

**IN THE MATTER OF
FREDERICK HEALTH
HOSPITAL**

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

Docket No.: 19-10-CP025

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

April 18, 2024

I. INTRODUCTION

A. Background

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

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

Frederick Health Hospital

Frederick Health Hospital (FHH), previously known as Frederick Memorial Hospital¹, is a 257-bed acute care general hospital located in Frederick, Maryland (Frederick County). FHH does not have a cardiac surgery program on-site. FHH initiated primary PCI services on March 14, 2008, and has continued performing primary PCI without cardiac surgery on-site through waivers issued in 2009, 2011, and 2013. 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. FHH is in the Baltimore/Upper Shore health planning region, which consists of 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 primary and elective PCI services. Six of these hospitals also provide cardiac surgery services across this health planning region.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

FHH established its primary PCI program under a waiver prior to August 18, 2014, and as provided in COMAR 10.24.07A(2) and (3), the hospital may continue to provide primary and elective PCI services when it has not yet completed a scheduled review to consider the grant of its first Certificate of Ongoing Performance. FHH filed a Certificate of Ongoing Performance application on September 14, 2019. MHCC staff reviewed the application and requested additional information on February 25, 2021, April 8, 2021, July 21, 2023, and March 5, 2024. MHCC received additional information on March 18, 2021, April 12, 2021, August 4, 2023, September 5, 2023, and March 20, 2024. The gaps in requesting additional information were due to a lack of

¹ The Frederick News-Post. *Frederick Memorial Hospital gets new name as part of health system's rebranding*. October 3, 2019. Available at: https://www.fredericknewspost.com/news/health/hospitals_and_doctors/frederick-memorial-hospital-gets-new-name-as-part-of-health-system-s-rebranding/article_e61bfa78-c7d0-53ac-b3b2-d2c63b5f4b3f.html.

MHCC staff resources in late 2019 and 2020, and the time it took to complete a focused review. MHCC staff concluded that updated information for the hospital's application should be requested due to the amount of time that had passed since the hospital first submitted an application.

MHCC staff also received information as part of a focused review that was conducted, based on the hospital's risk-adjusted mortality rates for non-ST-elevation myocardial infarction (STEMI) PCI cases in the 12-month reporting period ending on June 30, 2020 (Table 6). The preliminary report of the focused review was provided to FHH on June 22, 2023. MHCC staff met with representatives for FHH on August 4, 2023, and the focused review report was finalized on August 11, 2023, without changes.

Based on the findings from the focused review, the actions taken by FHH prior to the focused review to address concerns identified by the hospital, and the hospital's improved performance with respect to mortality, MHCC staff concluded that a formal plan of correction was not required.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07C(3) and .07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACC-NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

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

Staff Analysis and Conclusion

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

MHCC staff concludes that FHH 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.

FHH states that the hospital's cardiac catheterization laboratory (CCL) was available around the clock during the review period, without disruption. On September 26, 2022, FHH

moved the CCL from the second floor to its current location on the third floor. The new space includes three CCL procedure rooms and one special procedure room without x-ray equipment. FHH also provided a report of downtime for each of the CCLs between January 2015 and July 2023. MHCC staff’s summary of this information is shown in Table 1. Appendix 1 contains a complete list of the date, time, and duration of downtimes for each CCL, as well as the reasons for downtimes.

Table 1: FHH Reported Frequency of CCL Downtime by CCL and Time Period, January 2015 – July 2023

Time Period	Number of Downtime Occurrences			Overlapping Downtime
	CCL 1	CCL 2	CCL 3	
CY 2015	2	2	--	No
CY 2016	3	5	--	No
CY 2017	2	2*	--	No
CY 2018	7	10	--	Yes
CY 2019	4	3	--	No
CY 2020	6	3	--	No
CY 2021	2	2	--	No
CY 2022	4	8	1	No
January – July 2023	3	2	2	No

Source: FHH 2019 PCI Certificate of Ongoing Performance application and supplemental response to Q2 (2023).

*Room 2 was down from May 19, 2017, through August 11, 2017, for construction.

Staff Analysis and Conclusion

MHCC staff reviewed the information on CCL room closures submitted by FHH and determined that, except for in one instance, it is unlikely that both rooms were unavailable simultaneously. On June 21, 2018, an unscheduled repair contributed to the downtime of both CCLs at FHH for the same 24-hour period. The hospital reported that during this downtime, Operating Room 14 was available for STEMI² patients; however, no STEMI patients presented during this timeframe. Staff’s analysis also determined that the times when PCI services were not available were unavoidable.

MHCC staff concludes that FHH complies with this standard.

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

FHH provided a signed statement from Thomas A. Kleinhanzl, President and Chief Executive Officer (CEO) of FHH, stating that the hospital commits to providing primary PCI

² 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.

services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, and FHH commits to tracking door-to-balloon (DTB) times for transfer cases and evaluating areas for improvement if the hospital receives transfer cases. Additionally, FHH provided quarterly median DTB times for the period from January 2015 through March 2019, as well as the number and percentage of non-transfer PCI cases with a DTB time of less than 90 minutes from January 2015 through March 2023, as shown in Table 2. During this period, the hospital reports that 75 to 100 percent of cases met the DTB standard. The hospital did not report any PCI transfer cases during the review period.

**Table 2: FHH Reported Compliance with DTB Benchmark
by Quarter January 2015 - March 2023**

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	34	30	88.2%
CY2015 Q2	29	26	89.7%
CY2015 Q3	37	31	83.8%
CY2015 Q4	36	34	94.4%
CY2016 Q1	20	20	100.0%
CY2016 Q2	30	28	93.3%
CY2016 Q3	29	26	89.7%
CY2016 Q4	23	20	87.0%
CY2017 Q1	24	21	87.5%
CY2017 Q2	27	25	92.6%
CY2017 Q3	23	21	91.3%
CY2017 Q4	21	19	90.5%
CY2018 Q1	35	28	80.0%
CY2018 Q2	25	22	88.0%
CY2018 Q3	24	23	95.8%
CY2018 Q4	29	27	93.1%
CY2019 Q1	33	28	84.8%
CY2019 Q2	28	26	92.9%
CY2019 Q3	31	28	90.3%
CY2019 Q4	32	30	93.8%
CY2020 Q1	31	30	96.8%
CY2020 Q2	24	21	87.5%
CY2020 Q3	36	32	88.9%
CY2020 Q4	26	21	80.8%
CY2021 Q1	20	15	75.0%
CY2021 Q2	23	21	91.3%
CY2021 Q3	24	22	91.7%
CY2021 Q4	21	19	90.5%
CY2022 Q1	24	21	87.5%
CY2022 Q2	28	27	96.4%
CY2022 Q3	29	27	93.1%
CY2022 Q4	15	14	93.3%
CY2023 Q1	20	18	90.0%

Source: MHCC staff analysis of data in FHH 2019 PCI Certificate of Ongoing Performance application and response to MHCC questions September 6, 2023.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases for the period 2015 Q1 to 2022 Q4, as shown in Table 3a. MHCC staff found that FHH met the DTB benchmark in all quarters. 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.

**Table 3a: FHH Reported Compliance with DTB Benchmark
by Quarter January 2015 – December 2022**

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	30	26	86.7%
CY2015 Q2	27	26	96.3%
CY2015 Q3	36	30	83.3%
CY2015 Q4	32	31	96.9%
CY2016 Q1	18	18	100.0%
CY2016 Q2	27	25	92.6%
CY2016 Q3	26	24	92.3%
CY2016 Q4	20	20	100.0%
CY2017 Q1	22	21	95.5%
CY2017 Q2	26	24	92.3%
CY2017 Q3	22	21	95.5%
CY2017 Q4	17	16	94.1%
CY2018 Q1	31	26	83.9%
CY2018 Q2	24	20	83.3%
CY2018 Q3	25	23	92.0%
CY2018 Q4	29	27	93.1%
CY2019 Q1	31	28	90.3%
CY2019 Q2	23	22	95.7%
CY2019 Q3	29	26	90.0%
CY2019 Q4	31	29	93.5%
CY2020 Q1	30	30	100.0%
CY2020 Q2	22	19	86.4%
CY2020 Q3	29	27	93.1%
CY2020 Q4	24	20	83.3%
CY2021 Q1	17	14	82.4%
CY2021 Q2	23	20	87.0%
CY2021 Q3	23	22	95.7%
CY2021 Q4	17	16	94.1%
CY2022 Q1	23	21	91.3%
CY2022 Q2	28	27	96.4%
CY2022 Q3	28	26	92.9%
CY2022 Q4	15	14	93.3%

Source: MHCC staff analysis of ACC-NCDR CathPCI data for CY 2015 - CY 2022.

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 rolling eight-quarter periods, as shown in Table 3b.

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

Time Period	Quarter			Rolling Eight-Quarters		
	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes
CY2015 Q1	30	26	86.7%			
CY2015 Q2	27	26	96.3%			
CY2015 Q3	36	30	83.3%			
CY2015 Q4	32	31	96.9%			
CY2016 Q1	18	18	100.0%			
CY2016 Q2	27	25	92.6%			
CY2016 Q3	26	24	92.3%			
CY2016 Q4	20	20	100.0%	216	200	92.6%
CY2017 Q1	22	21	95.5%	208	195	93.8%
CY2017 Q2	26	24	92.3%	207	193	93.2%
CY2017 Q3	22	21	95.5%	193	184	95.3%
CY2017 Q4	17	16	94.1%	178	169	94.9%
CY2018 Q1	31	26	83.9%	191	177	92.7%
CY2018 Q2	24	20	83.3%	188	172	91.5%
CY2018 Q3	25	23	92.0%	187	171	91.4%
CY2018 Q4	29	27	93.1%	196	178	90.8%
CY2019 Q1	31	28	90.3%	205	185	90.2%
CY2019 Q2	23	22	95.7%	202	183	90.6%
CY2019 Q3	29	26	90.0%	209	188	90.0%
CY2019 Q4	31	29	93.5%	223	201	90.1%
CY2020 Q1	30	30	100.0%	222	205	92.3%
CY2020 Q2	22	19	86.4%	220	204	92.7%
CY2020 Q3	29	27	93.1%	224	208	92.9%
CY2020 Q4	24	20	83.3%	219	201	91.8%
CY2021 Q1	17	14	82.4%	205	187	91.2%
CY2021 Q2	23	20	87.0%	205	185	90.2%
CY2021 Q3	23	22	95.7%	199	181	91.0%
CY2021 Q4	17	16	94.1%	185	168	90.8%
CY2022 Q1	23	21	91.3%	178	159	89.3%
CY2022 Q2	28	27	96.4%	184	167	90.8%
CY2022 Q3	28	26	92.9%	183	166	90.7%
CY2022 Q4	15	14	93.3%	174	160	92.0%

Source: MHCC staff analysis of ACC-NCDR CathPCI data CY 2015 - CY 2022.

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

As shown in Table 3b, over rolling eight-quarter periods, between 89.3% and 95.3% of PCI cases met the DTB time standard.

MHCC staff concludes that FHH complies with this standard.

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

As shown in Table 4a, below, FHH reports the number of physicians, nurses, and technicians who were available to provide cardiac catheterization services to acute myocardial infarction patients, as of March 18, 2024.

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

Staff Category	Number/FTEs	Cross Training (S/C/M)*
Physician	4	Interventional Cardiologist
Nurse	11.95	S/C/M
Technician	6.05	S/C/M

Source: FHH's 2019 PCI Certificate of Ongoing Performance application and supplemental response to Q6a (2024).

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

Staff Analysis and Conclusion

MHCC staff compared the staffing levels described by FHH to information reported by three other existing PCI program applications for Certificates of Ongoing Performance with similar case volumes. A comparison of volume and staffing levels for FHH, Medstar Southern Maryland Hospital Center (MSMHC), Johns Hopkins Hospital (JHH), and St. Agnes Hospital is shown in Table 4b. FHH has a greater number of full-time equivalent (FTE) nurses than the PCI programs for MSMHC, JHH, and St. Agnes. FHH reported fewer technician FTEs than JHH, which performed a higher volume of PCI cases than FHH. Additionally, FHH reported more technical FTEs than MSMHC and St. Agnes Hospital; MSMHC performed a lower volume of PCI cases than FHH, while St. Agnes Hospital performed a higher volume of PCI cases than FHH, as shown in Table 4b.

Table 4b: CCL Staffing for FHH and Other Select PCI Programs

Program & Year Reported	Total PCI Volume	Number of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
FHH – 2024	368*	4	11.95	6.05
Medstar Southern Maryland Hospital Center - 2023	318	2 FTE, 3 PTE	11	5
Johns Hopkins Hospital - 2023	418*	7.58	6.65	9.5 + 2 PRN
St. Agnes Hospital - 2023	429	4	8.3	5

Sources: FHH 2019 PCI Certificate of Ongoing Performance application and supplemental updates to Q6a (2024), Medstar Southern Maryland 2019 PCI Certificate of Ongoing Performance application with supplemental updates to Q6a (2023), Johns Hopkins Hospital 2019 PCI Certificate of Ongoing Performance application with supplemental updates to Q6a (2023), St. Agnes Hospital 2023 PCI Certificate of Ongoing Performance application.

*Volumes are for rolling 4-quarters ending in Q3 2023.

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

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

FHH provided a letter of commitment, signed by Thomas A. Kleinhanzl, President and CEO of FHH, acknowledging that FHH will provide primary and elective 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 FHH 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.

FHH reported that the hospital retains two FTEs for data management, reporting, and coordination with institutional quality improvement efforts for PCI services. In addition, FHH stated that the performance improvement department dedicates staff to support additional data requests, peer review and medical staff functions as needed.

Staff Analysis and Conclusion

MHCC staff concludes that FHH complies with this standard.

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

Dr. Chao-Wei Hwang and Dr. Thomas Wang are the current co-medical directors and have held those roles since July 1, 2016, with some exceptions. Dr. Faisal Rahman served as co-medical director from September 19, 2022, through July 2, 2023, in place of Dr. Hwang. Upon Dr. Hwang's return on July 3, he reassumed the co-medical director role. During the period from July 21, 2022, through September 19, 2022, Dr. Thomas Wang served as the sole medical director.

As described by FHH, the medical directors of the CCL are responsible for providing clinical leadership and direction to the FHH's CCL and interventional cardiology service; for developing, implementing, managing, and monitoring a quality and performance improvement process and, for maintaining a supportive environment for clinicians across the continuum of invasive and interventional cardiology services. FHH submitted a copy of the formal position description and descriptions of the individual duties for each medical director.

Staff Analysis and Conclusion

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

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

FHH 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 2022. FHH states that staff participate in educational activities and services throughout the year as needed or required. For example, the American Registry of Radiologic Technologists (ARRT) requires 24 continued education credits be completed every two years for all practicing radiology technologists. Another example noted by FHH is that the Maryland Board of Physicians has an attestation requirement of 24 continuing education credits relevant to practice when a radiology technologist renews their license every year or are currently registered by the ARRT. Furthermore, all registered nurses are required to meet 24 continuing education units.

FHH also requires staff to participate in an education day annually that focuses on competencies specific to the CCL. This full day of training is attended by all staff and attendance is documented in FHH's net learning system. The hospital also hosts in-house monthly staff case review meetings. During these meetings, PCI cases are reviewed and topics relevant to quality improvement are discussed.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. MHCC staff concludes that FHH is in compliance with this standard.

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

Thomas A. Kleinhanzl, President and CEO of FHH, signed and dated agreements with both Washington Adventist Hospital and Adventist HealthCare White Oak Medical Center, which operate tertiary care centers that 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 agreements and concludes that FHH meets this standard.

10.24.17.07D(4)(i) The hospital shall maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

Thomas A. Kleinhanzl, FHH President and CEO, signed an agreement with Butler Medical Transport, LLC (Butler) that covers transportation to FHH. The agreement provides that, for patients identified as meeting the MIEMSS defined STEMI criteria for needing transfer to another hospital, Butler will arrive at FHH for pick-up within 30 minutes of a request.

Thomas A. Kleinhanzl also signed an agreement with Washington Hospital Center Medstar Transport Service for the helicopter transfer of critically ill patients. The agreement states that transportation will arrive at FHH within 30 minutes of a request for patient transport.

Staff Analysis and Conclusion

MHCC staff reviewed the transport agreements and concludes that FHH complies with this standard.

Quality

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

FHH explained that there are several meetings that take place monthly. The first meeting is the CCL Case Review/Staff Education meeting. This meeting is led by the Co-Medical Director Chao-Wei Hwang, M.D.; he reviews cases specifically selected by staff for on-going educational purposes. The meeting is attended primarily by CCL staff. Staff in the Intensive Care Unit (ICU) and the dedicated Post-Cardiac Cath Unit are invited too. Attendance is not mandatory, but strongly encouraged. FHH notes that this meeting is well attended with an engaged staff who appreciates the learning opportunity. This meeting was formally implemented with attendance tracking in April of 2016. Prior to this date, FHH provided informal education without tracking attendance.

Cases are also reviewed and discussed at mandatory CCL Operations meetings that take place monthly with a larger multidisciplinary group including Emergency Medical Services (EMS), Emergency Department (ED), and inpatients departments as applicable. Interventional Cardiology Peer Review meetings also take place monthly and are attended by CCL staff, CCL data coordinators, staff responsible for performance improvement, and medical staff appropriate for the case being reviewed.

FHH submitted dates and attendance records for meetings held between CY 2015 through CY 2022.

Staff Analysis and Conclusion

The documentation submitted by FHH included attendance records and meeting dates for eleven meetings in CY 2015, twelve meetings in CY 2016 through CY 2018, eleven meetings in CY 2019, twelve meetings in CY 2020, nine meetings in CY 2021, and eleven meetings in CY 2022. Interventional Cardiology Peer Review meetings included physicians, nurses, and technicians who care for primary PCI patients, as required.

MHCC staff concludes that FHH complies with this standard.

10.24.17.07C(4)(b) and .07D(5)(b) The hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

FHH provided dates and attendance records for monthly Cath Lab Operations meetings. This group meets monthly following the Interventional Cardiology Peer Review meeting. It is expected that representation be present from all areas of the organization in which care for the PCI patient took place. The meetings consist of a multidisciplinary team including, but not limited to, EMS, ED, CCL, ICU, Post-Cardiac Cath Unit, Performance Improvement, and Pharmacy. This team reviews key dashboard metrics populated by the ACC-NCDR CathPCI data registry results. FHH notes that on rare occasions, this meeting is cancelled due to weather, patient needs, etc. However, FHH states that if meeting cancellations occurred, the dashboard is reviewed and discussed on a modified basis at the next peer review meeting.

Staff Analysis and Conclusion

The documentation submitted by FHH included dates and attendance records for eleven meetings in CY 2015 and CY 2016, ten meetings in CY 2017 and CY 2018, twelve meetings in CY 2019, nine meetings in CY 2020, twelve meetings in CY 2021, and eleven meetings in CY 2022.

MHCC staff concludes that FHH complies with this standard.

10.24.17.07C(4)(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed

in the applicable time period as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

FHH submitted copies of the external review reports for PCI cases performed between January 2015 and December 2022. FHH uses an MHCC approved review organization, the Cardiac Community Core Lab, Inc. (CCCL), to review medical records and images for elective PCI cases on a semi-annual basis.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 5. Although only 5% of cases are required to be reviewed externally, between 7.7% and 13.3% of cases were reviewed each year.

Table 5: FHH External Review, January 2015 - December 2022

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
CY 2015	337	26	7.7%	Semi-annually	Yes
CY 2016	287	29	10.1%	Semi-annually	Yes
CY 2017	286	29	10.1%	Semi-annually	Yes
CY 2018	309	30	9.7%	Semi-annually	Yes
CY 2019	324	29	9.0%	Semi-annually	Yes
CY 2020	210	28	13.3%	Semi-annually	Yes
CY 2021	216	25	11.6%	Semi-annually	Yes
CY 2022	203	21	10.3%	Semi-annually	Yes

Source: MHCC staff analysis of CCCL reports (CY 2015 – CY 2022).

* Each semiannual review must include at least three cases per physician or all cases if interventionalist performed fewer than three cases during the review period: beginning in the second half of 2015.

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 December 2022, MHCC staff verified that, if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by the CCCL from CY 2015 to CY 2021. During the period from July through December 2022, only two cases were reviewed instead of three for one physician. FHH reports that, in this instance, the third PCI patient for one physician was inadvertently left off the blinded list sent to the CCCL, due to the case being classified incorrectly as a STEMI in the hospital’s internal database. Because this was minor and unintentional, MHCC staff concludes the standard was also met for CY 2022.

For external review, FHH states that a list is provided to its external review organization, CCCL, with the list of all PCIs (excluding STEMIs) over a six-month period. CCCL assigns a random number to each PCI, and per MHCC protocols, provides FHH with a list of PCIs randomly selected for external review for each six-month period.

MHCC staff concludes that FHH 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 three cases at the hospital during the relevant period, as provided in Regulation .08; or*
- (iii)** *A quarterly review or other review period conducted in a manner approved by Commission's Executive Director that assures that the review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in 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).*

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

- (i) Include a review of angiographic images, medical test results, and patients' medical records; and*
- (ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.*

In addition to the external reviews described above, FHH states that internal review of PCI cases take place through two modalities. First, PCI cases may be presented at the FHH's monthly departmental peer review meetings, which are based on FHH's Performance Improvement (PI) policy. These cases are not randomized and are reviewed by at least one other interventionalist, with the operating interventionalist in attendance, as well as a PI. The review includes angiographic images, medical test results, and the patient's medical record. Secondly, internal review of all PCI cases is performed quarterly. Each interventionalist's PCI cases are listed and then randomized. If the respective interventionalist's PCI cases do not meet the quantity of ten, then all that interventionalist's PCI cases are reviewed. The review is performed by one of two other interventionalists using angiographic images, medical test results, and the patient's medical record.

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 semi-annually. 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 ten percent 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).³ This guidance continues to be applicable to case reviews.

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 CCCL meet the requirements of 10.24.17.07D(5)(d) because CCCL has been approved by MHCC as a reviewer that meets the requirements for an external review organization, and the review of cases by CCCL includes a review of angiographic images, medical test results, and patients' medical records. In addition to cases review by external review, all cases were reviewed internally between January 2015 and December 2022.

³https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

Based on the documentation and information provided, MHCC staff concludes that FHH meets the standards in COMAR 10.24.17.07D(5)(c) and (d) and COMAR 10.24.17.07C(4)(d) and (e).

10.24.17.07C(4)(f) and 10.24.17.07D(5)(e) The chief executive officer of the hospital shall certify upon request by Commission staff that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in this chapter, including those regarding internal peer review of cases and external review of cases.

FHH submitted an affidavit (Form B) from Thomas A. Kleinhanzl, 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 semi-annual interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff reviewed Form B and concludes that FHH complies with this standard.

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

- (i) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.***
- (ii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.***

The hospital's PCI case review process is performed via monthly case review meetings for primary and elective PCI cases that meet the inclusion criteria. Additionally, if an area of improvement is identified by either internal or external peer review processes, quality assurance activities and improvements are undertaken by a multidisciplinary group, as necessary. FHH provided its policy for case reviews.

One example of FHH's quality improvement efforts is a change to allow EMS providers to directly activate a Code Heart alert if they identified a STEMI in the field, which resulted in a significant improvement in DTB times. FHH submitted meeting minutes from its CCL Operations meetings for December 2017 through February 2018, as well as minutes for meetings in September 2015 and November 2015 from the subgroup that planned this process change.

FHH has also focused on improving its performance on the metric for PCI risk adjusted bleeding. FHH notes that a thorough review of each case was completed, which revealed no documented bleeding but instead a drop in hemoglobin, which after review was found to reflect

many cases of hemodilution and not bleeding. A review of FHH's process led to changing the time of drawing the patient's hemoglobin to reflect the patient's status more accurately. FHH provided the CCL Operations meeting minutes from May 2015, August 2015, and September 2017 that discussed this change.

More recently, FHH submitted select meeting minutes from April 2018 through May 2023 that show the hospital has continued to take action in response to concerns identified through its quality assurance processes.

Staff Analysis and Conclusion

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

Patient Outcome Measures

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

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

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

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

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

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

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

(c) A hospital shall be subject to a focused review if it has a risk-adjusted mortality rate for non-STEMI PCI cases that exceeds an established benchmark beyond the 95 percent confidence interval calculated for the hospital's all-cause in-hospital risk-adjusted mortality rate for non-STEMI PCI cases.

- (i) The primary benchmark is the national median in-hospital risk-adjusted mortality rate for non-STEMI PCI cases calculated from the CathPCI Registry data; and*
- (ii) If the statewide median risk-adjusted mortality rate for elective PCI cases is obtained by the Commission within twelve months of the end of a reporting period, then the statewide median in-hospital risk-adjusted mortality rate for elective PCI cases will be used as a second benchmark.*

FHH submitted adjusted mortality by rolling 12-month reporting period for 2015 Q1 through 2023 Q3 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: FHH 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
2022q4-2023q3	*0.00	[0.00, 11.75]	*1.91	Yes	0.55	[0.01, 3.06]	2.02	Yes
2022q3-2023q2	*0.00	[0.00, 10.06]	*1.89	Yes	1.02	[0.12, 3.66]	2.02	Yes
2022q2-2023q1	*0.00	[0.00, 8.76]	*1.89	Yes	1.10	[0.13, 3.94]	2.05	Yes
2022q1-2022q4	*0.00	[0.00, 7.79]	*2.00	Yes	1.16	[0.14, 4.15]	2.14	Yes
2021q4-2022q3	*0.00	[0.00, 6.68]	*2.11	Yes	1.40	[0.17, 5.03]	2.20	Yes
2021q3-2022q2	*0.00	[0.00, 7.72]	*2.18	Yes	0.72	[0.02, 4.00]	2.26	Yes
2021q2-2022q1	*0.00	[0.00, 7.98]	*2.82	Yes	0.76	[0.02, 4.19]	2.25	Yes
2021q1-2021q4	*0.00	[0.00, 8.57]	*2.17	Yes	0.86	[0.02, 4.73]	2.23	Yes
2020q4-2021q3	*2.23	[0.06, 11.98]	*2.18	Yes	0.00	[0.00, 2.98]	2.23	Yes
2020q3-2021q2	7.46	[2.78, 15.61]	7.51	Yes	0.64	[0.02, 3.52]	1.18	Yes
2020q2-2021q1	6.56	[2.44, 13.73]	7.55	Yes	2.20	[0.46, 6.37]	1.21	Yes
2020q1-2020q4	5.17	[1.93, 10.86]	6.89	Yes	2.54	[0.94, 5.46]	1.13	Yes
2019q4-2020q3	4.57	[1.87, 9.09]	6.37	Yes	2.21	[0.89, 4.49]	1.06	Yes
2019q3-2020q2	4.45	[1.82, 8.82]	6.06	Yes	2.67	[1.08, 5.42]	1.00	No
2019q2-2020q1	4.86	[1.98, 9.65]	5.99	Yes	1.71	[0.63, 3.69]	0.95	Yes
2019q1-2019q4	6.05	[2.81, 11.06]	6.01	Yes	1.03	[0.21, 2.98]	0.95	Yes
2018q4-2019q3	7.33	[3.42, 13.36]	6.06	Yes	1.06	[0.13, 3.79]	0.98	Yes
2018q3-2019q2	6.74	[2.76, 13.37]	6.38	Yes	1.11	[0.30, 2.82]	1.00	Yes
2018q2-2019q1	7.92	[3.24, 15.66]	6.13	Yes	1.27	[0.26, 3.67]	0.99	Yes
2018q1-2018q4	6.54	[2.44, 13.67]	6.00	Yes	1.32	[0.36, 3.34]	1.00	Yes
2017q4-2018q3	6.64	[2.19, 14.89]	6.54	Yes	1.37	[0.37, 3.46]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC CathPCI Data Registry							
2017q2-2018q1	5.41	[1.49, 13.35]	6.91	Yes	0.55	[0.01, 3.06]	1.03	Yes
2017q1-2017q4	3.28	[0.40, 11.45]	6.86	Yes	0.65	[0.02, 3.60]	0.99	Yes
2016q4-2017q3	1.72	[0.04, 9.30]	6.75	Yes	0.80	[0.10, 2.85]	0.98	Yes
2016q3-2017q2	1.08	[0.03, 5.87]	6.64	Yes	0.76	[0.09, 2.72]	0.95	Yes
2016q2-2017q1	3.11	[0.86, 7.70]	6.77	Yes	0.66	[0.08, 2.36]	0.97	Yes

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

2016q1-2016q4	4.28	[1.60, 8.96]	6.82	Yes	0.34	[0.01, 1.88]	0.95	Yes
2015q4-2016q3	4.64	[2.17, 8.43]	6.71	Yes	NR	[0.00, 2.04]	0.95	Yes
2015q3-2016q2	5.24	[2.31, 9.92]	6.66	Yes	NR	[0.00, 2.22]	0.93	Yes
2015q2-2016q1	4.15	[1.54, 8.71]	6.45	Yes	NR	[0.00, 2.48]	0.90	Yes
2015q1-2015q4	3.56	[1.17, 8.04]	6.26	Yes	0.40	[0.01, 2.22]	0.90	Yes

*Source: MHCC staff compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and September 2022.

Notes: 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 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.

*Reporting on STEMI cases in the ACC-NCDR CathPCI reports changed beginning in the period ending 2021q3; for this period and later, the performance metric excludes cases with cardiogenic shock.

Staff Analysis and Conclusion

This standard is not applicable for the review periods that were included in FHH's Certificate of Ongoing Performance prior to CY 2019, 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 FHH's performance relative to the current standard over the period between January 2015 and September 2022.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's risk-adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period, except for the period 2019q3-2020q2 for non-STEMI cases. The national benchmark fell within the 95% confidence interval for FHH for all other 12-month reporting periods between January 2019 and September 2022. MHCC staff notes that FHH also would have met this standard if it had been applicable for the period from January 2015 through December 2018, for both STEMI and non-STEMI cases.

The hospital's statistically significantly worse than average performance on the mortality metric for non-STEMI cases triggered a focused review of non-STEMI patient deaths in the 12-month period ending June 2020. The focused review evaluated the quality of care provided and whether the hospital responded appropriately to issues identified. MHCC staff contracted with an organization to provide an independent review by a board certified interventionalist. A total of seven cases were reviewed. The reviewer provided his conclusions about the cases, an assessment of the hospital's own peer review of the cases, and recommendations.

The focused review report was provided to FHH on June 22, 2023. The hospital initially responded on June 29, 2023, requesting to meet with MHCC staff. MHCC staff and FHH met to discuss the focused review on August 4, 2023. The hospital explained the steps that it had taken previously, beginning in March 2020 that address a key concern identified in the focused review. Following the meeting, the hospital provided a formal written response to questions from MHCC staff that addressed all the recommendations from the focused review report. Commissioners should refer to Appendix 2. This information is confidential and protected by MHCC's status as a medical review committee.

Based on the hospital's acceptable performance on the mortality metric for STEMI cases since the period ending 2020 Q3, and the hospital already having taken action to address concerns identified in the focused review, MHCC staff recommends that the Commission find that FHH complies with this standard.

Physician Resources

10.24.17.07C(6)(a) and .07D(7)(a) Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24-month period. A hospital without on-site cardiac surgery shall track physicians' volume

on a rolling eight-quarter basis and report the results to the Commission on a quarterly basis.

FHH submitted information on the volume of primary and elective PCI cases at FHH and other hospitals, by physician and quarter, for the period for January 2015 through December 2022 for Drs. Hwang, Wang, Williams, Hasan, Czarny, Patel, and Rahman. 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 FHH in CY 2015 through CY 2022 and determined that each interventionalist performed at least 50 PCI procedures annually on average over the 24-month periods from January 2015 through December 2022, even in years when the standard was waived. The requirement to perform at least 50 PCI procedures annually average over a 24-month period was waived for 2020 and 2021, due to the COVID-19 pandemic.⁴

MHCC staff concludes that FHH complies with this standard.

10.24.17.07C(6)(b) and .07D(7)(b) For each physician who performs primary PCI at a hospital without on-site cardiac surgery and does not perform a minimum of 50 PCI procedures annually averaged over a 24-month period, for reasons other than a leave of absence, the hospital shall arrange for an external review of all the physician's cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to the Commission. A hospital may be required to develop a plan of correction based on the results of the physical evaluation.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to FHH because each physician performing primary PCI procedures at FHH 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*

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https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/documents/MHCC%20bulletin_cardiac_covid19_20200331.pdf

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

Staff Analysis and Conclusion

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

10.24.17.07C(6)(e) and .07D(7)(e) Each physician shall be board-certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or who completed training before 1998 and did not seek board certification before 2003 [for physicians who completed a fellowship in interventional cardiology less than three years ago].

10.24.17.07C(6)(f) and .07D(7)(f) Each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

FHH submitted a signed and dated statement from Drs. Hwang and Wang, co-medical directors of Interventional Cardiology, acknowledging that all physicians performing primary PCI services at FHH are board certified in interventional cardiology.

Staff Analysis and Conclusion

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

10.24.17.07C(6)(g) and .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.

FHH submitted signed and dated attestations from Drs. Wang, Hwang, Williams, Patel, Hasan, and Czarny stating that each 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 FHH meets this standard.

10.24.17.07C(6)(h) and .07D(7)(h) Each physician who performs primary PCI agrees to participate in an on-call schedule.

FHH submitted a signed statement from the Co-Medical Directors for Interventional Cardiology, 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. FHH also submitted a

copy of its on-call schedule for July 2019, August 2019, and February 2024. One physician, Dr. Hasan, was not on the August schedule due to vacation, but was on-call on July 25, 2019.

Staff Analysis and Conclusion

Staff examined the on-call schedules for July 2019, August 2019, and February 2024 and observed that all the practicing physicians were all scheduled to be on-call at different times during the month. MHCC staff observed that Dr. Hasan did not appear on the August 2019 on-call schedule submitted, but as noted above, FHH stated that the physician was on vacation.

MHCC staff concludes that FHH 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.

FHH provided PCI volume information for CY 2015 through CY 2022, as shown in Table 7. This information shows that FHH performed between 383 and 465 cases annually.

Table 7: FHH Total PCI Volume, CY 2015 - CY 2022

Calendar Year	Total PCI
2015	407
2016	393
2017	383
2018	418
2019	465
2020	420
2021	401
2022	403

Source: FHH application for Certificate of Ongoing Performance 2019, and supplemental response to Q28 (2023).

Staff Analysis and Conclusion

MHCC staff reviewed the PCI volume information submitted by FHH and determined at least 200 PCI procedures were completed per year between CY 2015 and CY 2022.

MHCC staff concludes that FHH 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.

FHH responds that this standard does not apply to the hospital.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2022. This analysis shows primary PCI volume ranged from 87 to 137 cases each calendar year (Table 8) and confirms that FHH exceeded the threshold of 49 cases annually referenced in the standard.

Table 8: FHH Primary PCI Volume, CY 2015 - CY 2022

Calendar Year	Primary PCI Volume
2015	125
2016	91
2017	87
2018	109
2019	137
2020	125
2021	100
2022	98

Source: MHCC staff analysis of ACC-NCDR CathPCI registry data CY 2015 – CY 2022.

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

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

FHH provided the number of primary PCI cases by interventionalist for CY 2015 through CY 2022.

Staff Analysis and Conclusion

MHCC staff reviewed the primary PCI case volume information submitted by FHH and analyzed the ACC-NCDR CathPCI registry. This analysis shows that between January 2015 and December 2022, at least 11 primary PCI procedures were completed per year for each interventionalist. Staff’s analysis of the data in the ACC-NCDR CathPCI confirms that all the interventionalists performed at least 11 primary PCI procedures.

MHCC staff finds that FHH complies with this standard.

Patient Selection

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

FHH submitted a letter signed by Co-Medical Directors, Dr. Hwang and Dr. Wang, that attested that to the best of their knowledge, no patient selection was deemed inappropriate for elective PCI services.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports from January 2015 through June 2023 and determined that there were no cases between January 2015 and June 2023 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.

MHCC staff concludes that FHH complies with this standard.

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

- (a) Patients described as appropriate for primary PCI in Expert Guidelines.***
- (b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) reasonable concludes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.***
- (c) Patients for whom primary PCI services were not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.***
- (d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) reasonably concludes that transfer to a tertiary institution may be harmful for the patient.***

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

Staff Analysis and Conclusion

MHCC staff analysis of the ACC-NCDR Cath PCI data for CY 2015 through CY 2021 is consistent with the information reported by the applicant. MHCC staff determines that FHH complies with this standard.

RECOMMENDATION

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

Appendix 1: FHH CCL Downtime, January 2015 through July 2023

Date	Time	Duration	Location	Detail
1/15/2015	12:00 AM	4 hrs	Room 2	Planned 6-month maintenance
2/19/2015	2:00 PM	4 hrs	Room 1	Planned 6-month maintenance
6/18/2015	8:00 AM	3 hrs	Room 2	Planned 6-month maintenance
8/21/2015	8:00 AM	4 hrs	Room 1	Planned 6-month maintenance
1/15/2016	8:00 AM	4 hrs	Room 2	Planned 6-month maintenance
2/3/2016	8:00 AM	4 hrs	Room 1	Planned 6-month maintenance
4/11/2016	10:00 AM	3.5 hrs	Room 2	Repair – chiller pump failure
5/19/2016	12:00 AM	1 hr	Room 2	Maintenance – replace footswitch
5/31/2016	11:30 AM	24.25 hrs	Room 1	Repair – chiller pump failure
7/6/2016	10:00 AM	1 hr	Room 2	Maintenance – replace footswitch
7/15/2016	8:00 AM	4 hrs	Room 2	Planned 6-month maintenance
9/15/2016	8:00 AM	4.5 hrs	Room 1	Planned 6-month maintenance
1/17/2017	8:00 AM	4 hrs	Room 2	Calibration/Testing
2/23/17	8:00 AM	4.25 hrs	Room 1	Planned 6-month maintenance
5/19/17-8/11/2017	N/A	N/A	Room 2	FD10 Installation
8/24/2017	8:00 AM	3.75 hrs	Room 1	Planned 6-month maintenance
1/3/2018	4:15 PM	0.75 hr	Room 2	Maintenance – Field change order
2/22/2018	4:00 PM	3 hrs	Room 1	Planned 6-month maintenance
2/23/2018	5:30 PM	2 hrs	Room 2	Maintenance – Hardware upgrade
2/26/2018	3:30 PM	2 hrs	Room 1	Maintenance – Hardware upgrade
3/15/2018	8:30 AM	5 hrs	Room 2	Preventative maintenance
5/1/2018	11:00 AM	4 hrs	Room 2	Corrective maintenance – networking/archiving
5/30/2018	8:00 AM	3.25 hrs	Room 2	Corrective maintenance – touch screen monitor repair/replace
6/21/2018	3:00 PM	24 hrs	Room 1	HVAC repair
6/21/2018	3:00 PM	24 hrs	Room 2	HVAC repair
8/22/2018	8:30 AM	1.25 hrs	Room 2	Corrective maintenance – Foot pedal connection repair
8/27/2018	8:00 AM	4 hrs	Room 1	Planned 6-month maintenance
8/30/2018	7:00 AM	29 hrs	Room 1	Repair – Chiller cooling off-line
9/13/2018	7:45 AM	6.5 hrs	Room 2	Preventative maintenance
9/14/2018	12:15 PM	3 hrs	Room 2	Power supply interruption
10/1/2018	5:00 AM	1.5 hrs	Room 2	Radiation safety survey
10/1/2018	8:30 AM	1.5 hrs	Room 1	Radiation safety survey
11/21/2018	4:30 PM	3.5 hrs	Room 1	Repair – Chiller failure
2/19/2019	8:00 AM	3.5 hrs	Room 1	Planned 6-month maintenance
3/5/2019	8:45 AM	4 hrs	Room 2	Preventative maintenance
4/8/2019	12:00 AM	22 hrs	Room 1	Repair – MacLab boot error
5/17/2019	6:00 PM	2 hrs	Room 1	PDM Hardware Install
5/17/2019	8:00 PM	2 hrs	Room 2	PDM Hardware Install
8/22/2019	1:00 PM	4 hrs	Room 1	Planned 6-month maintenance
9/16/2019	7:00 AM	5 hrs	Room 2	Preventative maintenance
2/7/2020	8:00 AM	8 hrs	Room 1	Hardware/software upgrade
2/8/2020	8:00 AM	8 hrs	Room 2	Hardware/software upgrade
2/10/2020	3:00 PM	2.5 hrs	Room 1	Repair – Disk error
2/24/2020	5:00 PM	3 hrs	Room 1	Planned 6-month maintenance
3/24/2020	1:00 PM	5 hrs	Room 2	Preventative maintenance
8/17/2020	9:00 AM	28 hrs	Room 1	Repair – cooling failure
8/27/2020	5:30 PM	4 hrs	Room 1	Planned 6-month maintenance
9/1/2020	12:00 PM	3.5 hrs	Room 1	Repair – Image drive
9/30/2020	1:00 PM	5 hrs	Room 2	Preventative maintenance

2/17/2021	5:00 PM	4 hrs	Room 1	Planned 6-month maintenance
3/11/2021	11:30 AM	6 hrs	Room 2	Preventative maintenance
8/27/2021	11:00 AM	3 hrs	Room 1	Planned 6-month maintenance
9/30/2021	5:45 PM	4.75 hrs	Room 2	Preventative maintenance
1/17/2022	12:45 PM	3.5 hrs	Room 2	Maintenance – DICOM worklist configuration
2/1/2022	4:30 PM	3 hrs	Room 1	Planned 6-month maintenance
3/10/2022	9:45 AM	6.25 hrs	Room 2	Preventative maintenance
5/17/2022	7:00 AM	3 hrs	Room 1	HVAC repair
8/18/2022	2:00 PM	4 hrs	Room 1	Planned 6-month maintenance
9/30/2022	4:30 PM	--	Room 1	Room permanently closed/moved to 3 rd floor
10/4/2022	9:15 AM	6.5 hrs	Room 2	Preventative maintenance
10/6/2022	10:00 AM	--	Room 2	Room permanently closed/moved to 3 rd floor
10/28/2022	8:00 AM	0.25 hr	Room 3	Maintenance – Intercom microphone replaced
10/28/2022	2:00 PM	3.5 hrs	Room 2	Maintenance – Flex spot monitor repair
10/28/2022	9:15 AM	5 hrs	Room 2	Maintenance – Reformat of TSM
10/31/2022	10:15 AM	2 hrs	Room 2	Maintenance – Reformat of TSM
10/31/2022	10:15 AM	2.75 hrs	Room 2	Repair – Control room acquisition display not centered
3/2/2023	9:00 AM	3 hrs	Room 1	Maintenance – footswitch replaced
3/7/2023	9:00 AM	5 hrs	Room 1	Preventative maintenance
3/14/2023	10:00 AM	5 hrs	Room 2	Preventative maintenance
5/17/2023	9:30 AM	6 hrs	Room 3	Preventative maintenance
6/26/2023	6:30 PM	3.5 hrs	Room 1	Maintenance – intercom installation
6/27/2023	6:00 PM	2.5 hrs	Room 3	Maintenance – intercom installation
7/10/2023	5:30 PM	4 hrs	Room 2	Maintenance – intercom installation

Source: FHH's application for Certificate of Ongoing Performance 2019 and updated information received for Q2.