IN THE MATTER OF	*	**BEFORE THE**
CARROLL HOSPITAL	*	**MARYLAND**
CENTER, INC.	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 19-06-CP011	*	

*** ***

STAFF REPORT AND RECOMMENDATION

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

September 17, 2020

I. INTRODUCTION

A. Background

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

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

B. Applicant

Carroll Hospital Center, Inc.

Carroll Hospital Center, Inc. (CHC) is a 161-bed general hospital located in Westminster (Carroll County). CHC does not have a cardiac surgery program on site. 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. In December 2014, the Commission issued a Certificate of Conformance to CHC to perform elective PCI services in December 2014 and the hospital currently provides both primary and elective PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. 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. Currently, one program provides only primary PCI services. 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 CHC's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services. A description of CHC's documentation and MHCC staff's analysis of this information follows.

II. PRODEDURAL HISTORY

CHC filed a Certificate of Ongoing Performance application on March 22, 2019. MHCC staff reviewed the application and requested additional information on September 13, 2019, March 25, 2020, and June 26, 2020. MHCC received additional information on October 18, 2019, November 15, 2019, May 21, 2020, July 17, 2020, August 20, 2020, and August 27, 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.

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

Staff Analysis and Conclusion

CHC has complied with the submission of the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of ACC-NCDR CathPCI data to validate that hospitals submitted accurate and complete information to the ACC-NCDR registry. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of CHC's data reported during the audit period.

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 stated that the hospital's cardiac catheterization laboratory (CCL) includes two rooms and that the rooms were never taken out of service simultaneously for preventative maintenance. However, over the review period, CHC reported that both rooms for were out of service simultaneously on five occasions. PCI services unavailable for approximately 14 hours total, as shown in Table 1.

Table 1: CHC CCL Closures

Date	Duration (hours)	Reason
4/28/15	4.34	Riot preventing physician arrival to hospital
1/11/16	1.22	Bomb threat
1/2/17	0.36	Power outage during upgrade of Uninterruptible Power Supply
1/3/17	1.14	Bomb threat
6/22/17	7.19	Hospital chiller out of service; rooms too hot to operate

Source: CHC Application Q2, CHC updated Q2 response

CHC also explained the process for handling closures of the CCL. The process begins with the shift coordinator notifying the manager of the CCL or the director of cardiology and making a

recommendation to shut down the CCL. The manager of the CCL or director of cardiology will then get approval from the president of the hospital and notify the shift coordinator that closure has been approved. The shift coordinator then contacts staff in the emergency department, who then notifies the Maryland Institute for Emergency Medical Services Systems (MIEMSS) of the shutdown. The manager of the CCL or the director of cardiology then speaks with the shift coordinator every 15 minutes until the CCL is opened. CHC reported that MIEMSS is notified in all CCL closure events and that there is a dedicated phone in the emergency department for these circumstances. Additionally, CHC reported that there was no impact to patient care during any of the instances shown in Table 1 above because there were no patients in need of primary PCI services during the downtimes.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided on closures of the CCL and requested clarification on the reasons provided. MHCC staff determined that the closures were unavoidable.

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 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.

CHC provided a signed statement from Leslie Simmons, R.N., F.A.C.H.E., President of CHC and Executive Vice President of LifeBridge Health, stating that CHC commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, and CHC commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement. Additionally, CHC provided quarterly median DTB times for the period from January 2015 through December 2019, as shown in Table 2. CHC reported that the hospital did not receive any PCI transfer cases during the review period.

Table 2: CHC Reported Compliance with DTB Benchmark by Quarter January 2015- December 2019

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	21	21	100.0%
CY2015 Q2	14	13	92.8%
CY2015 Q3	22	21	95.4%
CY2015 Q4	19	18	94.7%
CY2016 Q1	14	14	100.0%
CY2016 Q2	23	19	82.6%
CY2016 Q3	23	23	100.0%
CY2016 Q4	13	13	100.0%
CY2017 Q1	17	17	100.0%
CY2017 Q2	17	17	100.0%
CY2017 Q3	14	13	92.8%
CY2017 Q4	15	15	100.0%
CY2018 Q1	10	9	90.0%
CY2018 Q2	17	17	100.0%
CY2018 Q3	11	11	100.0%
CY2018 Q4	18	18	100.0%
CY2019 Q1	11	11	100.0%
CY2019 Q2	13	12	92.0%
CY2019 Q3	12	11	92.0%
CY2019 Q4	15	14	93.0%

Source: CHC Application, updated Q4.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer ST-elevation myocardial infarction (STEMI) cases, as shown in Table 3. MHCC staff found that CHC met the DTB benchmark in all but one quarter. In the quarter ending 2018 q1, 71.4% of cases met the DTB benchmark. MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases in reviewing compliance with this standard. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, CHC complied with this standard, with between 84.4% and 89.2% of PCI cases meeting the DTB time standard over rolling eight-quarter periods, as shown in Table 3.

MHCC staff concludes that CHC complies with this standard.

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

Quarter				Rolling 8-Quarters		
Time Period	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes
2015q1	25	21	84.0%			
2015q2	17	13	76.5%			
2015q3	22	21	95.5%			
2015q4	22	18	81.8%			
2016q1	17	14	82.4%			
2016q2	24	18	75.0%			
2016q3	25	23	92.0%			
2016q4	15	13	86.7%	167	141	84.4%
2017q1	18	18	100.0%	160	138	86.3%
2017q2	16	16	100.0%	159	141	88.7%
2017q3	17	13	76.5%	154	133	86.4%
2017q4	18	15	83.3%	150	130	86.7%
2018q1	14	10	71.4%	147	126	85.7%
2018q2	18	16	88.9%	141	124	87.9%
2018q3	12	11	91.7%	128	112	87.5%
2018q4	17	17	100.0%	130	116	89.2%
2019q1	14	11	100.0%	130	116	89.2%
2019q2	17	13	78.6%	126	109	86.5%
2019q3	16	11	82.4%	127	107	84.3%
2019q4	15	15	75.0%	126	106	84.1%

Source: MHCC analysis of ACC-NCDR CathPCI data CY 2015- CY 2019.
Note: Calculations for each quarter are based on the procedure date.

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

As shown in Table 4A, below, CHC reported the number of physicians, nurses, and technicians who were available to provide cardiac catheterization services to acute myocardial infarction patients, one week prior to the due date of the application.

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

Staff Category	Number/FTEs	Cross Training (S/C/M)*
Physician	N = 6	Interventional Cardiologist
Nurse	11.0	C, M
Technician	5.0**	S, M

Source: CHC Application, Q6a, updated Q6a.
*Scrub (S), circulate (C), monitor (M)
**At the time of application, there were 5 total FTE technician positions. However, 2 FTEs were unfilled; one has been filled as of May 2020.

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by CHC to information reported by three other existing PCI program applications for Certificates of Ongoing Performance. MHCC staff observed that CHC has a greater number of full-time equivalent (FTE) nurses than Johns Hopkins Bayview Medical Center, University of Maryland (UM) Prince George's Hospital Center, and Adventist HealthCare (AHC) Shady Grove. While CHC reported fewer technician FTEs than Johns Hopkins Bayview Medical Center and University of Maryland Prince George's Hospital Center, the hospital reported the same number of technician FTEs as AHC Shady Grove, which performed a higher volume of PCI cases than CHC, as shown in Table 4B. CHC also stated that two positions were open at the time of the application.

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

Program & Year Reported	2018 Total PCI Volume*	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
CHC 2019	185	N = 6	11.0	5.0
Johns Hopkins Bayview Medical Center 2019	200	N = 10	6.0	5.8
UM Prince George's Hospital Center 2019	247	N = 5	10.0	6.0
AHC Shady Grove 2019	269	N = 5	6.0	5.0

Sources: CHC 2019 PCI Certificate of Ongoing Performance Application, Johns Hopkins Bayview Medical Center 2019 PCI Certificate of Ongoing Performance Application, UM Prince George's Hospital Center 2019 PCI Certificate of Ongoing Performance Application, AHC Shady Grove 2019 PCI Certificate of Ongoing Performance Application.

*Volumes for either fiscal or calendar year

MHCC staff compared the staffing levels reported in the 2019 application for a PCI Certificate of Ongoing Performance to CHC's 2014 Certificate of Conformance application. CHC reported 4 physicians, 6.2 nursing FTEs, and 5.8 technical staff FTEs as of August 2014. While the technician FTEs have decreased slightly since the 2014 Certificate of Conformance application, likely because of the two open positions that were not filled at the time of application in 2019, the nursing FTEs have increased. The number of interventionalists has also increased.

MHCC staff concludes that there is adequate nursing and technical staff to provide services; CHC complies with this standard.

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

CHC provided a signed letter of commitment from Leslie Simmons, RN, FACHE, President, acknowledging that CHC 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 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 provided a description of the staff involved with these functions. CHC reported that the hospital retains 1.0 FTE for a Quality Reviewer, a position that is currently held by a registered nurse who is responsible for data management, reporting, and coordination. The hospital also utilizes Q-Centrix for outside data collection.

Staff Analysis and Conclusion

MHCC staff concludes that CHC 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.

Calin Maniu, M.D., is the medical director for CHC's interventional cardiology services. Dr. Maniu was named medical director on January 1, 2019. Anuj Gupta, M.D., served as the medical director prior to Dr. Maniu.

As described by CHC, the medical director of the CCL is required to meet or exceed standards set forth in Maryland regulations that govern full service cardiac catheterizations laboratories. The director is also expected to develop and implement a quality improvement plan, oversee all interventional cardiologists, schedule physicians to ensure adequate daily coverage, and participate in PCI Performance Committee meetings. In addition, the director has final authority on granting privileges for cardiologists practicing in the CCL, among many other responsibilities.

Staff Analysis and Conclusion

MHCC staff concludes that CHC complies with this standard.

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

CHC provided a list of the continuing educational programs and activities in which staff in the CCL and critical care unit participated between January 2015 and December 2018. CHC stated that staff participate in educational activities and services throughout the year as needed or required. These educational activities may include independent assigned learning, staff meetings, clinical inquiry meetings, best practice meetings, and PCI performance meetings. Additionally, CHC requires all registered nurses to complete ten continuing education credits per year, and all radiological technologist must complete twenty-four education credits every two years in order to maintain their license.

Staff Analysis and Conclusion

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

Garrett E. Hoover, CHC President/Chief Operating Officer, signed an amended revised transfer agreement with Sinai Hospital of Baltimore. The amendment states that transfer of a PCI patient who requires additional care, including emergent or elective cardiac surgery, will not be subject to any conditions, including the availability of beds, policies, or procedures of a facility or hospital.

Staff Analysis and Conclusion

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

Sharon L. Sanders, Vice President Clinical Integration, signed and dated and agreement with PLMD, LLC d/b/a Pulse Medical Transportation and Mark D. Olszyk, M.D., Vice President,

signed and dated an amendment to the Medical Transportation Service Agreement. Both the agreement and the amendment were submitted to MHCC with the application.

Staff Analysis and Conclusion

MHCC staff reviewed the agreement and amendment submitted by CHC. The amendment states that the transport company will arrive at CHC no more than thirty minutes after the receipt of a request or transfer for a PCI patient. If the provider is unable to meet this deadline, Pulse Medical Transportation is required to arrange with another specialty care ambulance service and ensure that this service arrives at CHC within 30-minutes of the original request for transportation. The agreement contains an exception that states the provider shall not be required to adhere to the response time frames in the event of unusual adverse weather, declared disasters, abnormal circumstances beyond the control of the provider including, but not limited to, traffic gridlock, accidents, and highway construction which in any way interferes with normal daily traffic operations.

MHCC staff concludes that the transport agreement and exceptions to providing transport within 30 minutes that are included in the agreement are acceptable and that CHC complies with this standard.

Quality

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

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.

CHC states that one combined meeting is held for both interventional case review and review of issues related to the primary PCI system. CHC explained that holding one meeting allows staff from multiple disciplines to receive education and a review of operations at the same time. CHC holds meetings monthly unless the regular meeting date, the fourth Wednesday of the month, is a holiday. If a meeting is canceled, then cases for that month are reviewed at the next meeting. CHC provided the meeting dates and attendees for meetings held from January 2015 through February 2019, with limited exceptions. CHC reported that 12 meetings were held in 2015 and 2017, and 11 meetings were held in both 2016 and 2018.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for the combined multiple care area group and interventional case review group meetings. The documentation submitted by CHC included attendance records and meeting minutes for twelve meetings in 2015, eleven meetings in 2016, ten

meetings in 2017, and eleven meetings in 2018. CHC stated that for two meetings held in 2017, the attendance records and minutes were not completed due to the assigned staff member being on leave.

MHCC staff concludes that CHC complies with these standards.

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 the external review reports for PCI cases performed between January 2015 and June 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed in shown in Table 5. As shown in Table 5, although only 5% of cases are required to be reviewed externally, between 15.7% and 27.0% of cases were reviewed each year.

Table 5: CHC External Review, January 2015- June 2019

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2015	127^	20	15.7%	Tri-annually	Yes
CY 2016	187^	32	17.1%	Semi-annually	Yes
CY 2017	127	31	24.4%	Semi-annually	Yes
CY 2018	126	34	27.0%	Semi-annually	Yes
2019 Q1Q2	49	11	22.4%	Semi-annually	Yes

Source: MHCC staff analysis of MACPAQ reports.
* Each semiannual review included at least three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.
^ The hospital included both primary and elective PCI cases prior to notification in April 2016 by MACPAQ that only elective and non-STEMI cases are required to be externally reviewed.

Beginning in the second half of 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. For the period between January 2015 and June 2019, MHCC staff verified that, if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by MACPAQ, as required.

CHC complies with this standard.

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

(i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases

if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or

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

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

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

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

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

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

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

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

(ii) Be conducted by a reviewer who meets all standards established by the Commission

to ensure consistent rigor among reviewers.

In addition to the external reviews described above, CHC stated that internal review consists of additional random selection of cases such that the higher of 10% or ten cases per interventionalist are reviewed by a combination of internal and external review, or all cases when an interventionalist performs less than ten PCI procedures. The hospital's PCI Performance Committee also reviews four to five cases monthly, which are selected based on several criteria, including cases in which the DTB time was greater than 90 minutes and cases with complications.

Staff Analysis and Conclusion

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number of cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of cases to be reviewed to satisfy the requirements for review of individual interventionalists. The bulletin states that a semi-annual review of at least three cases or 10% of cases, whichever is greater, per interventionalist, as part of an external review meets the standard, and the requirements in COMAR 10.24.17.07D(5)(c) are equivalent to those in COMAR 10.24.17.07C(4)(d).[1]

At least six cases per interventionalist were reviewed per year, as applicable, and additional cases were reviewed via internal review, as applicable. The requirement for external review changed with the adoption of an updated Cardiac Surgery Chapter in October 2015; for the period January to June 2015, a hospital was not required to include at least three cases per physician in its external review. The external reviews conducted by MACPAQ meet 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 concludes that CHC satisfactorily conducts individual interventionalist review as provided in COMAR 10.24.17.07C(4)(d) and described in the October 2015 bulletin, with respect to COMAR 10.24.17.07D(5)(c).[2]

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

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

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

CHC submitted an affidavit from Leslie Simmons, RN, FACHE, the President of Carroll Hospital and Executive Vice President of LifeBridge Health, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, and quarterly interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that CHC complies with this standard.

10.24.17.07D (5)(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review cases.

- ***(i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.***
- ***(ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.***
- ***(iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.***

CHC submitted meeting minutes from its PCI Performance Committee for February 2015 through February 2019. This committee meets monthly and reviews four or five cases. CHC also provided some examples of recent quality assurance activities related to PCI patients. For example, CHC requested that emergency medical services (EMS) staff make an attempt to do an electrocardiogram (EKG) every five to ten minutes on patients who are having continued chest pain or if a patient develops new symptoms during transport and requested that EMS transmit the EKGs during transport. Another example is in response to a potential delay in care of STEMI patients who have requested not to be resuscitated or intubated. The CCL instructed that the emergency department staff should call a STEMI and that the interventional cardiologist should be consulted with respect to the patient's documented preferences for resuscitation and intubation. The STEMI can be cancelled after this evaluation, if appropriate.

Staff Analysis and Conclusion

MHCC staff reviewed the meeting minutes and description of quality assurance practices provided and concludes that CHC complies with this standard.

<u>Patient Outcome Measures</u>

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

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

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

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

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

CHC submitted adjusted mortality by rolling 12-month reporting period for 2015 Q1 through 2019 Q4 when available, as shown in Table 6. These data are not available for any hospitals participating in the ACC-NCDR CathPCI data registry for the rolling 12-month period of 2017 Q3 through 2018 Q2.

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

Reporting Period	STEMI				Non-STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2019q1-2019q4	11.76	[3.26, 28.33]	6.01	Yes	NR	[0.00, 3.29]	0.95	Yes
2018q4-2019q3	6.71	[0.82, 23.16]	6.06	Yes	1.75	[0.21, 6.17]	0.98	Yes
2018q3-2019q2	3.67	[0.09, 19.61]	6.38	Yes	2.48	[0.30, 8.74]	1.00	Yes
2018q2-2019q1	6.42	[0.78, 22.17]	6.13	Yes	2.13	[0.44, 6.07]	0.99	Yes
2018q1-2018q4	10.03	[2.78, 24.36]	6.00	Yes	2.19	[0.45, 6.22]	1.00	Yes
2017q4-2018q3	15.65	[5.89, 32.07]	6.54	Yes	1.02	[0.03, 5.55]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	15.25	[5.74, 31.2]	6.91	Yes	2.26	[0.06, 12.28]	1.03	Yes
2017q1-2017q4	13.48	[4.47, 29.69]	6.86	Yes	2.09	[0.05, 11.36]	0.99	Yes
2016q4-2017q3	11.56	[2.24, 32.02]	6.75	Yes	1.57	[0.04, 8.58]	0.98	Yes
2016q3-2017q2	8.56	[2.37, 20.87]	6.64	Yes	1.4	[0.04, 7.64]	0.95	Yes
2016q2-2017q3	10.28	[3.39, 22.91]	6.77	Yes	0.91	[0.02, 4.97]	0.97	Yes
2016q1-2017q4	10.94	[3.61, 24.39]	6.82	Yes	1.01	[0.03, 5.56]	0.95	Yes
2015q4-2016q3	12.19	[4.55, 25.39]	6.71	Yes	2.18	[0.27, 7.74]	0.95	Yes
2015q3-2016q2	13.54	[3.37, 33.37]	6.66	Yes	2.34	[0.28, 8.32]	0.93	Yes
2015q2-2016q1	8.67	[1.06, 30.24]	6.45	Yes	2.53	[0.06, 13.84]	0.90	Yes
2015q1-2015q4	10.52	[2.9, 25.94]	6.26	Yes	2.96	[0.07, 16.14]	0.90	Yes

*Source: MHCC Staff compilation of results from the hospital's quarterly reports form the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and December 2019.

Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark for ST Elevated Myocardial Infarction (STEMI) or non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the national benchmark for STEMI or non-STEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEMI and non-STEMI cases for each reporting period.

Staff Analysis and Conclusion

This standard is not applicable for most of the review periods included in CHC's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar, earlier standard referenced a statewide average as the benchmark. However, MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. MHCC staff has provided information in Table 6 that shows CHC's performance relative to the current standard over the period between January 2015 and December 2019.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for CHC for all 12-month reporting periods between January 2015 and December 2019, when an adjusted mortality rate was reported. MHCC staff concludes that CHC would have met this standard, if it had been applicable for the period January 2015 through September 2019. The hospital meets the benchmark for both STEMI and non-STEMI cases for the period ending December 2019, the first and only reporting period to which the current standard applies.

MHCC staff concludes that CHC complies with this standard.

Physician Resources

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

CHC submitted information on the volume of primary and elective PCI cases at CHC and other hospitals, by physician and quarter, for the period for January through December 2018 for Drs. Finn, Gupta, Maniu, Pfeffer, Srivastava, Vesely, and Zimrin. The interventionalists signed and dated affidavits affirming under penalties 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 reported physician volumes for the interventionalists who performed primary PCI services at CHC in 2015, 2016, 2017, and 2018 and determined that each interventionalist performed at least 50 PCI procedures annually on average over the 24-month periods of January 2015 through December 2016 and January 2017 through December 2018. One physician only completed 31 PCI cases total for 2017 and 2018 combined. However, because this physician did not perform any primary PCI cases at CHC or any other Maryland hospital without cardiac surgery on-site in 2017 and 2018, it was acceptable for the physician to provide elective PCI services at CHC despite performing less than 50 PCI cases on average annually. CHC removed

this physician from its roster in March 2019. For the interventionalists who performed primary PCI at CHC in 2015 and 2016, MHCC staff verified that each interventionalists performed at least 50 PCI procedures annually on average over the 24-month period of January 2015 through December 2016, if the interventionalist was part of the roster for 24-months. CHC provided documentation that a physician, Diljon Chahal, M.D., who was added to the roster in March 2019, meets this standard.

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

CHC responded that this regulation is not applicable.

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 procedures at CHC performed 50 PCI procedures annually on average over a 24-month period.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI procedures annually averaged over a 24 month period, who took a leave of absence of less than one year during the 24 month period measured, may resume the provision of primary PCI provided that:

(i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;

(ii) The physician continues to satisfy the hospital's credentialing requirements; and

(iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.

CHC responded that this regulation is not applicable.

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 who performed primary PCI at CHC during the review period performed at least 50 PCI procedures annually on average over a 24-month period.

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.

CHC submitted a signed and dated statement from Dr. Calin Maniu, Medical Director of Cardiac Interventional Services, acknowledging that all physicians performing primary PCI services at CHC are 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 credits in the area of interventional cardiology during every two years of practice.

CHC submitted signed and dated attestations from Drs. Finn, Gupta, Maniu, Pfeffer, Srivastava, and Vesley stating that each has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years. Additionally, CHC provided a log of continuing medical education credits for Dr. Zimrin between January 1, 2015 and September 18, 2019 documenting a total of 117 hours completed during this time frame.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that CHC meets 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 Medical Director of the Cardiac Interventional Service, Dr. Calin Maniu, acknowledging that each physician who performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. CHC also submitted a copy of its on-call schedule for March 2019 and August 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedule for March 2019 and observed that Drs. Srivasava, Vesely, Maniu, Pfeffer, and Gupta were all scheduled to be on-call at different times during the month. MHCC staff observed that Dr. Finn appeared on the August 2019 on-call schedule submitted. CHC stated that this was due to a change in who managed staffing for the CCL. At the

time the schedule was submitted, LifeBridge Health providers were able to assume the on-call responsibilities and Dr. Finn was not required at that time. The on-call schedule submitted by CHC also included Diljon Chahal, M.D., who was added to the roster in March 2019.

MHCC staff concludes that CHC 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.

CHC provided PCI volume information by fiscal year 2015 through 2019, as shown in Table 6. This information shows that CHC performed between 137 and 240 cases annually.

Table 6: CHC Total PCI Volume, FY 2015- FY 2019

Fiscal Year	Total PCI
2015	137
2016	240
2017	202
2018	185
2019	182

Source: CHC application, question 28, and updated question 28 provided May 21, 2020.

Staff Analysis and Conclusion

MHCC staff reviewed the PCI volume information submitted by CHC and analyzed the ACC-NCDR CathPCI data submitted. Staff determined at least 200 PCI procedures were completed per fiscal year in 2016 and 2017. During fiscal year 2015, the number of cases reported was 137. However, CHC did not start performing elective PCI until January 2015, half-way through fiscal year 2015. CHC failed to meet the target volume of 200 cases in both fiscal year 2018 and 2019, performing 185 and 182 PCI cases respectively. CHC explained that the lower volume was a result of the merger between LifeBridge Health and CHC. University of Maryland physicians were unsure of the status of their contract and likely sent patients to other facilities. CHC reports that LifeBridge Health physicians were not staffed at full capacity. Additionally, CHC revoked diagnostic cardiac catheterization privileges from two physicians due to a lack of board certification, which caused these two physicians to send patients to other facilities. For CY 2019, MHCC staff's analysis of the ACC-NCDR CathPCI data indicates a total of 192 PCI cases were performed.

MHCC staff concludes that explanations provided by CHC suggest that the lower volume of PCI cases in recent years is likely temporary. Because MHCC staff does not have concerns

about the quality of the program, it concluded that a focused review is not necessary. Staff also notes that 200 PCI cases is a target, not a requirement. 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.

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

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2019. This analysis shows primary PCI volume ranged from 60 to 102 cases each calendar year, and confirms that CHC exceeded the threshold of 49 cases annually referenced in the standard.

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

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

CHC provided the number of primary PCI cases by interventionalist for 2015 through 2018.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by CHC, and it shows that between January 2017 and December 2018, at least 11 primary PCI procedures were completed per year for each interventionalist, with the exception of one physician. This physician performed primary PCI only once in 2017 and subsequently did not perform any primary PCI cases at CHC in 2018 or 2019. Staff also analyzed the data in the ACC-NCDR CathPCI registry for CY 2015 through CY 2018 and concluded that each interventionalist met the target of 11 or more primary PCI cases annually, except for one physician in 2017, as previously noted.

MHCC staff concludes that CHC meets this standard.

<u>Patient Selection</u>

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

(a) Patients described as appropriate elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular

Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.

(b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, are not suitable for elective PCI.

In its initial application submission, CHC stated that all cases in CathPCI Registry PCI Appropriate Use Criteria (AUC) Metric reports from 2013-2018 Q2 were reviewed. CHC reconciled all cases to meet Appropriate Use Criteria based on the ACCF/AHA/SCAI Guidelines. Later, CHC also stated that external review did not identify any inappropriate PCI cases and submitted results from external reviews from January 2015 through June 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports from January 2015 through June 2019 and determined that there were only two cases between January 2015 and June 2019 that were determined to be "rarely appropriate" with respect to one or more of the following: clinical criteria; angiographic criteria; and ACC/AHA appropriateness criteria. CHC provided additional information about the follow-up on these two cases. In response to one case, CHC stated that the interventionalist agreed that the patient needed by-pass surgery but that the patient continually refused surgery and wanted to try PCI first. Medical Staff Quality Committee members reviewed the informed consent and noted that the interventionalist had listed all known complications that could have happened during the procedure. For the second PCI case deemed rarely appropriate by one or more criteria, the interventionalist was counselled regarding the issue. CHC also reported that its standard process for handling external review reports is to send them to each PCI interventionalist, the Vice President of Medical Affairs, and CCL managers for review. Additionally, the external review reports are reviewed at the PCI Committee meetings.

MHCC staff concludes that CHC complies with this standard.

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

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

(b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician (s) believes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

(c)Patients for whom the primary PCI system was not initially available who received

thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.

(d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believes that transfer to a tertiary institution may be harmful to the patient.

In its application, CHC initially stated that all cases in ACC-NCDR CathPCI Registry PCI Appropriate Use Criteria Metric reports from 2013-2018 Q2 were reviewed. CHC later reconciled all cases to meet Appropriate Use Criteria based on the ACCF/AHA/SCAI Guidelines. When asked about the number of PCI patients who received thrombolytic therapy that subsequently failed during the review period, CHC responded that this was not applicable. No patients received thrombolytic therapy during the review period that subsequently failed.

Staff Analysis and Conclusion

MHCC staff determines that CHC complies with the standard.

RECOMMENDATION

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