IN THE MATTER OF	*	
	*	BEFORE THE MARYLAND
MEDSTAR FRANKLIN SQUARE	*	
MEDICAL CENTER	*	
	*	HEALTH CARE COMMISSION
DOCKET NO. 13-03-0069 WR	*	

****

REPORT AND RECOMMENDATION ON REQUEST TO RENEW WAIVER TO PROVIDE PRIMARY PCI WITHOUT CARDIAC SURGERY ON-SITE

I. INTRODUCTION

MedStar Franklin Square Medical Center (Franklin Square or the "Hospital") is located in Baltimore (Baltimore County), and it has a current licensed acute care bed capacity of 355 beds, including 285 medical/surgical/gynecology/addiction (MSGA) beds and 28 critical care beds as part of the larger MSGA bed inventory.[1] Franklin Square is accredited by the Joint Commission and is a Medicare provider in good standing. It is part of MedStar Health, which owns and operates ten hospitals, including seven Maryland hospitals and three hospitals in Washington, D.C.

Franklin Square began providing primary percutaneous coronary intervention (pPCI) services under a research waiver in May, 2003 as a participating hospital in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials, investigating the safety of performing pPCI in hospitals without cardiac surgery. Subsequently, the hospital was authorized to provide pPCI on a regular basis, subject to ongoing performance requirements and periodic waiver renewal. Franklin Square's most recent two-year waiver renewal was issued in 2011.

In order to retain this pPCI waiver, Franklin Square timely applied to the Commission on February 4, 2013 for renewal of its two-year pPCI waiver. This Report and Recommendation analyzes Franklin Square's compliance with the requirements for pPCI programs without on-site cardiac surgery.

II. STAFF REVIEW AND ANALYSIS OF WAIVER RENEWAL

Background

Under *COMAR 10.24.17 State Health Plan for Cardiac Surgery and PCI Services*, the Commission may waive any of the policies in Regulations .04 or .05 of this Chapter for a specified time period if the hospital requesting the waiver can demonstrate the ability to comply with all requirements for primary (emergency) PCI programs without on-site cardiac surgery as specified in Table A-1. Following development of the pPCI program, the Commission may issue a waiver for a two-year period provided that the hospital has met and will continue to meet all

[1] Maryland Health Care Commission, *Annual Report on Selected Maryland Acute Care and Special Hospital Services, Fiscal Year 2011*, Effective July 1, 2010, pages 3 and 9.

requirements for primary PCI programs without on-site cardiac surgery. From January 2006 to December 2009, hospitals with a pPCI waiver used the Commission's data registry for patients presenting with ST-segment elevation myocardial infarction (STEMI) and for PCI services provided to patients meeting certain eligibility criteria. Since July 1, 2010, all Maryland acute care hospitals that provide PCI services have been required to use the American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR) ACTION Registry-GWTG to report quarterly data to the Commission for eligible patients discharged on or after July 1, 2010. The hospitals are also required to enroll in the NCDR CathPCI Registry effective July 1, 2010, and they use the CathPCI Registry to report quarterly data to the Commission. Staff analyzed the consistency of the Franklin Square renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on reported experience and ACCF-NCDR CathPCI Registry data.

Compliance with COMAR 10.24.17.05D(1) Waiver from Policies. Primary Percutaneous Coronary Intervention in Hospitals without On-Site Cardiac Surgery.

Category: Institutional Resources

1) All institutions should provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week.

Analysis

Franklin Square reports that it has one cardiac catheterization laboratory (CCL).The routine hours of CCL operation are 7:00 a.m. to 4:30 p.m., Monday through Friday. On-call hours are 4:30 pm to 7 am, Monday through Friday, and 24 hours per day on weekends. Table 1 below shows the dates during 2011 and 2012 when the lab was unavailable for primary PCI services.

NCDR data shows that, during 2011 and 2012, no STEMI patients had thrombolytic therapy. Franklin Square also reported that at no time was the cardiac catheterization laboratory unavailable because procedures on another patient were under way.

Table 1. Cardiac Catheterization Laboratory Services Unavailable by Date and Room

- **January 1, 2012-December 31, 2012**

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
CCL	5/5/12	5/5/12	4.0	Both departmental balloon pumps were in use and department had to rent an additional unit.
CCL	3/16/12	3/16/12	6.5	System scheduled periodic maintenance

- **January 1, 2011-December 31, 2011**

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
CCL	10/5/11	10/5/11	6.5	System scheduled periodic maintenance
CCL	10/3/11	10/3/11	7.0	MacLab and DMS issues
CCL	8/22/11	8/22/11	12.0	Physician coverage was not available.
CCL	7/2/11	7/2/11	0.5	Balloon pump switched to battery and power cord was replaced.
CCL	6/27/11	6/28/11	23.0	MacLab system upgrade

Source: MedStar Franklin Square Medical Center, Application for Renewal of Waiver, February 4, 2013, p. 15-16.

During the reporting period, Franklin Square maintained a substantial level of compliance with the requirement to provide pPCI services 24 hours per day, seven days per week.

2a) All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.

2b) Effective January 1, 2010, all institutions should provide primary PCI as soon as possible and not to exceed 90 minutes from patient arrival (i.e., door-to-balloon time of ≤ 90 minutes) for 75 percent of appropriate patients.

<u>Analysis</u>

Based on the Commission Staff's analysis of NCDR data for calendar years 2011 and 2012 (Table 2), Franklin Square met the required threshold for door-to-balloon (DTB) time, providing pPCI within 90 minutes or less of hospital presentation for 77 percent of patients (137 of 180 patients) over the combined two year period shown in Table 2. However, the most recent two quarters of data, the second half of CY 2012, show that the door-to-balloon time fell below the required standard of 90 minutes or less for 75 percent of primary PCI cases. In the third quarter of 2012, only 71 percent of cases had a DTB time of 90 minutes or less, and in the fourth quarter of 2012, only 65 percent of primary PCI cases had a DTB time of 90 minutes or less.

Although some hospitals in Maryland sometimes find it challenging to meet the DTB time standard due to the number of transfer cases received, Franklin Square did not have any transfer cases in 2011 or 2012. Instead, Franklin Square cites a variety of other reasons that account for the drop in performance in the last two quarters of CY 2012, such as patients' atypical presentation of symptoms, symptoms that suggested a different type of test should precede PCI, and misread electrocardiograms (EKGs). Franklin Square explained that it has taken steps to address the slip in compliance with the DTB standard for the last two quarters of CY 2012. Franklin Square explained that it has re-engineered its process for the Emergency Department, but it has not addressed the misread EKGs through systematic changes because there was not an apparent pattern or person responsible for the errors. Franklin Square stated that DTB times in February, March, and April of 2013 improved and were 75 percent, 91 percent, and 100 percent respectively. Franklin Square's improved DTB times for the early months of 2013 suggest that it has taken effective steps to assure that its DTB time performance will comply with the standard in COMAR 10.24.17. However, Commission staff is concerned about the initially misread EKGs, which also contributed to failing to meet the DTB time standard in the last six months of CY 2012. Therefore, as a condition of the waiver renewal, Commission staff recommends that Franklin Square report to the Commission on a quarterly basis during CY 2013 on all cases in which it failed to achieve a DTB times of 90 minutes or less for pPCI and the reasons for this failure. This information will be used by the Commission to evaluate the extent of this particular performance issue and assess whether appropriate corrective actions are being taken.

As shown in Table 3, Franklin Square's internal data indicate that, during calendar years 2011 and 2012, the Hospital provided pPCI within 90 minutes to 78 percent of patients (141 of 181 patients), overall, during the two year period shown. This data is consistent with Commission Staff's analysis of NCDR data, also showing that the door to balloon time for the two most recent quarters reported fell below the standard of 90 minutes or less for 75 percent of primary PCI cases.

Table 2. Primary PCI Volume, Median Door-to-Balloon (DTB) Time, and Number and Percentage of Patients by DTB ≤ 90 minutes by Quarter: NCDR Data for MedStar Franklin Square Medical Center, 2011 and 2012

Quarter and Year	Primary PCI Volume	Median Door-to-Balloon Time (Minutes)	Door-to-Balloon Time ≤ 90 Minutes (N)	≤90 Minutes (%)
Quarter 4 (Oct-Dec 2012)	23	71.5	15	65
Quarter 3 (July-Sept 2012)	17	79.5	12	71
Quarter 2 (Apr-June 2012)	19	62.0	15	79
Quarter 1 (Jan-Mar 2012)	31	64.0	26	84
Quarter 4 (Oct-Dec 2011)	23	65.0	19	83
Quarter 3 (July-Sept 2011)	26	67.0	19	73
Quarter 2 (Apr-June 2011)	22	73.5	18	82
Quarter 1 (Jan-Mar 2011)	19	61.0	14	74
All Quarters	180	Not Calculated	138	77

Source: MHCC staff analysis of NCDR data for calendar years 2011 and 2012 and Additional information April 30, 2013 and May 6, 2013.

Notes: PCI volume refers to the number of cases where a device was used. All patients undergoing PCI were appropriate for primary PCI in settings without on-site cardiac surgery. DTB time is the difference in minutes between the patient's arrival in the hospital emergency room and the time of first device use (usually a balloon-type device, but occasionally a thrombectomy device). Exceptions to this calculation method most commonly occur when the patient arrives with a *history* of chest discomfort but a normal or non-diagnostic initial (first) electrocardiogram (ECG). *If and only if* the first ECG is normal/non-diagnostic *and* is noted in the NCDR CathPCI Registry database for review and confirmation along with a second ECG showing STEMI, then the date and time of the second (diagnostic) ECG are used as the "door" or "clock start" time to calculate DTB time. Historically, this same approach has been used for patients already hospitalized: the "door" ECG is the first ECG recorded showing STEMI. However, the NCDR CathPCI Registry does not capture the ECG date and time for these patients, unless the first ECG was negative. For each quarter, the case count is based on the discharge date of the patient.

Table 3. Primary PCI Volume, and Number and Percentage of Patients With DTB ≤ 90 Minutes by Quarter: Internal Data for MedStar Franklin Square Medical Center, 2011 and 2012

Quarter and Year	Primary PCI Volume	Median Door-to-Balloon Time (Minutes)	Door-to-Balloon Time ≤ 90 Minutes (N)	Door-to-Balloon Time ≤ 90 Minutes (%)
Quarter 4 (Oct-Dec 2012)	23	71	15	65
Quarter 3 (July-Sept 2012)	18	80	12	67
Quarter 2 (Apr-June 2012)	18	62	14	78
Quarter 1 (Jan-Mar 2012)	32	64	28	88
Quarter 4 (Oct-Dec 2011)	24	65	20	83
Quarter 3 (July-Sept 2011)	26	63	20	77
Quarter 2 (Apr-June 2011)	22	73	18	82
Quarter 1 (Jan-Mar 2011)	18	61	14	78
Total	181	Not Reported	141	78

Source: Franklin Square Application for Renewal of Waiver, February 4, 2013, p. 8.
Note: For each quarter, the case count is based on the procedure date of the patient.

When the two-year period is viewed as a whole, Franklin Square has met the DTB requirement. Based on the NCDR data analyzed by Commission staff, overall, it achieved a 77 percent level of performance for pPCI cases within the target DTB time of 90 minutes or less. However, as previously noted, the dip in performance on this standard that occurred in the latter half of 2012 is concerning. For this reason, it is recommended that performance of the Hospital on this requirement be closely monitored in the coming year.

3) All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.

Analysis

Table 4 shows the total number of staff involved in providing primary PCI services at Franklin Square. The pPCI program is staffed by 5.1 FTE nurses and 5.8 FTE cardiovascular technologists. Compared to the last waiver renewal application, Franklin Square has less than half as many physicians providing primary PCI services (six versus 15).

Table 4. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: MedStar Franklin Square Medical Center (as of December 31, 2012)

Staff	Number	Cross-Training (S/C/M)*
Physicians	6	
Nurses	5.1 FTE	C/M
Cardiovascular Technologists	5.8 FTE	S/C/M

Source: Franklin Square Application for Renewal of Waiver, February 4, 2013, p. 6.
*Note: Staff are cross-trained to scrub (S), circulate (C), and monitor (M).

The number of physicians, nurses, and technicians who make up each on-call team is shown in Table 5. Franklin Square permits cardiologists to have simultaneous on-call duties at other hospitals. Franklin Square indicated that its policies and procedures for when an interventionalist on call is unavailable have not changed since its last waiver renewal. A back-up interventionalist is called if the interventionalist on call is unavailable. If the back-up interventionalist is not available, the patient is immediately transferred to Union Memorial Hospital (about 10.5 miles from Franklin Square) or another tertiary institution.

Table 5. On-Call Primary PCI Team Staffing, Rotation, and Response Time: MedStar Franklin Square Medical Center

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	1	Per Medical Director's monthly physician on-call schedule	30 minutes
Nurses	2	10 shifts per month to include three weekend shifts	30 minutes
Cardiovascular Technologists	2	10 shifts per month to include three weekend shifts	30 minutes

Source: Franklin Square Application for Renewal of Waiver, February 4, 2013, p. 7.
*Note: Response time is the time established by the hospital's policy for on-call staff to respond to the call (phone, pager). Response time covers the period from receipt of call to arrival at the hospital.

Patients who are post pPCI are admitted to the hospital's intensive care unit (ICU), which has 28 licensed beds. During the period from July 1, 2011 to June 30, 2012, the average daily census for the ICU beds was 22 patients. Paid FTEs in calendar year 2012 included 68.8 RNs providing direct nursing care. Multifunctional technicians (15.0 paid FTEs) and a student nurse extern (0.6 paid FTE) support the unit. The Society of Critical Care Medicine has provided a basic measure of nurse staffing:

> Depending on the tasks that the nurse performs (for example, recovering patients from general anesthesia after a direct admission to the ICU, or accompanying them on intrahospital transports) and the technology being used (for example, intra-aortic balloon pump or left ventricular assist device), nurse

staffing between 14 to 17 nurse care hours is typical. Thus, staffing at the 17 nursing care-hour level allows for a ratio of about 1:1.[2]

Franklin Square stated that there is dedicated physician coverage of the ICU unit. There is on-site coverage 10 hours a day and on-call coverage 14 hours a day.

Franklin Square meets this requirement.

4) All institutions should have a written commitment by hospital administration signed by the hospital president to support the program, and

Analysis

Franklin Square provided a letter from Samuel Moskowitz, President, dated November 7, 2012, committing to support the pPCI program. Franklin Square meets this requirement.

[All institutions should] be required to:

i) 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;

Analysis

Shahid Saeed, M.D., FACC, FSCAI continues as the Medical Director of the Cardiac Catheterization Laboratory at Franklin Square. The Hospital previously provided a position description for the Medical Director of the CCL, whose primary function is to manage the clinical, administrative, and educational components of invasive cardiac services. The responsibilities of the Director address the requirements of COMAR 10.24.17.

Franklin Square meets this requirement.

ii) develop a formal, regularly scheduled (meetings every other month) interventional case review that requires attendance by a critical mass of interventionalists and other physicians, nurses, and technicians who care for primary PCI patients; and

Analysis

Franklin Square provided information concerning dates and attendance at primary PCI case review meetings during calendar year 2012. Over this period, Peer-to-Peer Quality Review

---

[2] Joint Commission Resources. Improving Care in the ICU, 1st Edition. Oak Brook Terrace, Illinois: Joint Commission Resources, 2004.

meetings were held monthly (a second meeting was held at the end of May instead of in early June). Franklin Square meets this requirement.

iii) 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.

Analysis

The multiple care area group at Franklin Square includes physicians (CCL Medical Director; Chair and Associate Chair of the Emergency Department), nurses (CCL Manager; pPCI Data Coordinator; ED Manager and ED/EMS Liaison; ICU nurses, technician tem leader, and other staff (Administrative Director, BioMed Lead, Inpatient Pharmacy staff, and ED Admitting staff). Representatives of Baltimore County EMS also attended meetings of the group. The pPCI multidisciplinary group met 12 times during calendar year 2012, one time each month.

Franklin Square meets this requirement.

5) All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.

Analysis

Franklin Square provided a summary of continuing educational activities provided to staff in the CCL and the Coronary Care Unit from January 1, 2012 through December 31, 2012. Over this time period, educational activities encompassed the following topics: Cancer Genetics, Cordis ExoSeal, Controlled Substance Review, Xarelto, Brilinta, Mynx Closure Device, Pronto Catheters, Arctic Sun temperature management system, Resolute Stent, EKG Rhythm Recognition, Therapeutic Hypothermia, and the Intra-Aortic Pump.

Franklin Square meets this requirement.

6) There must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

Analysis

The hospital submitted a revised Memorandum of Understanding between Union Memorial Hospital and Franklin Square. Franklin Square meets this requirement.

7) **There must be a formal, written agreement with an advanced cardiac life support emergency medical services provider that 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.**

<u>Analysis</u>

The Hospital submitted a revised Memorandum of Understanding between LifeStar Response Corporation and Franklin Square. Franklin Square meets this requirement.

<u>Category: Physician Resources</u>

1) **Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.**

<u>Analysis</u>

Table 6 provides the total PCI cases performed by the physicians with pPCI privileges at Franklin Square during the period from January 2012 to December 2012.

The data show that all of the physicians performed at least 75 PCI cases during the most recent 12 months at the time of the application.

Table 6. Total Number of PCI Cases Performed by Physician: MedStar Franklin Square Medical Center, 2012

Physicians for Reporting Period 1/1/12-12/31/12	Number of pPCI Cases at Franklin Square	Total PCI Cases-All Hospitals
George D. Bittar, M.D.	11	159
Jerald Insel, M.D.	9	97
David B. Peichert, M.D.	10	153
Kerry C. Prewitt, M.D.	14	251
Shahid Saeed, M.D.	34	95
John C. Wang, M.D.	13	299

Source: Franklin Square Application for Renewal of Waiver, February 4, 2013, Exhibit 7.

Franklin Square complied with this requirement in 2012.

2) **Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MIs during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.**

Analysis

Franklin Square reported that no physicians with privileges are less than three years out of fellowship training.

3) **Physicians who perform primary PCI should agree to participate in an on-call schedule.**

Analysis

Each of the physicians who currently perform pPCI at Franklin Square participates in the hospital's on-call schedule. Franklin Square complies with this requirement.

4) **Physicians who perform primary PCI should meet the credentialing criteria for the institution.**

Analysis

Franklin Square submitted the delineation of cardiology privileges granted to each physician. Franklin Square is in compliance with this requirement.

Category: [PCI should be performed on] Patient Groups Suitable for Primary PCI in Settings without On-Site Cardiac Surgery

a) **ST-segment elevation myocardial infarction (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) who are thrombolytic eligible or thrombolytic ineligible.**

b) **When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, 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 all cases.**

A waiver hospital is required to provide pPCI as routine treatment of choice 24/7 and achieve certain door-to-balloon times for "appropriate patients," as provided in Table A-1 of the Cardiac Surgery and PCI Services Chapter, Institutional Resources, provisions (1) and (2). The above list of Patient Groups Suitable for Primary PCI in Settings without On-Site Cardiac Surgery delineates what patients are appropriate for PCI under the Commission-issued waiver.

Based on Commission staff's review of the NCDR data, in calendar years 2011 and 2012, the patients undergoing pPCI at Franklin Square met the above inclusion criteria and were appropriate for primary PCI in settings without on-site cardiac surgery. Data from the NCDR

also suggest that patients were always taken emergently to the cardiac catheterization laboratory as required.

Franklin Square meets this requirement.

Category: Minimum and Optimal Institutional Volume

All institutions should perform a minimum of 36 and optimally 49 primary PCI procedures annually.
(Note: A program performing at least 49 cases annually, or approximately one case per week, is more likely to have the logistics and staff available for timely reperfusion of acutely ill patients. If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available.)

Analysis

Because Franklin Square is located in the metropolitan area of Baltimore, the program is required to perform a minimum of 49 pPCI cases annually. Based on Franklin Square's internal data for individual physicians, which was reviewed by those physicians, the hospital reported performing 91 primary PCI cases during 2012 (Table 8). This information is also consistent with the reported primary PCI case volume reported in the NCDR data for CY 2012. The Hospital's institutional volume is above the required minimum number of cases. The Hospital was not required to submit information for 2011 and did not include it. Commission staff notes that NCDR data for CY 2011 shows Franklin Square performed 90 cases in that year.

Table 8. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: MedStar Franklin Square Medical Center, 2012

Quarter and Year	Number of pPCI Cases
Quarter 1 (Jan-Mar 2012)	32
Quarter 2 (Apr-Jun 2012)	18
Quarter 3 (Jul-Sep 2012)	18
Quarter 4 (Oct-Dec 2012)	23
Calendar Year 2012	***91***

Source: Franklin Square Application for Renewal of Waiver, February 4, 2013, Exhibit 7.

Franklin Square meets this requirement.

Category: Process and Outcome Measures for Ongoing Quality Assessment

> **Monitoring of the outcomes of care for patients presenting with ST-elevation MI will facilitate ongoing quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project. Included would be data on: patient demographic and clinical characteristics; times of symptom onset, arrival in the emergency department, arrival in the catheterization lab, catheterization procedure onset and termination, balloon inflation, procedural outcome; complications; need for emergency cardiac surgery; incidence and indication for hospital transfers, adjunctive medical therapies and clinical outcomes (including in-hospital mortality and stroke and long-term follow-up).**

Analysis

Franklin Square is a current participant in the American College of Cardiology Foundation's NCDR ACTION Registry-GWTG and the NCDR CathPCI Registry. Franklin Square meets this requirement.

III. RECOMMENDATION

Based on the above analysis and the record in this review, MedStar Franklin Square Medical Center has substantially complied with the COMAR 10.24.17.05D(1) requirements for institutional resources, physician resources, patient groups suitable for pPCI in settings without on-site cardiac surgery, institutional volume, and process and outcome measures for ongoing quality assessment during the past two years of its most recent waiver. The only concerning compliance issue is the drop in DTB time performance in the second half of 2012. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a two-year waiver renewal that permits MedStar Franklin Square Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services, but with a condition on this renewal that will allow closer monitoring of DTB time performance for the first year of the renewal period.

Table 9. Summary of Analysis: MedStar Franklin Square Medical Center

COMAR 10.24.17.05D(1) Requirement	Compliance
Provision of primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week	Yes
Provision of primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients Effective January 1, 2010, provision of primary PCI as soon as possible and not to exceed 90 minutes from patient arrival (i.e., door-to-balloon time of ≤ 90 minutes) for 75 percent of appropriate patients	Yes
Adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week	Yes
Written commitment by hospital administration signed by the hospital president to support the program	Yes
Identification of a physician director of interventional cardiology services responsible for overall primary PCI program management	Yes
Formal, regularly scheduled (meetings every other month) interventional case review	Yes
Monthly meetings of a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory)	Yes
Formal continuing medical education program for staff, particularly in cardiac catheterization laboratory and coronary care unit	Yes
Formal, written agreement with a tertiary institution that provides for unconditional transfer	Yes
Formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request	Yes
Physicians perform 75 or more total PCI cases per year.	Yes
Physicians newly out of fellowship completed a minimum of 50 acute MIs during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.	N/A
Physicians agree to participate in an on-call schedule.	Yes
Physicians meet the credentialing criteria for the institution.	Yes
PCI performed on patient groups suitable for primary PCI in settings without on-site cardiac surgery	Yes
Optimal institutional volume of 36 or more primary PCI cases annually	Yes
Provision of data for ongoing assessment of quality of care for patients presenting with ST-elevation MI	Yes

MARYLAND HEALTH CARE COMMISSION

Two-Year Waiver Permitting Primary Percutaneous Coronary Intervention Services Without On-Site Cardiac Surgery

TO: Samuel Moskowitz
President
MedStar Franklin Square Medical Center
9000 Franklin Square Drive
Baltimore, Maryland 21237

May 16, 2013
Date

RE: Provision of Primary
Percutaneous Coronary Intervention Services
Without On-Site Cardiac Surgery

13-03-0069 WR
Docket No.

PROJECT DESCRIPTION

On May 19, 2011, the Commission issued a two-year waiver permitting MedStar Franklin Square Medical Center (Franklin Square or the "Hospital") to provide primary percutaneous coronary intervention (pPCI) services without on-site cardiac surgery services under the circumstances and conditions provided in the Waiver. In order to retain the waiver, Franklin Square applied to the Commission on February 4, 2013 for renewal of its two-year pPCI waiver.

WAIVER

The Maryland Health Care Commission has reviewed the Report and Recommendation in this matter and, based on that analysis and the record in this review, ordered on May 16, 2013, that a two-year waiver be issued that permits MedStar Franklin Square Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services under the circumstances and conditions provided in this waiver. The two-year waiver will commence on June 21, 2013 and end on June 21, 2015.

In order for the Hospital to retain the waiver, MedStar Franklin Square Medical Center must maintain compliance with the requirements for primary PCI programs found in COMAR 10.24.17, Table A-1. Table A-1 is attached to, and incorporated in, this two-year waiver. In addition, MedStar Franklin Square Medical Center shall report to MHCC, on a quarterly basis, throughout CY 2013, on all pPCI cases in which a door-to-balloon time of 90 minutes or less was not achieved and the reasons for the longer than 90 minute DTB time. The first report, covering the period of January 1, 2013 through March 31, 2013 will be due to MHCC by June 1, 2013 and the next three reports should be provided to MHCC by August 1, 2013 (for the second quarter), October 1, 2013 (for the third quarter), and February 1, 2014 (for the fourth quarter).

CHANGES TO APPROVED WAIVER

Before making any changes to the facts as stated in its application for renewal of waiver or in other information provided by the Hospital prior to Commission consideration of its application, MedStar Franklin Square Medical Center must notify the Commission in writing and receive Commission approval of each proposed change.

RENEWAL OF WAIVER

The Hospital must submit an application for renewal of its waiver before its waiver is scheduled to expire on June 21, 2015. The Commission will publish the schedule for the submission of primary PCI waiver renewal applications in the *Maryland Register* and in a posting on the Commission's website.

ACKNOWLEDGEMENT OF RECEIPT OF TWO-YEAR WAIVER

Acknowledgement of your receipt of this two-year waiver permitting MedStar Franklin Square Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery, stating acceptance of its terms and conditions, is required within thirty (30) days.

MARYLAND HEALTH CARE COMMISSION

____

Ben Steffen
Executive Director

cc: Patricia Nay, M.D., Acting Director, Office of Health Care Quality
Gregory Wm. Branch, M.D., Health Officer, Baltimore County
Robert Bass, M.D., FACEP, Executive Director, MIEMSS
Steve Ports, Acting Executive Director, HSCRC