IN THE MATTER OF	*	**BEFORE THE**
MEDSTAR FRANKLIN	*	**MARYLAND**
SQUARE	*	**HEALTH CARE**
MEDICAL CENTER	*	**COMMISSION**
Docket No.: 19-03-CP014	*	

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STAFF REPORT AND RECOMMENDATION

CERTIFICATE OF ONGOING PERFORMANCE FOR PRIMARY PERCUTANEOUS CORONARY INTERVENTION SERVICES

July 16, 2020

I. INTRODUCTION

A. Background

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

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

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

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

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

elective (nonprimary) PCI services, for a period specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must demonstrate that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide PCI services.

B. Applicant

MedStar Franklin Square Medical Center

MedStar Franklin Square Medical Center (Franklin Square) is a 338-bed general hospital located in Baltimore (Baltimore County). Franklin Square is part of MedStar Health and does not have a cardiac surgery program on site.

Franklin Square began providing primary PCI services under a research waiver in May 2003 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. Franklin Square last applied for a primary PCI waiver in February 2013, and the two-year waiver was granted by MHCC on May 16, 2013. Currently, Franklin Square provides primary PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. JHBMC is in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties and Baltimore City. Fourteen hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; all the other programs provide both primary and elective PCI services. Five of the fourteen hospitals also provide cardiac surgery services, and one additional hospital in this region has a Certificate of Need to establish a cardiac surgery program.

C. Staff Recommendation

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

II. PRODEDURAL HISTORY

Franklin Square filed a Certificate of Ongoing Performance application on March 22, 2019, in accordance with the review schedule determined by the Commission. MHCC staff reviewed the application and requested additional information on October 28, 2019, April 15, 2020, June 24, 2020, July 6, 2020, and July 7, 2020. Additional information was submitted on November 15, 2019, May 4, 2020, July 2, 2020, July 7, 2020, and July 9, 2020.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

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

Franklin Square stated that there were no deficiencies in data collection or reporting identified by MHCC staff. There is one nurse that is the team leader for the ACC-NCDR registry. She attends the ACC-NCDR conference, quarterly State data manager meetings for PCI services, and an annual meeting for the ACC-NCDR ACTION registry[1] to maintain her competency.

Staff Analysis and Conclusion

Franklin Square has complied with the required submission of ACC 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. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of Franklin Square's data reported during the audit period.

MHCC staff concludes that Franklin Square 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.

Franklin Square reported that there is one interventional cardiac room that was replaced in 2017. During downtimes for maintenance or other reasons, including when the interventional cardiac room was replaced in 2017, Franklin Square utilizes a cardiovascular hybrid operating room. Franklin Square explained that this arrangement results in almost zero downtime for the CCL. Franklin Square submitted work order logs from March 2015 through August 2018 for the cardiac catheterization laboratory (CCL). Franklin Square stated that the hybrid operating room, which is used as a backup for the CCL, was unavailable for patients only three times between January 2015 and December 2018. There was one time in 2016 when a patient was diverted because PCI services were not available due to downtime for maintenance in the hybrid operating room. In 2016, there were also two other patients who were transferred because the hybrid

[1] The ACC-NCDR ACTION registry was renamed to be the Chest Pain- MI registry in 2018.

operating room was already in use for another patient. As shown in Table 1, there were two times in 2017 when the need for repairs resulted in downtime of the CCL; Franklin Square reported that patient care was not affected on either date.

Table 1: Franklin Square CCL Closures

Date	Duration of Closure	Reason/Explanation
3/16/2017	3 days	CCL Service
11/8/2017	2 hours	CCL Equipment

Source: Franklin Square Application, Updated Q2

Staff Analysis and Conclusion

MHCC Staff reviewed the log of work orders submitted and asked additional clarifying questions. Franklin Square explained that the reason for closure for three days during March 2017 was that a part for essential equipment in the CCL had to be ordered and it was slow to arrive, so the process of diagnosing and fixing the issues spanned three days.

MHCC staff concludes that Franklin Square 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.

In its initial application, Franklin Square provided a signed statement from Samuel E. Moskowitz, FACHE, President, acknowledging that Franklin Square is committed to providing primary PCI service as soon as possible and not exceeding 90 minutes from the patient arrival at the hospital for at least 75% of appropriate cases. Subsequently, Franklin Square provided a statement from the current President, Stuart M. Levine, M.D. Additionally, Franklin Square provided quarterly percentages of non-transfer patients who received PCI within 90 minutes and median door-to-balloon (DTB) times for 2015 through June 2019 according to data gathered from the ACC-NCDR CathPCI registry. Franklin Square reported that they are committed to improving DTB times for transfer patients. However, for the requested reporting period, Franklin Square did not receive any transfers from other acute care facilities.

Table 2: Franklin Square Reported Compliance With DTB Benchmark and Median DTB by Quarter, January 2015 to June 2019

Quarter	Non-Transfer Cases			
	PCI w/in 90 min	Total PCI	% 90 minutes or less	Median DTB (minutes)
CY2015 Q1	22	25	88.0%	56
CY2015 Q2	24	30	80.0%	57
CY2015 Q3	19	19	100.0%	61
CY2015 Q4	18	20	90.0%	55
CY2016 Q1	21	24	87.5%	59
CY2016 Q2	26	28	92.8%	60
CY2016 Q3	19	21	90.4%	65
CY2016 Q4	12	12	100.0%	62
CY2017 Q1	28	29	96.5%	58
CY2017 Q2	20	22	90.9%	65
CY2017 Q3	18	18	100.0%	57
CY2017 Q4	23	24	95.8%	58
CY2018 Q1	16	17	94.1%	65
CY2018 Q2	12	13	92.3%	55
CY2018 Q3	30	31	96.9%	67
CY2018 Q4	19	19	100.0%	63
CY2019 Q1	16	17	94.1%	Not provided
CY2019 Q2	12	13	92.3%	Not provided

Source: Franklin Square Application, Q4, updated Q4

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR data and concluded that Franklin Square met the door-to-balloon time standard in all but two quarters, as shown in Table 3. MHCC staff's analysis differs from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, and MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods that include multiple quarters. Over rolling eight quarter periods, Franklin Square complied with this standard, with between 83% and 8% of PCI cases meeting the door-to-balloon time standard, as shown in Table 3.

MHCC staff concludes that Franklin Square complies with this standard.

Table 3: Franklin Square 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	28	23	82.1%			
2015q2	35	25	71.4%			
2015q3	21	21	100.0%			
2015q4	21	17	81.0%			
2016q1	26	22	84.6%			
2016q2	29	25	86.2%			
2016q3	22	19	86.4%			
2016q4	15	12	80.0%	197	164	83%
2017q1	31	28	90.3%	200	169	85%
2017q2	23	18	78.3%	188	162	86%
2017q3	21	18	85.7%	188	159	85%
2017q4	25	23	92.0%	192	165	86%
2018q1	20	16	80.0%	186	159	85%
2018q2	18	13	72.2%	175	147	84%
2018q3	37	30	81.1%	190	158	83%
2018q4	21	19	90.5%	196	165	84%

Source: MHCC staff analysis of ACC-NCDR CathPCI registry data, CY 2015- CY 2018.
Note: Calculations for each quarter are based on the procedure date.

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

Franklin Square provided the number of physicians, nurses, and technicians who can provide cardiac catheterization services to acute myocardial infarction patients as of March 15, 2019.

Table 4: Total Number or Full-Time Equivalent (FTE) CCL, Physician, Nursing, and Technical Staff

Staff Category	Number/FTEs	Cross Training (S/C/M)
Physician	5	Interventional Cardiologist
Nurse	5.5	C, M
Technician	4.0	S, M, C

Source: Franklin Square Application, updated Q6a (Table 3)
*Scrub (S), circulate (C), monitor (M)

Staff Analysis and Conclusion

MHCC staff compared the staff levels described by Franklin Square to information reported in Franklin Square's application for renewal of its waiver for primary PCI services in 2013. The hospital reported that on February 4, 2013, there were 5.1 nursing FTEs, 5.8 technician FTEs, and six physicians. Franklin Square reports that its volume of primary PCI cases in 2012 was 91 cases.

MHCC staff also compared the staffing level reported by Franklin Square to another existing program with only a primary PCI program, until recently, Howard County General Hospital (HCGH). HCGH, in its Certificate of Ongoing Performance application, reported having six nurse FTEs, four technician FTEs, and eight interventionalists. HCGH also stated that an additional two nurse FTEs and two technician FTEs are sometimes used, if needed. The primary PCI volume reported by HCGH for 2018 was 122 cases.

MHCC staff concludes that there is adequate nursing and technical staff to provide services; Franklin Square meets this standard.

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

In its initial application, Franklin Square provided a signed letter of commitment from Samuel E. Moskowitz, FACHE, President, acknowledging that Franklin Square will provide primary PCI services in accord with the requirements established by the Commission. In his letter, Mr. Moskowitz stated that MedStar Health and MedStar Health's Board of Directors support the program and agree to continue to resource it appropriately and maintain outcomes as required by MHCC. Subsequently, Franklins Square provided a second letter of commitment from the current President, Stuart M. Levine, M.D.

Staff Analysis and Conclusion

MHCC staff concludes that Franklin Square 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.

Franklin Square described that, as a site that does not provide elective PCI, a full-time employee is not required for data management. The data are currently extracted by a CCL nurse who is well trained. Franklin Square states that this nurse dedicates 0.1 FTEs to data collection efforts.

Staff Analysis and Conclusion

The number of FTEs reported by Franklin Square in response to this standard was for specifically data collection, rather than the broader tasks of data management, reporting, and

coordination. Franklin Square reported a much lower number of FTEs as compared to HCGH, in its Certificate of Ongoing Performance application, which was .8 FTEs. However, Franklin Square's response reflects a much narrower set of responsibilities, only data collection.

MHCC staff concludes that Franklin Square is compliant with this standard.

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

Dr. Shahid Saeed, interventional cardiologist, was appointed at the Director of the CCL at Franklin Square in 2004. Franklin Square provided a copy of the job description for the Director of CCL and Interventional Cardiology. The Director provides medical leadership for the CCL and interventional cardiology, assures the quality and appropriate need of patient care, monitors clinical outcomes and makes appropriate changes as necessary, oversees quality improvement activities, monitors patient satisfaction, attends Cardiology Section and CCL staff meetings, ensures 24/7 primary PCI cardiologist coverage, and supports administration and staff in maintaining compliance with standards.

Staff Analysis and Conclusion

MHCC staff concludes that Franklin Square is compliant with this standard.

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

Franklin Square provided a list of the continuing educational programs for staff for the period between January 2015 and December 2018. All MedStar employees complete annual e-learning modules (e.g. Fire and Safety, Hand Washing). Nurses have specific nursing modules that must be completed, and the CCL has individualized clinical conferences and e-learning requirements.

Franklin Square also stated that all registered nurses are required to complete 15 continuing educational units per year. Technologists are required to meet the requirements of the American Registry of Radiologic Technologists and the requirements of the State of Maryland for continuing education credits. The State of Maryland requires 24 continuing education credits over a two-year period for technologists. Finally, interventionalists are required to meet the State of Maryland requirements for licensure, which include 50 CME credits over a two-year period. MedStar Health utilizes a web-based continuing education portal called Cloud CME. This portal allows for tracking of all MedStar Health conferences and learning opportunities. The manager of the unit monitors nurse CEUs, and the CEUs for technologists and physicians are monitored via their licensing boards.

Staff Analysis and Conclusion

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

MHCC staff concludes that Franklin Square meets this requirement.

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 PCl, for hospitals performing primary PCI without on-site cardiac surgery.

Samuel Moskowitz, FACHE, President, signed and dated an agreement with MedStar Union Memorial Hospital, a tertiary care center, for the unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI. This agreement remains in place, although the current President for Franklin Square is Stuart M. Levine, M.D.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that Franklin Square 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.

Cheryl Lunnen, RN, Vice President, MedStar Union Memorial, signed and dated an agreement with Procare Ambulance of Maryland Inc. (Procare) that covers transportation to Franklin Square. The agreement described that for emergent transport requests, Procare is required to arrive at the sending facility for pick-up within 30 minutes or less, except to Maryland hospitals over 20 miles from Procare's office.

Staff Analysis and Conclusion

MHCC reviewed the agreement and noted an on-time performance goal and penalty included in the agreement. Specifically, Procare shall meet an on-time performance goal of 90% or greater for all transfers. Staff determined that this is allowable, as the performance goal does not negate the requirement for transport within 30 minutes for emergency transport request.

Franklin Square complies with this standard.

Quality

10.24.17.07D(5)(a) The hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists

and other physicians, nurses, and technicians who care for primary PCI patients.

Franklin Square provided attendance records for 2015 through 2019. Franklin Square also submitted a sample form that is completed at each meeting.

Staff Analysis and Conclusion

Franklin Square schedules monthly peer case review meetings and few meetings have been canceled. Twelve meetings were held in 2015, 2016, and 2018. In 2017, one meeting was cancelled and many of the cases (12 out of 15) were reviewed in the following month. In 2019, one meeting was cancelled, and all cases were reviewed in the following month.

MHCC staff concludes that Franklin Square complies with this standard.

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

Franklin Square submitted attendance records for January 2015 through December 2019 for the monthly Primary Angioplasty Multi-Disciplinary Committee, when available. Franklin Square reported that two meetings were canceled in 2015, one meeting was cancelled in 2016, one meeting was cancelled in 2018, and three meetings were cancelled in 2019. Franklin Square also submitted attendance records for the Cardiology Service Line Meetings for 2015 through January 2019; attendance records were submitted for six meetings in 2015, ten meetings in 2016, eight in 2017, eight in 2018, and one in 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation provided and concluded that Franklin Square is holding meetings of a multiple care area group monthly with only rare exceptions.

MHCC staff recommends that the Commission find that Franklin Square 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.

Franklin Square submitted copies of the external review reports for January 2015 through June 2019. The external reviews were completed by the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ), which has been approved by MHCC as an external review organization that meets the requirements in COMAR 10.24.17 for conducting external reviews of PCI cases.

Franklin Square also explained that five STEMI cases are randomly selected for review on a monthly basis, and the analyst who selects the cases monitors the number of case pulled to ensure that the requirements for review of individual interventionalists are met. Franklin Square reported that this approach results in review of approximately 50% of the total case volume for the program. In addition, the same physicians that provide primary PCI services at Franklin Square also provide elective PCI services at MedStar Union Memorial Hospital and tracking is done by this hospital to assure that the MHCC requirement is met.

Staff Analysis and Conclusion

MHCC staff reviewed the MACPAQ reports and the description of internal case review for individual interventionalists. The MACPAQ reports indicate that usually only one or two cases are reviewed in each review cycle, as shown in Table 5. However, through the additional internal review of cases described by Franklin Square, the hospital is reviewing at least ten cases per interventionalist or 10% of cases.

MHCC staff concludes that Franklin Square complies with this standard.

Table 5: Range of Case Volume at Franklin Square and Percentage of Cases Reviewed Externally for Each Interventionalist, by Review Period

Review Period	Range for Each Individual Interventionalist		
	Primary PCI Volume	Percentage of Cases Reviewed	Number of Cases Reviewed
11/2014-8/2015	4-47 cases	unknown	[0,3]
9/2015-12/2015	2-9 cases	unknown	[1,2]
2016 Q1Q2	5-24 cases	8%-20%	[1,2]
2016 Q3Q4	3-21 cases	10%-33%	[1,2]
2017 Q1Q2	5-21 cases	10%-20%	[1,2]
2017 Q3Q4	5-16 cases	6%-20%	[1]
2018 Q1Q2	3-20 cases	5%-33%	[1]
2018 Q3Q4	9-21 cases	5%-11%	[1]

Source: MHCC staff analysis of MACPAQ reports provided by Franklin Square and ACC-NCDR CathPCI data for CY 2014- CY 2018.

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.

Franklin Square submitted an affidavit from Dr. Shahid Saeed, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, and quarterly interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff concludes that Franklin Square 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.

Franklin Square submitted meeting minutes and provided information about on-going performance improvement initiatives that are reported to the Hospital Quality Council. In addition, initiatives to improve DTB times include, activating off of LifeNet, working with the Emergency Department to ensure that a patient is ready to transport within 30 minutes of activation of the CCL team, and having the transition transport team start in the Emergency Department. Another quality initiative has been to decrease bleeding by transitioning from a femoral approach to a radial approach.

Staff Analysis and Conclusion

MHCC staff reviewed quality assurance activities described by Franklin Square and the meeting minutes submitted; MHCC staff concludes that Franklin Square complies with this standard.

Patient Outcome Measures

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.

© 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.

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

	STEMI			
Reporting Period	**Hospital AMR**	**95% CI**	**National AMR**	**Meets MHCC Standard**
2018q3-2019q2	8.00	[3.02, 16.32]	6.38	Yes
2018q2-2019q1	8.18	[3.37, 15.93]	6.13	Yes
2018q1-2018q4	7.97	[3.52, 14.96]	6.00	Yes
2017q4-2018q3	7.08	[2.64, 14.80]	6.54	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry			
2017q2-2018q1	7.92	[1.65, 22.32]	6.91	Yes
2017q1-2017q4	9.95	[2.07, 28.16]	6.86	Yes
2016q4-2017q3	12.87	[3.55, 31.77]	6.75	Yes
2016q3-2017q2	9.16	[3.04, 20.16]	6.64	Yes
2016q2-2017q3	11.48	[5.65, 20.07]	6.77	Yes
2016q1-2017q4	10.95	[5.39, 19.13]	6.82	Yes
2015q4-2016q3	11.13	[5.47, 19.52]	6.71	Yes
2015q3-2016q2	14.65	[6.85, 26.57]	6.66	**No**
2015q2-2016q1	13.07	[4.30, 29.39]	6.45	Yes
2015q1-2015q4	16.75	[7.38, 31.52]	6.26	**No**

Source: MHCC Staff compilation of results from the hospital's quarterly reports form the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between January 2015 and June 2019.

Notes: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) included the National AMR or indicated statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or Non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI or non-STEMI cases, as applicable.

Staff Analysis and Conclusion

This standard is not applicable for the majority of the review period of Franklin Square's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. The previous standard only 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 on how Franklin Square performed over the period between January 2015 and June 2019, as shown in Table 6.

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 statistically significantly worse than the national benchmark in two reporting periods because the national benchmark fell outside of the 95% confidence interval for Franklin Square. However, staff also notes that this last occurred for the reporting period ending June 2016. Franklin Square's performance over the subsequent three years was not statistically different than the national benchmark. A report for the hospital's performance for the period ending December 2019, will be the first period for which the current standard applies.

Physician Resources

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

For each physician who performs PCI at Franklin Square, the hospital submitted the volume of primary PCI cases at Franklin Square as well as primary and elective cases at other hospitals by quarter from 2015 through the end of 2018. Drs. Saeed, Peichert, Wang, Kaliyadan, and Siddiqi signed and dated affidavits affirming under penalties of perjury that the information provided on PCI case volume is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

Staff determined that the interventionalists, who currently perform PCI procedures at Franklin Square, performed at least 50 PCI procedures on average for each of two 24-month periods between 2015 and 2018. For an inteventionalist who performed less than 50 procedures in 2015 and who did not provide PCI services at Franklin Square in subsequent years, staff calculated the physician's average PCI case volume for 2014 and 2015. The physician's volume was over 50 PCI procedures annually on average.

Franklin Square 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.

This regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to Franklin Square. While Franklin Square does not have on-site cardiac surgery each physician performing primary PCI performed 50 PCI procedures annually averages over a 24 month period.

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

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

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

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

Franklin Square responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to Franklin Square. While Franklin Square lacks on-site cardiac surgery, each physician who performs primary PCI at Franklin Square performed at least 50 PCI procedures annually on average, over a 24 month period.

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

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

Franklin Square submitted a signed and dated statement from Dr. Shahid Saeed, Director of CCL, acknowledging that all physicians performing primary PCI services at Franklin Square (i.e. Drs. Wang, Siddiqi, Kaliyadan, and Saeed) are board certified in interventional cardiology, with the exception of Dr. Peichert. Dr. Peichert is exempt from this requirement because he

completed his training prior to 1998 and did not seek board certification before 2003. Franklin Square reported that he has a lifetime PCI case volume of over 500 cases, and he is board certified in Internal Medicine and Cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the letter provided and concludes that Franklin Square meets these standards.

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.

Franklin Square submitted signed and dated attestations from Drs. Saeed, Peichert, Wang, Kaliyadan, and Siddiqi stating each physician completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

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

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

Franklin Square submitted a signed statement from the Director of the CCL, Dr. Shahid Saeed, acknowledging that each physician who has performed primary PCI services during the performance review period (January 2015 through December 2017) participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. Franklin Square also submitted a copy of the on-call schedule for October 2017.

Staff Analysis and Conclusion

Staff examined the on-call schedule for October 2017 and observed that Drs. Saeed, Wang, Peichart, Siddiqi, and Kaliyadan were all scheduled to be on-call at different times during the month.

MHCC staff concludes that Franklin Square meets this standard.

Volume

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: Franklin Square PCI Volume, CY 2015 - CY 2019

Calendar Year	Primary PCI Volume
2015	83
2016	78
2017	89
2018	77
2019	99

Source: MHCC Analysis of Franklin Square Application, updated Q28

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2018. This analysis is consistent with the volume reported by Franklin Square, and it confirms that Franklin Square exceeded the threshold of 49 cases annually referenced in the standard.

MHCC staff concludes that this standard is not applicable for Franklin Square.

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

Franklin Square provided the number of primary PCI cases by interventionalist from January 2015 to December 2018. This information shows that between July 2014 and December 2018, each interventionalist performed at least 11 primary PCI procedures annually.

Staff Analysis and Conclusion

Staff analyzed the data in the ACC-NCDR CathPCI registry for the period CY 2015 to CY 2018 and concluded that each interventionalist met the target of 11 or more primary PCI cases annually.

MHCC staff concludes that Franklin Square meets 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.

Franklin Square stated that all cases in the ACC-NCDR CathPCI Registry PCI included in the metric for Appropriate Use Criteria (AUC) for reports from 2013-2018 Q2 were reviewed. The internal and external review of primary PCI cases found that no patients received primary PCI services inappropriately. Franklin Square also reported that no PCI patients received thrombolytic therapy that subsequently failed during the review period.

Staff Analysis and Conclusions

MHCC staff reviewed the external review reports from January 2015 through June 2019 and concludes that Franklin Square meets this standard.

RECOMMENDATION

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