IN THE MATTER OF	*	**BEFORE THE**
HOLY CROSS HOSPITAL	*	**MARYLAND**
OF SILVER SPRING	*	**HEALTH CARE**
Docket No.: 19-15-CP026	*	**COMMISSION**

* *

STAFF REPORT AND RECOMMENDATION

CERTIFICATE OF ONGOING PERFORMANCE FOR PRIMARY PERCUTANEOUS CORONARY INTERVENTION SERVICES

March 18, 2021

I. INTRODUCTION

A. Background

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

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

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

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

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

authorizes a hospital to continue to provide PCI services, either primary or both primary and elective (non-primary) PCI services, for a time period specified by the Commission that cannot exceed five years. At the end of the period, the hospital must renew its authorization to provide PCI services by obtaining a Certificate of Ongoing Performance demonstrating that it continues to meet the applicable requirements in COMAR 10.24.17.

B. Applicant

Holy Cross Hospital

Holy Cross Hospital (HCH) is a 377-bed general hospital located in Silver Spring (Montgomery County). HCH does not have a cardiac surgery program on site.

HCH began providing primary PCI services under a research waiver in 1996 through participation in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials. Subsequently, the hospital was authorized to provide primary PCI on a regular basis, subject to ongoing performance requirements and periodic waiver renewal. HCH last applied for a primary PCI waiver in September 2013, and the two-year waiver was granted by MHCC on December 19, 2013. Currently, HCH provides primary PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. HCH is in the Metropolitan Washington health planning region. This region includes Calvert, Charles, Frederick, Montgomery, Prince George's and Saint Mary's Counties and the District of Columbia. Seven Maryland hospitals in this health planning region provide PCI services. One program, HCH, has only provided primary PCI services since its inception; all the other programs provide both primary and elective PCI services. Three of the seven Maryland hospitals also provide cardiac surgery services.

C. Staff Recommendation

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

II. PRODEDURAL HISTORY

HCH filed a Certificate of Ongoing Performance application on September 21, 2019, in accordance with the review schedule determined by the Commission. MHCC staff reviewed the application and requested additional information on December 30, 2020, February 24, 2021, and March 9, 2021. Additional information was submitted on January 22, 2021, March 4, 2021, and March 11, 2021.

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.

HCH stated that there were no deficiencies in data collection or reporting identified by MHCC staff.

Staff Analysis and Conclusion

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

MHCC staff concludes that HCH 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.

HCH responded that there were no times in which cardiac catheterization laboratory (CCL) downtime prevented delivery of PCI services in CY 2015 through mid-September 2020. As shown in Table 1, HCH provided a report of downtime for each of the two cardiac catheterization laboratories (CCLs) between January 2015 and September 2020.

Table 1: HCH Reported Frequency of CCL Downtime by CCL and Time Period, January 2013- September 2020

Time Period	Number of Downtime Occurrences		Overlapping Downtime
	CCL 1	CCL 2	
CY 2015	7	4	No
CY 2016	7	7	No
CY 2017	13	6	No
CY 2018	12	5	No
CY 2019	2	5	No
February 1- September 14, 2020	2	9	No

Source: HCH application and updated response to Q2.

Staff Analysis and Conclusion

MHCC staff reviewed the tables of CCL downtime and information submitted by HCH. On October 30, 2015, May 10, 2016, March 16, 2017, and March 15, 2018 there were instances when Room 1 and Room 2 were both down for scheduled maintenance. HCH stated that the downtime for the two rooms did not overlap at any time on those dates, and the length of time for the repairs and the non-critical nature of the work allowed the repairs to be completed without simultaneous downtime for both rooms. Additionally, HCH provided downtime records for calendar years 2013 and 2014, although not required for this review period. MHCC staff reviewed the information for those years and concludes that HCH also met this standard in 2013 and 2014.

MHCC staff concludes that HCH 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 DTB times for transfer cases and evaluate areas for improvement.

HCH provided a signed statement from Louis Damiano, M.D., President of HCH, acknowledging that HCH is committed to providing primary PCI service as soon as possible and not exceeding 90 minutes from the patient's arrival at the hospital for at least 75% of appropriate cases. Additionally, HCH provided quarterly door-to-balloon (DTB) times of non-transfer patients who received PCI within 90 minutes for July 1, 2013 through June 2020, based on data gathered from the ACC-NCDR CathPCI registry. HCH did not receive any transfers from other acute care facilities during the review period. See Table 2A on the following page.

Table 2A: HCH Reported Compliance with DTB Benchmark by Quarter
January 2015 - June 2020

Quarter	Total Primary PCI Case Volume	Cases with DTB ≤ 90 Minutes	Percent of Total Primary PCI Cases with DTB ≤ 90 Minutes
CY2015 Q1	15	14	93.3%
CY2015 Q2	15	12	80.0%
CY2015 Q3	22	18	81.8%
CY2015 Q4	20	14	**70.0%**
CY2016 Q1	28	25	89.2%
CY2016 Q2	13	11	84.6%
CY2016 Q3	18	15	83.3%
CY2016 Q4	13	11	84.6%
CY2017 Q1	14	14	100.0%
CY2017 Q2	12	9	75.0%
CY2017 Q3	15	12	80.0%
CY2017 Q4	15	12	80.0%
CY2018 Q1	20	17	85.0%
CY2018 Q2	18	13	**72.2%**
CY2018 Q3	14	13	92.8%
CY2018 Q4	14	11	78.5%
CY2019 Q1	14	11	78.5%
CY2019 Q2	22	20	90.9%
CY2019 Q3	19	15	78.9%
CY2019 Q4	18	14	77.7%
CY2020 Q1*	20	17	85.0%
CY2020 Q2*	13	7	**53.8%**

Source: HCH application, Q4, updated Q4.
*Note: MHCC staff issued a bulletin on March 31, 2020 informing hospitals that certain standards, including the DTB time standard will be waived due to the pandemic; standards will be waived beginning March 1, 2020 until the end of the month when the state of emergency declared by Maryland's governor ends.

Staff Analysis and Conclusion

MHCC staff analyzed the NCDR CathPCI data for non-transfer STEMI[1] cases for the period 2015 Q1 to 2020 Q2 and concluded that HCH met the door-to-balloon time standard in all but two quarters, as shown in Table 2B. Although it was not required, HCH provided data for the period 2013 Q3 through 2014 Q4. Additionally, MHCC staff analyzed the NCDR CathPCI data for CY 2014 and concluded that HCH met the door-to-balloon time standard overall during CY 2014. In the quarter ending 2015 Q4, 71.4% of cases met the DTB benchmark, and in the quarter ending 2019 Q4, 72.2% met the DTB benchmark. MHCC staff requested additional information from HCH regarding why the DTB standard was missed in two quarters, and HCH provided detailed information on individual cases. The reasons included delay in processes outside of the hospital's control. HCH notes that these issues were discussed and reviewed in Cardiovascular Services Meetings that occurred in 2015 and 2019.

[1] An ST-segment elevation myocardial infarction or STEMI is a type of heart attack that, in most cases, is best treated through performance of a primary PCI procedure.

MHCC staff's analysis differs from the information provided by the hospital because the NCDR CathPCI reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, HCH complied with this standard, with between 80.9% and 86.4% of primary PCI cases meeting the door-to-balloon time standard, as shown in Table 2B.

MHCC staff concludes that HCH complies with this standard.

Table 2B: HCH 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	17	16	94.1%			
2015q2	16	13	81.3%			
2015q3	22	18	81.8%			
2015q4	21	15	**71.4%**			
2016q1	27	25	92.6%			
2016q2	13	11	84.6%			
2016q3	17	14	82.4%			
2016q4	12	11	91.7%	145	123	84.8%
2017q1	14	14	100.0%	142	121	85.2%
2017q2	12	9	75.0%	138	117	84.8%
2017q3	15	12	80.0%	131	111	84.7%
2017q4	15	12	80.0%	125	108	86.4%
2018q1	20	17	85.0%	118	100	84.7%
2018q2	17	13	76.5%	122	102	83.6%
2018q3	14	13	92.9%	119	101	84.9%
2018q4	14	11	78.6%	121	101	83.5%
2019q1	14	11	78.6%	121	98	81.0%
2019q2	21	17	81.0%	130	106	81.5%
2019q3	18	15	83.3%	133	109	82.0%
2019q4	18	13	**72.2%**	136	110	80.9%

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

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 3, below, HCH provided the number of physicians, nurses, and technicians who can provide cardiac catheterization services to acute myocardial infarction patients as of one week before the due date of the application.

Table 3: Staffing for Holy Cross Hospital's CCL

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	8 persons	
Nurse	5 persons; 3.0 (FTE)	C – 5
Technician	10 persons; 4.0 (FTE)	SCM – 8; S – 2

Source: HCH application, Q6a.
*Scrub (S) circulate (C), monitor (M).

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by HCH to information reported in HCH's application for renewal of its waiver for primary PCI services in 2013. Table 3 shows the total number of staff currently involved in providing primary PCI services at HCH. In the hospital's 2013 waiver renewal application, there were three full-time equivalent (FTE) nursing staff reported with three additional pro re nata (PRN) nurses available as needed including one nurse practitioner, four technicians available as needed, and six interventionalists on staff. As compared to the staffing reported in the hospital's previous waiver renewal application, the number of FTE nurses has been reduced by one, and the number of technicians changed from four PRN to four FTEs.

MHCC staff also compared the staffing level reported by HCH to another existing program with only a primary PCI program, MedStar Franklin Square Medical Center (Franklin Square). Franklin Square, in its Certificate of Ongoing Performance application in 2019, reported having 5.5 nurse FTEs, four technician FTEs, and five interventionalists. Franklin Square also stated that an additional nurse (0.1FTE) is responsible for data management and reporting for PCI services. The primary PCI volume reported by Franklin Square for 2019 was 99 cases compared to 73 cases for HCH. MHCC staff observed that Franklin Square has a greater number of nurse FTEs and physicians than HCH. However, both programs reported the same number of technician FTEs. The higher staffing levels for Franklin Square compared to HCH may be due to the difference in primary PCI volume between the two programs.

MHCC staff concludes that HCH has adequate nursing and technical staff to provide services.

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

HCH provided a signed letter of commitment from Dr. Damiano, acknowledging that HCH will provide primary PCI services in accordance with the requirements established by the Commission. Dr. Damiano also stated that HCH has not received any transfer cases to date; but if transfer cases are received in the future, HCH will track the DTB times for those cases and evaluate areas for improvement.

Staff Analysis and Conclusion

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

HCH provided a list of the staff involved with these functions. As shown in Table 4, there are four positions with some responsibility for data management and quality, but only a total of 1.40 FTEs.

Table 4: HCH Data Management and Quality Improvement Staff FTEs

Position Title	FTEs
Supervisor, Registered Cardiovascular Interventional Specialist (RCIS), Cardiac Cath Lab	0.60
Manager, Performance Improvement Department	0.50
Abstractor, Performance Improvement Department	0.14
Administrative Assistant, Emergency Department	0.16
Total	1.40

Source: HCH application Q8.

Staff Analysis and Conclusion

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

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

Rajeev Patel, M.D., interventional cardiologist, was appointed as the medical director of the Cardiac Catheterization Laboratory (CCL) at HCH in 2016. Dr. Patel's appointment was renewed in 2018 for a period of three years. Unless his appointment is renewed again, it will end on July 19, 2021. Dr. Patel is responsible for the elements listed in the standard. Prior to Dr. Patel, Yuri A. Deychak, M.D. served as the Medical Director of the CCL from January 1, 2015 to July 27, 2016.

Staff Analysis and Conclusion

MHCC staff concludes that HCH 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.

HCH provided a list of continuing educational activities between July 2013 and June 2019 for staff managing the Critical Care Unit and CCL. HCH stated that Registered Cardiovascular Invasive Specialist staff are required to obtain 36 hours of continuing education credits over three years, and 30 of these credits must be cardiovascular-related. In addition, HCH stated that while the hospital does not track continuing education credits, HCH tracks employees' registry status with Cardiovascular Credentialing International, which must be maintained as a condition for continued employment.

Staff Analysis and Conclusion

MHCC reviewed the information provided and concludes that HCH 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.

Dr. Damiano signed and dated agreements with Suburban Hospital, Inc., Adventist HealthCare, Inc., d/b/a Washington Adventist Hospital, and MedStar Washington Hospital Center Corporation, all of which operate tertiary care centers that will provide for the unconditional transfer of patients for any required additional care, including emergent or non-primary cardiac surgery or PCI.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that HCH 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.

Norvelle V. Coots, M.D., President and Chief Executive Officer, of Holy Cross Health, Inc., signed and dated an agreement with Butler Medical Transport, LLC (Butler) that covers transportation to HCH. The agreement provides that, for emergent transport requests, Butler is required to arrive at the sending facility for pick-up within 30 minutes of a request.

Staff Analysis and Conclusion

MHCC staff reviewed the transport agreement and concludes that HCH meets this standard.

<u>Quality</u>

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.

HCH stated that there are two separate meetings held back-to-back, one meeting is for interventional case review and the other is for STEMI process review. The case review meeting consists of a review of cases performed the previous month. The STEMI process review meeting includes a discussion of opportunities for improvement around the STEMI process for enhancing patient-centered care. The meetings are scheduled sequentially for the convenience of the participants. Although only 2015 through 2019 meeting records were required, HCH provided attendance records for meetings held between July 2013 through August 2019, with limited exceptions.

Staff Analysis and Conclusion

MHCC staff reviewed attendance records submitted for the combined interventional case review meetings and multiple care area group meetings. The frequency of these meetings was greater than once every two months for most of the review period. Twelve meetings were held in both 2013 and 2014, eleven meetings were held in 2015, twelve meetings were held in 2016, ten meetings were held in 2017, eleven meetings were held in 2018, and at the time of the application submission, eight meetings were held in 2019. Interventional case review meetings included physicians, nurses, and technicians who care for primary PCI patients, as required.

MHCC staff concludes that HCH complies with this standard.

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.

Prior to the update in November 2015, COMAR 10.24.17.07D(5)(c) did not require external review of primary PCI cases, and HCH only performed primary PCI services from the time the program was first established through the end of the review period for its Certificate of Ongoing Performance application. Although external review was not required for most of the review period, HCH submitted a copy of its external review reports for August 2014 through August 2015. The external reviews were completed by an MHCC-approved review organization, the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ).

Staff Analysis and Conclusion

MHCC staff reviewed the MACPAQ report submitted. A list of 82 cases was forwarded to MACPAQ for random selection. Although only 5% of cases are required to be reviewed, 6% of cases were reviewed during this 12-month period. Five operators performed interventions at HCH during this 12-month review period. The regulations in place prior to October 2015 did not require a minimum number of cases per interventionalist.

HCH reported the number of cases reviewed externally for August 2014 through August 2015. HCH explained that in addition to external reviews, the hospital also reviews a 100% of STEMI cases internally. Performance reviews are conducted monthly at the Cardiac Services Committee's Cardiovascular Conference meetings. The meetings are attended by interventionalists and other physicians including the Emergency Department physicians and intensivists, and by clinical staff including nurses and technicians. A member of HCH Performance Improvement Department is also present. The information provided by HCH shows that the hospital is reviewing at least ten cases, ten percent of cases, or all cases as required. The hospital's review of individual interventionalists also includes a review of angiographic images, medical test results, and patients' medical records. With the exception of a brief period between August 2014 and August 2015, the hospital routinely relies solely on the internal review of individual interventionalists. While the Commission has adopted standards for the process of internally reviewing individual interventionalists, the Commission has not established specific standards for reviewers for internal case review.

MHCC staff concludes that HCH complies with this standard.

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.

HCH submitted an affidavit from Dr. Damiano certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, semi-annual external review, and monthly internal review of individual interventionalists consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that HCH 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.

HCH provided a description of the processes for quality improvement. HCH explained that the hospital's quality assurance activities in the CCL are centered on the monthly interdisciplinary Cardiac Catheterization Conference. The first part of these sessions involves a review of completed STEMI cases from the previous month. The second part of the meeting is dedicated to an open forum around suggestions for improving the STEMI process from a patient-centered perspective. For example, during the August 18, 2020 process review meeting, roles and responsibilities were clarified for staff who respond to STEMI procedures resulting in the creation of a document with official roles and responsibilities. During the same meeting, the Cardiac catheterization medical director, Dr. Patel, requested that a similar document be drafted for staff who respond to a cardiac or respiratory arrest.

HCH described two additional areas targeted by the hospital for improvement. HCH decided to work on improving door to electrocardiogram (EKG) times. This included, assigning a dedicated EKG technician to the ambulatory triage unit during specific hours Sunday through Saturday. In addition, an EKG is to be performed immediately prior to registration on anyone with

signs and symptoms of a STEMI. Registered nurses will perform the EKG, if an EKG technician is unavailable.

The second area targeted for improvement by HCH is the in-house STEMI activation system. One of the solutions implemented by the hospital that resulted in a policy update is immediately calling the STAT team to avoid delays in communication with appropriate members of the team.

Staff Analysis and Conclusion

MHCC staff reviewed the information on quality assurance activities and concludes that HCH complies with this standard.

<u>Patient Outcome Measures</u>

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

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

- ***(c) A hospital with a risk-adjusted mortality rate for primary PCI cases that exceeds the statewide average 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 30-day risk-adjusted mortality rate for primary PCI cases.***

HCH submitted adjusted mortality rates by rolling 12-month reporting period for 2015 Q1 through 2020 Q3 when available, as shown in Table 5 on the following page. 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. For the 12-month reporting periods ending 2018 Q3, 2018 Q4, and 2019 Q1, the hospital's performance in one or more quarters is not reflected in the 12-month reporting period because the hospital was unable to meet the deadline for reporting information to be included in the calculations of performance. Representatives for the hospital explained that three staff were taking leave allowed by the Family Medical Leave Act, so staff resources were insufficient to meet reporting deadlines of the ACC-NCDR CathPCI data registry.

Table 5: HCH Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2019q4-2020q3	7.75	[2.57, 17.10]	6.37	Yes
2019q3-2020q2	6.72	[2.22, 14.91]	6.06	Yes
2019q2-2020q1	8.32	[3.68, 15.57]	5.99	Yes
2019q1-2019q4	6.37	[2.39, 13.15]	6.01	Yes
2018q4-2019q3	5.68	[1.57, 13.81]	6.06	Yes
2018q3-2019q2	6.03	[1.26, 16.75]	6.38	Yes
2018q2-2019q1	3.32	[0.41, 11.39]	6.13	Yes
2018q1-2018q4	3.40	[0.71, 9.47]	6.00	Yes
2017q4-2018q3	6.16	[2.32, 12.64]	6.54	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry			
2017q2-2018q1	5.86	[1.63, 14.13]	6.91	Yes
2017q1-2017q4	6.11	[1.28, 16.17]	6.89	Yes
2016q4-2017q3	NR	[0.00, 9.86]	6.75	Yes
2016q3-2017q2	4.15	[0.51, 14.24]	6.64	Yes
2016q2-2017q3	8.22	[2.28, 19.78]	6.77	Yes
2016q1-2017q4	9.34	[4.15, 17.33]	6.82	Yes
2015q4-2016q3	10.29	[4.84, 18.45]	6.71	Yes
2015q3-2016q2	10.69	[5.02, 19.24]	6.66	Yes
2015q2-2016q1	9.00	[3.98, 16.85]	6.45	Yes
2015q1-2015q4	9.46	[3.90, 18.42]	6.26	Yes

Source: MHCC staff compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and December 2019.
Notes: NR means a value was not reported. When a hospital has zero deaths, then no value is reported for a hospital's adjusted mortality rate. A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark for 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 STEM and non-STEMI cases for each reporting period.

Staff Analysis and Conclusion

This standard is not applicable for most of the review period for HCH's Certificate of Ongoing Performance because the current standard did not become effective until January 14, 2019. A similar standard that was adopted previously referenced a statewide average as the benchmark and MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. However, MHCC staff has provided information in Table 5 that shows how HCH performed over the period between January 2015 and September 2020.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for STEMI cases and determined that the hospital's adjusted mortality rate was not statistically significantly different from the national benchmark in any reporting period because the national benchmark fell within the 95% confidence interval for HCH. MHCC staff concludes that HCH meets this standard for the periods ending December 2019, March 2020, June 2020, and September 2020. HCH also would have met this standard, if it had been applicable for the rest of the period reviewed.

<u>Physician Resources</u>

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

MHCC staff notes that HCH has been providing individual physician procedure volume numbers quarterly, which was required for a limited period in a condition included in the hospital's last waiver renewal in September 2013. At that time Maryland regulations required that each physician who performed elective PCI services at a hospital without on-site cardiac surgery had to perform 75 or more PCI procedures on an annual basis. The regulations were subsequently updated to lower the annual volume requirement from 75 to 50 procedures. HCH has maintained compliance with the requirements provided in the waiver.

For each physician who performs PCI at HCH, the hospital submitted the volume of primary PCI procedures at HCH as well as primary and elective procedures at other hospitals by quarter from 2013 through 2019 Q2. Drs. Patel, Chen, Finn, Flyer, Friedman, Gallagher, Marshall, and Wang signed and dated affidavits affirming under penalties of perjury that the information provided on PCI procedure volume is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed the reported physician procedure volumes for the interventionalists who performed primary PCI services at HCH between October 2013 and December 2019 and determined that each interventionalist performed at least 50 PCI procedures annually, on average, over the 24-month periods between October 2013 and December 2019. Staff notes that the waiver

issued to HCH included a condition regarding reporting of physician procedure volumes to demonstrate compliance with the standard at the time, and HCH continued to report physician procedure volumes quarterly to MHCC staff, even after it was no longer required.

HCH 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.

HCH responded that this regulation is not applicable. MHCC staff concludes that this standard does not apply to HCH.

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.

HCH responded that this regulation is not applicable because none of the physicians participating in the hospital's program from July 1, 2013 to the time of the application submission date requested a leave of absence.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to HCH. While HCH does not have on-site cardiac surgery, each physician performing primary PCI performed 50 PCI procedures annually, averaged 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.

HCH submitted a signed and dated statement from Dr. Patel, acknowledging that all physicians performing primary PCI services at HCH are board certified in interventional cardiology or exempt from this requirement.

Staff Analysis and Conclusion

MHCC staff concludes that HCH meets these standards, based on the letter provided.

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.

HCH submitted signed and dated attestations from Drs. Patel, Chen, Finn, Flyer, Friedman, Gallagher, Marshall, and Wang stating that each physician has completed a minimum of 30 hours of continuing medical education credits in interventional cardiology in the last two years.

Staff Analysis and Conclusion

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

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

HCH submitted a signed statement from Dr. Patel, acknowledging that Drs. Finn, Flyer, and Marshall participate in the on-call schedule. HCH also submitted a copy of the on-call schedule from August 27, 2019. HCH stated that Drs. Chen, Friedman, Gallagher, and Wang do not appear on the on-call schedule because they provide backup coverage for Dr. Patel if he is unable to cover his on-call obligations. MHCC staff was informed of this practice in March 2019 and concluded that this arrangement is acceptable.

Staff Analysis and Conclusion

MHCC staff reviewed the on-call schedule submitted, information on case volume provided by HCH, and NCDR CathPCI registry data. MHCC staff concludes that HCH meets this standard.

<u>Volume</u>

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.

Table 6: HCH Primary PCI Case Volume

Calendar Year	Primary PCI Case Volume
2015	76
2016	69
2017	56
2018	65
2019	71

Source: MHCC staff analysis of ACC-NCDR CathPCI data.

Staff Analysis and Conclusion

MHCC staff analyzed the NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2019. This analysis shows primary PCI volume ranged from 56 to 76 cases each calendar year and confirms that HCH met the threshold of 49 cases annually referenced in the standard. MHCC staff concludes that this standard is met.

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

HCH provided the number of primary PCI cases by interventionalist from October 2013 to December 2019 .

Staff Analysis and Conclusion

MHCC staff notes that 11 primary PCI cases is a "target" rather than a strict standard. MHCC staff reviewed the tables submitted by HCH for the review period 2015 through 2019 Q2. Although not required for this review period, HCH also provided primary PCI volumes for calendar years 2013 and 2014. According to the tables, at least 11 primary PCI procedures were completed per year for practicing interventionalists at the time of application for most of the review period except 2014. Two interventionalists did not meet the target in 2014.

MHCC staff concludes that HCH complies with this standard.

Patient Selection

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.

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

Staff Analysis and Conclusions

MHCC staff concludes that HCH complies with the standard.

RECOMMENDATION

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

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