the MACPAQ finding.

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 Expert Guidelines.

(b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) reasonably concludes 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 primary PCI services were 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) reasonably concludes that transfer to a tertiary institution may be harmful

to the patient.

The hospital responded that there have been no patients who received thrombolytic therapy that subsequently failed, and there were no patients who received primary PCI services inappropriately during the review period.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI Registry data and noted that between CY 2019 and CY 2023, there were no patients who received thrombolytic therapy. In addition, the hospital's ACC-NCDR CathPCI reports for the period from CY 2019 to CY 2023 indicate that no PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate.

MHCC staff concludes that CHC complies with this standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff recommends that the Commission find that CHC meets all the requirements for a Certificate of Ongoing Performance and issue a Certificate of Ongoing Performance that permits CHC to continue providing primary and elective percutaneous coronary intervention services for four years, with the following condition:

> CHC shall hold interventional case review meetings at least every other month that include physicians, nurses, and technicians, as required in COMAR 10.24.17.07D(5)(a). CHC shall track the attendance of physicians, nurses, and technicians at each of these meetings. CHC shall submit to Commission staff attendance lists for each of these meetings held between May and October by December 1 of each year and attendance lists for meetings held between November and April by June 1 of each year, beginning with meetings held after November 30, 2024, until at least December 31, 2026, to document compliance with this condition. After this date, the Executive Director may release CHC from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

Appendix 1. CHC's CCL Downtime by Room, Date, and Duration, January 2019 – December 2023

Room	Date	Duration (Hours)	Description
Lab 2	2/12/2019	0.70 hour	Repair – error message
Lab 3	2/20/2019	0.45 hour	Preventive maintenance
Lab 2	3/15/2019	0.45 hour	Preventive maintenance
Lab 2	3/29/2019	0.90 hour	Preventive maintenance
Lab 3	5/9/2019	1.00 hour	Preventive maintenance
Lab 2	5/10/2019	1.30 hours	Repair – computer monitor not working
Lab 2	8/12/2019	1.00 hour	Repair – fixed injector plunger
Lab 2	8/16/2019	1.05 hours	Repair – screen broken
Lab 3	8/28/2019	0.85 hour	Preventive maintenance
Lab 2	9/23/2019	0.40 hour	Preventive maintenance
Lab 2	10/7/2019	0.40 hour	Repair – worklist not populating
Lab 2	10/23/2019	0.60 hour	Repair - injector
Lab 3	11/7/2019	0.60 hour	Preventive maintenance
Lab 2	11/19/2019	0.65 hour	Repair – arm will not move
Lab 2	12/27/2019	0.50 hour	Repair – injector cord loose
Lab 2	1/6/2020	1.80 hours	Repair – multiple issues
Lab 2	1/29/2020	0.30 hour	Repair – silver tube disconnected
Lab 3	2/24/2020	5.05 hours	Repair – lab not working
Lab 3	2/25/2020	0.85 hour	Preventive maintenance
Lab 2	3/18/2020	0.76 hour	Preventive maintenance
Lab 2	3/26/2020	1.00 hour	Preventive maintenance
Lab 3	4/30/2020	0.80 hour	Repair – mouse not working
Lab 3	5/6/2020	1.50 hours	Repair – button missing from control panel
Lab 2	5/8/2020	0.60 hour	Repair – missing images
Lab 3	5/28/2020	2.80 hours	Preventive maintenance
Lab 2	5/28/2020	1.00 hour	Repair – Injector error
Lab 3	6/9/2020	4.80 hours	Repair – arm not working
Lab 3	6/17/2020	1.25 hours	Repair – unit had errors/tube moving slowly
Lab 3	7/6/2020	3.55 hours	Repair – mic not working
Lab 3	8/14/2020	1.60 hours	Preventive maintenance
Lab 2	8/28/2020	1.10 hours	Repair – replaced foot pedal
Lab 3	9/8/2020	0.50 hour	Repair – monitor not working
Lab 2	9/10/2020	0.60 hour	Preventive maintenance
Lab 2	9/23/2020	0.80 hour	Repair – bolus runoff not working
Lab 2	11/13/2020	0.59 hour	Repair – patient picture would not save
Lab 3	11/17/2020	0.55 hour	Preventive maintenance
Lab 2	1/28/2021	0.40 hour	Repair – frayed wire
Lab 2	3/25/2021	1.10 hours	Preventive maintenance
Lab 2	9/7/2021	0.70 hour	Repair - injector
Lab 1	March 31, 2021 – September 22, 2021	175 days	Room installation
Lab 1	9/22/2021	0.50 hour	Inspection of new equipment
Lab 1	10/15/2021	1.20 hours	Repair - lights/rewiring
Lab 1	1/18/2022	1.00 hours	Repair – error/system rebooted
Lab 1	1/24/2022	0.50 hour	Repair – x-ray issues
Lab 1	2/22/2022	1.00 hours	Repair – swivel arm broken
Lab 1	2/25/2022	0.25 hour	Repair – foot pedal error
Lab 2	3/10/2022	0.75 hour	Preventive maintenance
Lab 2	3/18/2022	1.50 hours	Repair – exposed wire
Lab 1	3/24/2022	0.35 hour	Preventive maintenance

Lab 1	3/25/2022	0.50 hour	Repair – pedal delaying x-ray
Lab 1	4/27/2022	Unknown	Repair – no power
Lab 1	5/2/2022	6.15 hours	Repair – no power
Lab 1	8/12/2022	1.10 hours	Repair – lab won't boot up
Lab 1	9/7/2022	0.35 hour	Preventive maintenance
Lab 2	3/13/2023	2.35 hours	Preventive maintenance
Lab 2	3/16/2023	2.60 hours	Repair – screen not working
Lab 1	3/22/2023	0.35 hour	Preventive maintenance
Lab 1	5/1/2023	2.85 hours	Repair – loose arm holding monitor
Lab 2	5/4/2023	2.20 hours	Repair – injector error
Lab 3	January 5, 2023 – May 11, 2023	127 days	Room renovation
Lab 1	6/21/2023	0.60 hours	Repair – speakers not working
Lab 1	7/6/2023	0.80 hours	Repair – odd noise
Lab 2	8/10/2023	2.00 hours	Repair - injector
Lab 2	8/23/2023	1.30 hours	Repair - injector
Lab 2	8/31/2023	0.40 hours	Repair – piston from injector
Lab 1	9/21/2023	0.60 hours	Preventive maintenance
Lab 3	10/20/2023	0.25 hours	Preventive maintenance
Lab 1	11/21/2023	0.40 hours	Repair – error message
Lab 1	12/21/2023	0.50 hours	Repair – error message

Source: CHC's application for a Certificate of Ongoing Performance 2024, p. 3, and supplemental information received on August 23, 2024, and October 17, 2024.

Notes: Installation of Lab 1 was completed on September 22, 2021, and renovation of Lab 3 was completed between January 5, 2023, and May 11, 2023.