IN THE MATTER OF	*	
	*	
ESTABLISHMENT OF ELECTIVE	*	
	*	**BEFORE THE**
PERCUTANEOUS CORONARY	*	
	*	
INTERVENTION SERVICES BY	*	
	*	**MARYLAND HEALTH**
MEDSTAR FRANKLIN SQUARE	*	
	*	
MEDICAL CENTER	*	
	*	**CARE COMMISSION**
DOCKET NO. 21-03-CC033	*	
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Staff Report and Recommendation

April 21, 2022

I. INTRODUCTION

On July 21, 2021, MedStar Franklin Square Medical Center (Franklin Square) submitted a Certificate of Conformance application to establish elective percutaneous coronary intervention (PCI) services. Following a description of the background on regulation of primary and elective PCI services in Maryland, staff presents analysis and recommendations regarding Franklin Square's compliance with the standards for obtaining a Certificate of Conformance.

A. Background

In 2012, Maryland established a new regulatory model for PCI and cardiac surgery services. PCI is a procedure whereby a catheter is inserted in a blood vessel and guided to the site of a partially or fully blocked coronary artery to relieve narrowing of the artery and includes rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents, and other catheter devices for treatment of coronary atherosclerosis.

Under the 2012 law, PCI became a service explicitly regulated by the Maryland Health Care Commission (MHCC or Commission), rather than indirectly regulated through regulation of "open heart surgery." Establishment of new PCI programs are now considered through a process called Certificate of Conformance review, with all providers of PCI services now subject to revalidation and authorization through periodic on-going performance reviews.

Two categories of PCI programs are addressed in the Certificate of Conformance regulations found in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Coronary Intervention Services chapter (Cardiac Services Chapter) of the State Health Plan: (1) emergency, or primary, PCI programs, that provide only emergent PCI intervention in a heart attack shortly after it begins, and; (2) programs that provide both emergency/primary PCI services and elective/non-primary PCI services. Elective PCI is non-emergent and involves intervention to revascularize coronary arteries that are substantially blocked but have not resulted in an immediate cardiac event requiring emergency treatment.

Most PCI cases in Maryland are performed in the eleven hospitals that provide cardiac surgery and both types of PCI services. However, in the last two decades, research studies have shown that both emergency and elective PCI services can be provided in hospitals without on-site cardiac surgery and achieve levels of patient safety, with respect to mortality and complication rates, comparable to the performance achieved in cardiac surgery hospitals. The initial research study, in which Maryland hospitals participated, showed that in hospitals without cardiac surgery on site (SOS), the provision of primary PCI to certain heart attack patients provided better outcomes than thrombolytic therapy, which previously had been standard care for heart attack patients in non-SOS hospitals. For this reason, the Commission permitted non-SOS hospitals that could meet certain volume and quality standards to provide primary PCI services. Ultimately, 13 such programs were established, more than doubling the number of Maryland sites at which primary PCI can be performed, with the benefit of enabling better emergency interventions to occur more quickly following the onset of a heart attack. Early intervention is a critical factor in

preserving life and minimizing the damage to heart muscle, improving the recovery potential for the patient.

More recently, the changing science in heart disease treatment showed that the provision of elective PCI in non-SOS hospitals was not inferior to the provision of elective PCI in hospitals with cardiac surgery on-site. As a result, the Commission granted authority to provide elective PCI services to eight of the 13 non-SOS hospitals that were providing primary PCI. The potential benefit of allowing a hospital with only primary PCI services to provide elective PCI programming is that a more active program with more PCI cases may support the sustainability of the hospital's provision of needed primary PCI services, a life-saving procedure. These eight hospitals all experienced a regulated and monitored sequence of first operating their elective PCI programs as research "waiver"[1] hospitals, graduating to "registry waiver"[2] status at the conclusion of the active research phase and now, through the 2012 legislation and resulting MHCC action, are regular clinical providers of both primary and elective PCI, subject to on-going performance reviews by MHCC. Additional background on the evolution of PCI regulation in Maryland can be found in Section .02 of the Cardiac Services Chapter, which can be accessed through the following link: http://www.dsd.state.md.us/artwork/10241701.pdf.

Two Maryland hospitals are currently authorized to only provide emergency PCI services. These hospitals are MedStar Franklin Square Medical Center and Holy Cross Hospital in Germantown. Howard County General Hospital is the hospital that last was granted a Certificate of Conformance (April 2020) to add elective PCI services to its established primary PCI program.

B. Applicant

MedStar Franklin Square Medical Center

MedStar Franklin Square Medical Center is a 338-bed general hospital located in Baltimore County. It currently has one cardiac catheterization laboratory (CCL) for primary PCI cases and a hybrid operating room used for backup in case the CCL is unavailable. Franklin Square has indicated that the introduction of elective PCI services will not require a capital expenditure by the hospital. This is consistent with prior applications reviewed by MHCC staff for hospitals with a primary PCI program that requested approval to add an elective PCI program. Franklin Square qualifies to submit a Certificate of Conformance application to add elective PCI because Franklin Square has been providing primary PCI in accordance with established standards for more than two years, as provided in COMAR 10.24.17.04A(2)(b).

Service Area Population Characteristics

The most recent population forecast of the Maryland Department of Planning projects that

[1] Authorized to provide the service under the control and protocols of a clinical trial examining the safety of elective PCI in hospitals without cardiac surgery back-up.
[2]Authorized to provide the service with mandatory American College of Cardiology National Cardiac Data Registry reporting requirements for performance monitoring.

Baltimore County's population will increase about two percent between 2020 and 2030.[3] Projected population growth in this jurisdiction is lower than that for Maryland overall (5.6% between 2020 and 2030). Baltimore County is projected to see growth over the next decade in its elderly population, age 65 and over, of approximately 23 percent. Statewide, projected growth in this elderly population is higher, at 33 percent.

Table 1: Projected Population and Population Change: Baltimore County and Maryland Statewide, 2020-2030

	2020		2030		Percent Change	
Jurisdiction	Total Pop.	Age 65+	Total Pop.	Age 65+	Total Pop.	Age 65+
Baltimore County	830,310	147,857	846,560	182,291	2.0%	23.3%
Statewide	6,074,725	974,979	6,413,698	1,296,675	5.6%	33.0%

Source: MHCC staff analysis of Maryland Dept. of Planning, population projection series (December, 2020).

II. PROCEDURAL HISTORY

Franklin Square filed a Certificate of Conformance application on July 21, 2021. Subsequently, in response to requests for additional information and clarification, Franklin Square submitted additional filings on September 21, 2021, October 5, 2021, March 28, 2022, and March 30, 2022.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

A. Commission Program Policies, COMAR 10.24.17.04A(2)

Consideration of New Programs.

(2) Elective Percutaneous Intervention
(a) A hospital shall obtain a Certificate of Conformance to establish elective PCI services, unless the hospital is exempt from this requirement under Health General §19-120.1(d).

Franklin Square is required to obtain a Certificate of Conformance.

(b) A hospital shall have been providing primary PCI services for at least two years before seeking a Certificate of Conformance to provide elective PCI services, unless the hospital is located in a part of Maryland that does not have sufficient access to emergency PCI services. In such cases, sufficiency of access will be evaluated by the Commission based on a review of evidence presented by the applicant and collected by Commission staff. An applicant shall show that the population in the service area of the proposed program is receiving suboptimal therapy

[3] Maryland Department of Planning. "Projections to 2045." Total Population Projections (Excel file). https://planning.maryland.gov/MSDC/Pages/S3_Projection.aspx

for STEMI. This review shall include an analysis of emergency transport data and patient-level outcome data.

Franklin Square has been providing primary PCI services for more than two years.

(c) A review schedule for the establishment of elective PCI programs will be published in the Maryland Register at least annually for each health planning region where there is at least one hospital that provides only primary PCI services. An application to establish primary PCI and elective PCI services based on insufficient access pursuant to .04A(2)(b) of this regulation may be filed at any time.

Two hospitals that currently provide only primary PCI were eligible to file in this Certificate of Conformance review cycle for elective PCI services. Only Franklin Square filed an application.

Certificate of Conformance Review Standards, COMAR 10.24.17.06

B. Elective PCI Services.

A hospital issued a Certificate of Conformance to establish an elective PCI service shall agree to voluntarily relinquish its authority to provide elective PCI services if it fails to meet the applicable standards for a Certificate of Conformance.

Acknowledgment of this agreement was part of Franklin Square's affidavit concluding its Certificate of Conformance application, which was signed by Stuart M. Levine, MD, FACP, MedStar Franklin Square Hospital President, Senior Vice President MedStar Health.

An applicant seeking to establish elective PCI services shall meet all applicable criteria for a Certificate of Conformance for a primary PCI program.

Franklin Square obtained its initial one-year waiver to provide primary PCI services in May 2006. Franklin Square received three renewals of its waiver to provide primary PCI services based on its compliance with the performance standards used by MHCC for primary PCI waivers prior to the 2012 law establishing the Certificate of Ongoing Performance process. The waiver for Franklin Square was last renewed in May 2013. In 2019, Franklin Square filed a Certificate of Ongoing Performance application in accordance with the review schedule determined by the Commission. A Certificate of Ongoing Performance was issued in July 2020 to permit Franklin Square to continue providing primary percutaneous coronary intervention services for four years.

Franklin Square has demonstrated compliance with all applicable criteria for a Certificate of Conformance for a primary PCI program, as required by COMAR 10.24.17.04B. Franklin Square addressed its compliance with the standards for primary PCI services in its application for a Certificate of Ongoing Performance filed in 2019 and in this review. Franklin Square's filings indicate that the hospital continues to meet the standards for hospitals with primary PCI services. The following information addresses Franklin Square's compliance with select standards in the Cardiac Services Chapter. MHCC staff also incorporates into this report the Staff report for

Franklin Square's Certificate of Ongoing Performance issued in July 2020 (Docket. No. 19-03-CP014).

Franklin Square maintains the necessary facilities and staffing to be able to perform primary PCI 24 hours per day, seven days per week with few exceptions. Franklin Square reports one fewer physician and higher levels of nurses and technical staff FTEs than reported in its Certificate of Ongoing Performance application and last waiver renewal in 2013, as shown in Table 2 below.

Table 2: Total Number of Cardiac Catheterization Laboratory Physicians, Nurses, and Technical Staff, by Time Period

Staff Type	Number/Full-Time Equivalents			Cross-Training
	June 6, 2021	March 15, 2019	December 31, 2012	
Physicians	5	5	6	
Nurses	6.5 FTE	5.5 FTE	5.1 FTE	Circulate, Monitor
Technical Staff	6.5 FTE	4.0 FTE	5.8 FTE	Scrub, Circulate, Monitor

Sources: Franklin Square Certificate of Conformance application 2021, Franklin Square Certificate of Ongoing Performance application 2019, Franklin Square Waiver Renewal 2013.

Franklin Square is achieving acceptable case volume and door-to-balloon (DTB) times for primary PCI cases. As shown in Table 3, Franklin Square reported meeting the DTB standard in all quarters except one from 2018q2 through 2020q4. MHCC staff conducted its own analysis of the American College of Cardiology National Cardiovascular Data Registry (ACC NCDR) CathPCI data submitted to MHCC through December 2020, as shown in Table 4. These results differ slightly from Franklin Square's submission, which may be due to use of patient discharge date rather than procedure date. For reporting periods ending in 2020, Franklin Square likely excluded some cases, consistent with the ACC's evaluation of DTB performance for hospitals in standardized reports. For example, patients who are unstable that require another intervention before PCI may be performed are excluded. Based on MHCC staff's analysis, Franklin Square met the DTB standard, for all periods, when measured over rolling eight-quarter periods between January 2015 and December 2020. Staff notes the DTB standard was suspended during the State of Emergency lasting from March 2020 through August 2021.

Table 3: Franklin Square Reported Compliance with DTB Benchmark by Quarter, April 2018 to December 2020

Quarter	Total STEMI receiving PCI	STEMI patients with PCI w/in 90 min	% 90 minutes or less
2018q2	18	12	67%
2018q3	40	32	80%
2018q4	23	20	87%
2019q1	25	22	88%
2019q2	27	22	81%
2019q3	20	18	90%
2019q4	20	17	85%
2020q1	19	19	100%
2020q2	20	21	95%
2020q3	20	21	95%
2020q4	26	26	100%

Source: Franklin Square application and response to MHCC questions March 28, 2022.

Table 4: 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	83.0%
2017q1	31	28	90.3%	200	169	85.0%
2017q2	23	18	78.3%	188	162	86.0%
2017q3	21	18	85.7%	188	159	85.0%
2017q4	25	23	92.0%	192	165	86.0%
2018q1	20	16	80.0%	186	159	85.0%
2018q2	18	13	72.2%	175	147	84.0%
2018q3	37	30	81.1%	190	158	83.0%
2018q4	21	19	90.5%	196	165	84.0%
2019q1	25	23	92.0%	190	160	84.2%
2019q2	24	21	87.5%	191	163	85.3%
2019q3	20	17	85.0%	190	162	85.3%
2019q4	20	17	85.0%	185	156	84.3%
2020q1	23	20	87.0%	188	160	85.1%
2020q2	22	19	86.4%	192	166	86.5%
2020q3	28	21	75.0%	183	157	85.8%
2020q4	25	25	100.0%	187	163	87.2%

Source: MHCC staff analysis of ACC-NCDR CathPCI registry data, CY 2015- CY 2020.

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

The volume of primary PCI cases at Franklin Square exceeded the minimum program volume standard of 49 cases per year for CY 2015 through CY 2020, as shown in Table 5.

Table 5: Franklin Square PCI Volume, CY 2015 - CY 2020

Calendar Year	Primary PCI Volume
2015	83
2016	78
2017	89
2018	77
2019	99
2020	105

Sources: Franklin Square Certificate of Ongoing Performance application filed in 2019 and Certificate of Conformance application.

MHCC staff's analysis of the ACC NCDR CathPCI data indicates that interventionalists performing PCI procedures at Franklin Square between January 2015 and December 2020 performed greater than the minimum requirement of 50 PCI procedures annually averaged over consecutive 24-month periods.

Compliance with General Standards

Franklin Square demonstrated that it met the general standards in COMAR 10.24.10.04A.

Franklin Square demonstrated that it complied with the charge information standard in COMAR 10.24.10.04A(1). This standard requires the applicant to maintain a defined "representative list of charges" that is updated at least quarterly and made available on the hospital's website, and to have policies that include procedures for promptly responding to individual requests for current charges for specific procedures and staff training. Franklin Square provided the required policies in Attachments B, C, D, and E of its application.

The hospital fell within the third quartile in the most recent ranking of Maryland hospitals for FY 2020, ordered by highest to lowest level of charity care provided, with the level of charity care defined as a percentage of total expenses. Franklin Square meets the charity care standard at COMAR 10.24.10.04A(2) because it does not fall in the bottom quartile for the level of charity care provided, and the charity care policy of Franklin Square[4] meets the determination of eligibility and notice requirements.

Franklin Square complied with the quality of care standard in COMAR 10.24.10.04A(3). Franklin Square has all necessary licenses, certifications, and accreditations. This standard also requires that a hospital document each action taken to improve its performance on each quality measure included in the current Maryland Hospital Performance Evaluation Guide when the hospital performs in the bottom quartile relative to other Maryland hospitals, unless the hospital has achieved 90% compliance or better. The performance measures have changed, and this standard is outdated. Instead, when a hospital performs below average on a performance measure, MHCC staff requests that a hospital explain the actions that it has taken to improve on the

[4] Franklin Square's charity care policy was provided as Attachment D in its Certificate of Conformance application.

performance measures. Franklin Square explained the actions it has taken to improve on each of the nine performance metrics where it performed below the statewide average for the metrics included on MHCC's web site for quality reporting.[5]

An applicant seeking to establish elective PCI services shall meet the following additional requirements:

(1) Need
The hospital shall demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.

Franklin Square identified the primary service area of the hospital overall as residents residing in the following zip code areas: 21221, 21220, 21222, 21237, and 21234. The volume of discharges from these zip code areas accounted for about half of all discharges in CY 2019 and CY 2020. For elective PCI services specifically, Franklin Square identified its primary service area as the zip codes 21220, 21221, 21222, 21234, and 21237, based on information on the number of patients from its primary and secondary service area who received elective PCI at MedStar Union Memorial Hospital during CY 2019 and CY 2020, with some exclusions. Franklin Square excluded patients who were identified in the ACC NCDR CathPCI registry as high complexity and patients who required PCI of a vein graft, left main coronary artery, or totally occluded vessel. These excluded patients are ones who are contraindicated for elective PCI services at a hospital without on-site cardiac surgery, like Franklin Square.

Franklin Square initially stated that travel time to another provider of primary PCI services would vary from 16 to 40 minutes for residents in its primary and secondary service area for primary PCI services. MHCC staff subsequently requested that Franklin Square provide detailed information on the travel times for patients in its service area to alternative hospitals, based on the pattern of arrivals and volume of arrivals.

Franklin Square also provided a map with drive-time information to three other hospitals, University of Maryland (UM) Upper Chesapeake Medical Center (UCMC), Johns Hopkins Bayview Medical Center (JHBMC), and the UM St. Joseph Medical Center (SJMC). The estimates of travel times to these alternative locations were based on the addresses for primary PCI patients treated at Franklin Square between January 2018 and February 28, 2022. This analysis shows that almost 60% of the patients treated at Franklin Square would have a travel time of over 30 minutes to UM UCMC, while 36.7% would have had a travel time of over 30 minutes to UM SJMC, as shown in Table 6. The closest alternative location for most primary PCI patients served at Franklin Square is JHBMC. Only 5.4% of patients treated at Franklin Square have an estimated travel time of over 30 minutes to JHBMC, as shown in Table 6. However, Franklin Square also noted that over 50% of primary PCI patients treated at Franklin Square have an estimated travel time of less than 15 minutes, but less than 20% of primary PCI patients have an estimated travel time of 15 minutes or less to Johns Hopkins Bayview Medical Center.

[5] https://healthcarequality.mhcc.maryland.gov/

Table 6: Estimated Drive Times to Alternative Hospitals for Franklin Square's STEMI PCI Cases Reported by Hospital and Percentage of Cases

	Hospital and Percent of Cases			
Drive-Time Range	UM UCMC	UM SJMC	JHBMC	Franklin Square
>0 and <5 minutes	0.0%	0.0%	0.0%	4.0%
>=5 and <10 minutes	0.5%	0.2%	2.1%	9.3%
>=10 and <15 minutes	0.9%	0.7%	16.1%	39.5%
>=20 and <25 minutes	0.5%	9.6%	47.2%	25.7%
>=15 and <20 minutes	6.8%	15.7%	16.1%	13.6%
>=25 and <30 minutes	32.9%	37.1%	13.1%	3.5%
>=30 minutes	58.4%	36.7%	5.4%	4.4%

Source: MHCC analysis of Franklin Square's response to MHCC questions 3-28-22.

Franklin Square stated that the differences in travel time to UM UCMC and to UM SJMC compared to the travel time to Franklin Square are substantial and "have a reasonable likelihood of adversely affecting clinical outcomes." The difference in travel time to JHBMC would be approximately five to ten minutes for most patients, based on Franklin Square's analysis of its patient data, which Franklin Square describes as a modest difference. However, Franklin Square noted that primary PCI patients are typically brought to a hospital by Emergency Medical Services (EMS) and EMS's decision is based on both travel time and a hospital's alert status, which indicates a hospital's ability to receive new patients. Franklin Square analyzed data on the amount of time Franklin Square and the nearest alternative hospitals for primary PCI services were on red alert status (indicating no available hospital cardiac monitoring capacity) or re-route status for the period of September 1, 2021 to January 13, 2022. Franklin Square reported that JHBMC, UM UCMC, and UM SJMC were on re-route approximately 1.5 times more often than Franklin Square and on red alert status approximately three times more often than Franklin Square. As a result, Franklin Square concluded that its location is the hospital with the most availability of primary PCI services for patients in its service area.

Franklin Square stated that it intends to maintain its primary PCI program, even though historically the program has been operating at a loss. The physicians who perform primary PCI at Franklin Square all also performed primary and elective PCI services at MedStar Union Memorial Hospital. Although Franklin Square stated it intends to maintain its primary PCI program, it also expressed concern about turnover among staff for the CCL at Franklin Square, and these staff are essential for the operation of the CCL.

MHCC staff requested additional information on staff turnover at the cardiac catheterization laboratory for Franklin Square. However, Franklin Square responded that staff turnover information is not tracked specifically for the cardiac catheterization laboratory. It could provide only limited information on turnover, based on some recent internal research. Franklin Square reported that in the past year, as of March 2022, there were no resignations of radiology technicians for the cardiac catheterization laboratory, and two resignations of nurses, one of which occurred in the past month. Franklin Square reported that since the pandemic all clinical inpatient positions have been adversely affected, including those in the catheterization laboratory.

Staff Analysis

Staff reviewed the travel times using Google Maps from zip code areas included in Franklin Square's primary service area for primary PCI services, on March 2, 2022 for each of four times (8:00am, noon, 5:00pm, and 8:00pm), as shown in Appendix 1. Staff included in Appendix 1 the average estimated travel time if multiple routes were suggested by Google Maps. If a range was provided by Google Maps, rather than a single value, staff included the average using the end points provided; if multiple ranges were suggested for multiple routes, staff included the average of the endpoints for all routes suggested. This analysis is less precise than the analysis Franklin Square was able to perform and suggests longer estimated average transport times to Franklin Square for residents in the hospital's service area for primary PCI services, but the relative proportion of patients with transport times of 15 minutes or less for Franklin Square and JHBMC appears to be consistent with the information reported by Franklin Square for its entire population receiving primary PCI services, even though MHCC staff's analysis focused on only the zip code areas in Franklin Square's primary service area for primary PCI services.

As shown in Table 6, the vast majority of patients in the Franklin Square's service area would have an estimated travel time of 30 minutes or less for primary PCI services, even if the primary PCI program at Franklin Square did not exist. A travel time of 30 minutes is considered reasonable access to primary PCI services at alternative locations, as indicated in the Cardiac Services Chapter. None of the five zip code areas in the primary service area of Franklin Square had an average travel time over 30 minutes for primary PCI at Franklin Square or JHBMC, based on MHCC's staff's drive time analysis. The more precise analysis of Franklin Square that relied on patients' addresses of primary PCI patients treated at Franklin Square supports the conclusion that few patients who received primary PCI services had a transit time over 30 minutes, with only around four to five percent expected to have a transit time over 30 minutes, as reported in Table 6. However, there are notable differences in potential access to primary PCI services than travel time alone suggests, based on the much higher percentage of days that JHBMC was on red alert status for six hours or more for the period from January 2021 to March 28, 2022. JHBMC was on red alert for over six hours per day for over three times the number of days as Franklin Square (285 days versus 75 days).

Timely care is critical for STEMI patients, and the importance of timely care, as established by research, is the basis for having a door-to-balloon time standard. Staff notes that while a door-to-balloon time standard of 90 minutes or less is the benchmark used to evaluate hospitals for Certificates of Ongoing Performance, the 2013 guidelines of the American College of Cardiology Foundation/American Heart Association for STEMI patients include a recommendation that the goal for first medical contact (FMC)-to-device time be 90 minutes. For STEMI patients who are transported to a hospital by ambulance, the first medical contact would likely be with emergency medical system personnel, and the time to travel to a hospital would be part of the calculation of FMC-to-device time for those patients. The change in the guidelines for treatment of STEMI patients, which emphasizes FMC-to-device time and sets a higher ideal standard of care for STEMI patients, suggests that reducing travel time for STEMI patients is an important component to improving outcomes for some STEMI patients. This lends further support to Staff's conclusion that the primary PCI program at Franklin Square is needed to preserve timely access to primary PCI services for the population in Franklin Square's primary service area (PSA).

Recommendation

Despite the close proximity of alternative hospitals with primary PCI programs, the primary PCI program at Franklin Square is necessary to preserve timely access. Although approximately 96% of the population residing in zip code areas that are part of the service area for Franklin Square would be expected to have a travel time of 30 minutes or less to the nearest alternate location, which is the benchmark recognized in COMAR 10.24.17 for timely access, the substantially worse access anticipated for some residents in the service area of Franklin Square merits consideration, when a primary PCI program has already been established at a hospital. The diminished access for residents that may occur due to the nearest alternative hospital being on red alert status and the significantly greater time to travel to other alternative hospitals, as noted by Franklin Square, is reasonably likely to adversely affect patient outcomes. Almost 60% of primary PCI patients served at Franklin Square would have a transit time of over 30 minutes to get to UM UCMC and almost 37% would have a transit time over 30 minutes to get to UM SJMC.

Franklin Square, although it is not reported as profitable with respect to PCI services, is profitable overall, based on information reported to the Health Services Cost Review Commission. The main concern of Franklin Square is staff retention, and Franklin Square provided some evidence to support the problems with retention of nurses. MHCC staff has concluded that Franklin Square presented credible evidence that its program may erode without an elective PCI program due to staff turnover and that Franklin Square's expectation that turnover may be reduced with the addition of an elective PCI program is reasonable. Another Maryland hospital, Howard County General Hospital, received Commission approval for the addition of elective PCI services to its existing primary PCI program in 2020 (Docket No. 19-13-CC008) based partially on the applicant's demonstration that staff turnover was high and the applicant's belief that adding elective PCI services would reduce staff turnover. Staff recommends that the Commission find that Franklin Square has demonstrated that its proposed elective PCI program is needed to preserve timely access to primary PCI services for the population to be served.

(2) Volume

The hospital shall demonstrate its proposed elective PCI program will achieve a volume of 200 or more total PCI cases (elective and emergency) by the end of the second year of providing elective PCI services.

Franklin Square stated that it has averaged over 100 primary PCI cases since CY 2018, and because its primary service area has grown anticipates the volume of PCI cases will increase based on market data projections for the next five years. For CY 2019 and CY 2020, Franklin Square estimated the number of elective PCI cases from its proposed service area that could have been performed at Franklin Square instead of MedStar Union Memorial; the respective estimates of elective PCI cases are 235 and 198. Franklin Square explained that it excluded elective PCI cases performed at MedStar Union Memorial that were labeled in the ACC NCDR CathPCI data as high complexity, required PCI of a vein graft or PCI of the left main coronary artery, or involved patients who had a totally occluded vessel because those cases are considered only appropriate for locations with cardiac surgery on-site. Franklin Square also provided the number of patients who were transferred from Franklin Square to MedStar Union Memorial for elective PCI services in

CY 2018, CY 2019, CY 2020, and January to August 2021, who otherwise would have received elective PCI services at Franklin Square. The respective number of these cases in CY 2018, CY2019, CY 2020, and January to August 2021 were 64, 69, 84, and 38 cases. In combination with the projected primary PCI volume for Franklin Square (approximately 100 cases annually), Franklin Square projects a total volume of over 300 cases each year, which is above the minimum target case volume of 200 PCI cases.

Staff Analysis

Staff noted that elective PCI volume was significantly lower statewide in CY 2020 compared to CY 2029 (6,549 cases versus 8,355), which may be attributed to hospitals suspending elective surgeries during part of the pandemic. For this reason, staff analyzed both CY 2019 and CY 2020 data.

Using the ACC NCDR CathPCI data, MHCC staff reviewed the zip code areas identified by Franklin Square as its primary service area for primary PCI patients over the period CY 2019 and CY 2020. Staff found the zip code areas included in Franklin Square's primary service area to be consistent with this analysis. Staff also analyzed the overlap with other hospitals for primary and elective PCI services performed on residents from the zip code areas identified by Franklin Square as its primary and secondary service area. MedStar Union Memorial Hospital has the greatest market share overlap with the proposed elective PCI service area of Franklin Square. In CY 2020, MedStar Union Memorial captured 53.5% of the elective PCI cases in the proposed service area of Franklin Square, which reflects its current primary[6] and secondary[7] service area for primary PCI services. The three hospitals that captured the next highest proportion of patients from the service area of Franklin Square for elective PCI cases were Johns Hopkins Hospital (JHH), UM SJMC, and JHBMC, which respectively captured 11.7%, 11.5%, and 11.4% of market share in CY 2020. As shown in Table 8, four hospitals captured less than 3% of market share in CY 2020, including the University of Maryland Medical Center (UMMC), University of Maryland Baltimore Washington Medical Center (UM BWMC), and Sinai Hospital of Baltimore (Sinai). In CY 2019, the level of market share capture for most hospitals was relatively similar to CY 2020, as shown in Table 8.

[6] Franklin Square defined its primary service area as the zip code areas for its primary PCI patients with the highest volume of primary PCI cases inclusive of 50% of the total volume.

[7] Franklin Square defined the secondary service area as the next 25% of zip codes for primary PCI patients, following the zip codes in its primary service area.

Table 8: Overlap with PSA of Franklin Square (FSq) for Elective PCI Cases by Hospital, CY 2019-2020

Location	CY 2019			CY 2020		
	Total Elective Cases	Cases in Service Area of FSq	Percent of Market Share	Total Elective Cases	Cases in Service Area of FSq	Percent of Market Share
Union Memorial	997	515	55.1%	748	385	53.5%
UM SJMC	564	151	16.2%	351	82	11.4%
JHBMC	130	85	9.1%	112	82	11.4%
JHH	496	69	7.4%	362	85	11.8%
UM UCMC	346	36	3.9%	272	32	4.4%
UMMC	456	35	3.7%	311	17	2.4%
Sinai	307	28	3.0%	129	7	1.8%
UM BWMC	227	5	0.5%	190	13	1.8%
Other	4,832	10	1.1%	3,931	12	1.7%
Total	8,355	934	100%	6,549	720	100%

Source: MHCC staff analysis of NCDR CathPCI Registry data, CY 2019-20.

Notes: Zip code area information was missing in approximately 2.6% and 3.4% of the elective PCI cases in the NCDR CathPCI Registry data for CY 2019 and CY 2020 respectively. Hospitals included in counts are Maryland hospitals and MedStar Washington Medical Center. Hospitals in the "Other" category are those that performed ten or less elective PCI cases in CY 2019 and CY 2020 that overlap with the service area of Franklin Square.

MHCC staff's analysis of the ACC NCDR CathPCI registry data suggests that the total volume of elective PCI cases projected by Franklin Square is reasonable. MHCC staff analyzed the market share for PCI services at two other hospitals that began with only primary PCI services and later added elective PCI services, Carroll Hospital Center (CHC) and UM UCMC, and two other suburban hospitals that do not have cardiac surgery on-site, UM BWMC and St. Agnes Hospital.

Franklin Square, with its projection of elective PCI cases annually, expects to capture approximately 28% of the elective PCI market share for its service area, resulting in total PCI case volume of over 300 cases. This projection seems reasonable, given that Franklin Square captured 44% of the market share for its service area for primary PCI services in CY 2020. The example of CHC suggests that a hospital adding elective PCI services should be expected to achieve about half of the market share it achieves for primary PCI services. MHCC staff's analysis shows that in CY 2020, CHC captured almost 79% of market share for the zip code areas included in its service area for primary PCI services (top 75% of zip codes ordered from highest to lowest volume) and for these same zip codes captured only 40% of elective PCI cases. In CY 2019, CHC captured 54.9% of market share for its service area for primary PCI services and 29.5% for these same zip codes for elective PCI cases.

UM UCMC, in CY 2020, captured 87.6% of market share for the zip code areas included in its service area for primary PCI services (top 75% of zip codes ordered from highest to lowest volume), and for these same zip code areas captured 60.3% of elective PCI cases. Similarly, in CY 2019, UM UCMC captured 82.6% market share for the zip code areas included in its service

area for primary PCI services and for these same zip codes captured 48.5% of elective PCI cases. UM UCMC is located farther from other hospitals with PCI services in Maryland compared to Franklin Square, as reflected in its very high percentage of market capture for emergency PCI services in both CY 2019 and CY 2020. The distance to other PCI providers also likely contributes to its high market share for elective PCI services too.

Both UM BWMC and St. Agnes Hospital achieved less capture of market share for primary PCI services, but both were able to maintain a relatively greater proportion of market share for elective PCI cases, compared to CHC and UM UCMC. In CY 2019, UM BWMC captured 55.7% of the market share for the zip code areas included in its service area for primary PCI services (top 75% of zip codes ordered from highest to lowest volume) and, for these same zip code areas, 36.5% of the market share for elective PCI services. Similarly, St. Agnes Hospital captured 48.8% of the market share for the zip code areas included in its service area for primary PCI services and, for these same zip code areas, captured 40.9% of the market share for elective PCI services in CY 2019. Franklin Square would only need to capture approximately 14% of the market share for elective PCI cases in its proposed service area to achieve a total PCI program volume over 200 cases. This is much lower than the percentage of market share Franklin Square can likely achieve based on MHCC staff's analysis of CHC, UM UCMC, UM BWMC, and St. Agnes Hospital.

Staff's service area analysis indicates that most elective PCI cases in the proposed service area of Franklin Square are currently performed at MedStar Union Memorial Hospital, consistent with Franklin Square's analysis of the source of its projected elective PCI cases. Although other hospitals could experience some loss of elective PCI case volume through the addition of this service at Franklin Square, the likely level of impact on these programs would not reduce the volume of most of these existing PCI program to levels inconsistent with the State Health Plan requirements because the total PCI volumes achieved by MedStar Union Memorial Hospital, UM UCMC, Johns Hopkins Hospital, and UM SJMC were well above 200 cases in CY 2019 and CY 2020. For JHBMC, its program volume for PCI cases was just under 200 cases in CY 2019 (198 cases) and then it declined to 167 cases for CY 2020. If Franklin Square was expected to take significant volume away from JHBMC, the potential impact of the addition of elective PCI services at Franklin Square might be concerning with respect to JHBMC. However, JHBMC had only 11.4% overlap with the proposed service area for elective PCI services at Franklin Square in CY 2020 and 9.1% overlap in CY 2019. In addition, the hospital with the greatest market share overlap with Franklin Square is MedStar Union Memorial, which is in the same health system; it is likely that most new volume for elective PCI services will be shifted from MedStar Union Memorial Hospital, as anticipated by the applicant.

Recommendation

Staff recommends that the Commission find that Franklin Square has demonstrated that its proposed elective PCI program is likely to achieve a volume of 200 or more total PCI cases (elective and emergency) by the end of the second year of providing elective PCI services. This case volume can be achieved without unacceptably reducing the volume at existing elective PCI programs and would require Franklin Square to capture only a modest market share for its proposed service area for elective PCI patients.

(3) Financial Viability

The Commission may waive the volume requirement in subsection (2) if the applicant demonstrates that adding an elective PCI program to its existing primary PCI program at its likely projected annual case volume will permit the hospital's overall PCI services to achieve financial viability.

Franklin Square is not seeking a waiver of the volume requirement in subsection (2) that permits an applicant to demonstrate that the addition of elective PCI services will permit the PCI program to achieve financial viability. Franklin Square reported that the primary PCI program has historically not generated a profit, but this is not a concern for the hospital based on its overall profitability. Franklin Square projects that the addition of an elective PCI program will result in the PCI program generating a net profit, in contrast to a net loss each year for the existing primary PCI program. Less revenue is projected for the first year of implementation, FY 2022, based on fewer months operating both elective and primary PCI services.

Table 9: Revenues and Expenses, Primary PCI Services at Franklin Square, FY 2019- FY 2020

	FY 2019	FY 2020
Gross Patient Services Revenue	$950,937	$794,263
Bad Debt, Contractual Allowances, Charity Care	($97,977)	($90,490)
Net Patient Services Revenue	$852,960	$703,773
Salaries, Wages, and Benefits	$773,661	$859,704
Contractual Services	-	-
Current Depreciation	-	-
Supplies	$342,140	$286,824
Total Operating Expenses	$1,115,801	$1,146,528
Income from Operations	($262,841)	($442,755)

Source: Franklin Square Certificate of Conformance application

Table 10: Projected Revenue and Expenses, Primary and Elective PCI Services at Franklin Square, FY 2022- FY2025

	FY 2022	FY 2023	FY 2024	FY 2025
Gross Patient Services Revenue Baseline	$977,402	$2,096,091	$2,620,113	$3,275,142
Bad Debt, Contractual Allowances, Charity Care	($111,355)	($238,808)	($298,510)	($373,128)
Net Patient Services Revenue	$866,047	$1,857,283	$2,321,603	$2,902,014
Salaries, Wages, and Benefits	$950,515	$950,515	$950,515	$950,515
Contractual Services	--	--	--	--
Current Depreciation	--	--	--	--
Project Depreciation	--	--	--	--
Supplies and Drugs	$332,255	$528,734	$660,918	$826,147
Total Operating Expenses	$1,282,770	$1,479,249	$1,611,433	$1,776,662
Income from Operations	($416,723)	$378,034	$710,170	$1,125,352

Source: Franklin Square Certificate of Conformance application

Recommendation

This standard is inapplicable to the review of the Franklin Square because the hospital is not requesting a waiver from the minimum volume standard on the basis of its ability to achieve financial viability through the addition of elective PCI. Staff concludes that Franklin Square can provide primary and elective PCI services on a financially viable basis, given that the hospital is profitable overall.

(4) Quality

A hospital shall demonstrate that it provided high quality emergency PCI services over a period of two years or longer, unless the hospital is not required to obtain a Certificate of Conformance to establish emergency PCI services before establishing elective PCI services.

As previously noted, Franklin Square was first authorized to provide primary PCI services in 2006 and has received three renewals of its waiver to continue providing the service. Before issuing each of the waiver renewals, the Commission found that the program met the applicable quality standards. Franklin Square obtained a Certificate of Ongoing Performance in July 2020. Based on the information submitted, MHCC staff has no concerns about the quality of Franklin Square's primary PCI program.

(5) Preference

A hospital that was providing primary PCI services on January 1, 2012 will be given preference

over another hospital that was not providing primary PCI services on January 1, 2012, when the two hospitals have service areas that overlap and only one additional PCI program is needed to provide adequate geographic access for the population in the service areas of both hospitals.

This standard is not applicable in this review**.** Franklin Square provided primary PCI services on January 1, 2012. It is also not in a competitive review with a hospital seeking to establish elective PCI services that was not providing primary PCI services on January 1, 2012.

(6) Patient Selection
The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

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

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

Franklin Square provided the required commitment, in writing, in its Certificate of Conformance application filing.

IV. SUMMARY AND RECOMMENDATION

The information considered in this review indicates that Franklin Square's primary PCI program is important for maintaining timely access to these services for the population in its primary service area. Franklin Square's existing primary PCI program has continued to be in conformance with the standards established by MHCC for primary PCI in the non-cardiac surgery hospital setting, and a total PCI volume of over 200 cases is likely to be met, if Franklin Square introduces elective PCI services. The hospital has demonstrated that timely access to primary PCI services will likely be jeopardized without the addition of an elective PCI program. Staff recommends that the Commission approve the request of MedStar Franklin Square Medical Center for a Certificate of Conformance to establish elective PCI services.

IN THE MATTER OF	*	
	*	
ESTABLISHMENT OF ELECTIVE	*	
	*	**BEFORE THE**
PERCUTANEOUS CORONARY	*	
	*	
INTERVENTION SERVICES BY	*	
	*	**MARYLAND HEALTH**
MEDSTAR FRANKLIN SQUARE	*	
	*	
MEDICAL CENTER	*	
	*	**CARE COMMISSION**
DOCKET NO. 21-03-CC033	*	
	*	

* *

FINAL ORDER

Based on the analysis and recommendations in the Staff Report and the record in this review, it is, this 21st day of April 2022, **ORDERED**:

That in accordance with and subject to the applicable requirements in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Intervention Services Chapter of the State Health Plan, the application filed by MedStar Franklin Square Medical Center for a Certificate of Conformance to establish elective, or non-primary, PCI services is hereby **APPROVED**,

MARYLAND HEALTH CARE COMMISSION

Appendix 1:

Estimated Travel Time to Nearest Alternative Hospitals with Primary PCI Services for Patients from the Zip Code Areas in the Primary Service Area of Franklin Square

Time of Day	Proportion of Fsq Service Area by Zip Code Area		Estimated Travel Times to Nearest Alternative Hospitals				Difference in Estimated Travel Times Compared to Travel to FSq		
			FSq	JHBMC	UM SJMC	UM UCMC	(Fsq-JHBMC)	(Fsq-UM SJMC)	(Fsq-UM UCMC)
8am	**21220**	18.1%	20.3	27.7	45.0	37.2	-7.3	-24.7	-16.8
Noon			21.7	28.5	39.3	38.8	-6.8	-17.6	-17.2
5pm			22.7	28.5	45.0	40.8	-5.8	-22.3	-18.2
8pm			20.0	26.5	37.3	35.5	-6.5	-17.3	-15.5
8am	**21221**	18.1%	19.0	22.7	42.3	39.7	-3.7	-23.3	-20.7
Noon			19.7	22.7	11.7	40.8	-3.0	8.0	-21.2
5pm			19.0	24.2	38.0	43.3	-5.2	-19.0	-24.3
8pm			18.0	22.0	34.3	38.0	-4.0	-16.3	-20.0
8am	**21222**	6.9%	20.0	20.0	46.3	47.5	0.0	-26.3	-27.5
Noon			21.5	20.0	41.0	48.3	1.5	-19.5	-26.8
5pm			26.7	20.3	44.0	50.8	6.3	-17.3	-24.2
8pm			20.0	17.7	38.5	44.2	2.3	-18.5	-24.2
8am	**21234**	12.7%	17.5	19.0	19.7	35.5	-1.5	-2.2	-18.0
Noon			17.0	17.0	15.7	33.8	0.0	1.3	-16.8
5pm			17.3	16.0	18.0	37.0	1.3	-0.7	-19.7
8pm			16.0	16.0	14.3	30.8	0.0	1.7	-14.8
8am	**21237**	13.2%	10.7	18.3	33.5	38.3	-7.7	-22.8	-27.7
Noon			11.3	17.7	28.0	38.7	-6.3	-16.7	-27.3
5pm			12.7	19.3	30.0	42.3	-6.7	-17.3	-29.7
8pm			9.7	17.3	25.8	35.0	-7.7	-16.1	-25.3

Source: MHCC staff estimates of travel time for primary PCI patients in the primary service area of Franklin Square, based on Google Maps estimates of travel time for March 3, 2022.