

IN THE MATTER OF *
*
FREDERICK MEMORIAL HOSPITAL * BEFORE THE MARYLAND
*
DOCKET NO. 13-10-0064 WR * HEALTH CARE COMMISSION
*

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

I. INTRODUCTION

Frederick Memorial Hospital (FMH) is located in Frederick, Maryland (Frederick County) and has a current licensed acute care bed capacity of 298 beds, including 240 medical/surgical/gynecology/addiction beds and 18 critical care beds.¹ The Hospital is accredited by the Joint Commission and a Medicare provider in good standing. The Hospital is also accredited as a Chest Pain Center by the Society of Chest Pain Centers.

FMH provides both primary percutaneous coronary intervention (pPCI) and non-primary percutaneous coronary interventions (npPCI). Staff recently reviewed FMH's compliance with the requirements of the C-PORT E Registry and COMAR 10.24.05 and 10.24.17, Table A-1. On December 20, 2012, the Commission concluded that FMH meets these requirements, thereby allowing FMH to continue providing npPCI services without obtaining a Certificate of Conformance, a new requirement resulting from legislation passed in 2012.

FMH began providing (pPCI) services on March 14, 2008. This approval authorized FMH to provide pPCI services for a one-year period. On February 19, 2009, the Commission approved a two-year waiver for FMH to provide pPCI services without on-site cardiac surgery. The Commission renewed this waiver for two more years on February 17, 2011.

In order to retain the waiver, FMH applied to the Commission on November 14, 2012 for renewal of its pPCI waiver. This Report and Recommendation analyzes FMH'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 (Chapter) 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

¹ Maryland Health Care Commission, *Annual Report on Selected Maryland Acute Care and Special Hospital Services, Fiscal Year 2013*, Effective July 1, 2012, pages 3 and 12.

comply with all requirements for primary (emergency) PCI services 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 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. Effective July 1, 2010, Maryland acute care hospitals with a waiver from the Commission to provide pPCI are 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 use the CathPCI Registry to report quarterly data to the Commission. Staff analyzed the consistency of the FMH renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on FMH internal data 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

FMH provides primary PCI services in two cardiac catheterization laboratories. The laboratories have regular hours of operation, Monday-Friday, from 7:00 a.m. to 5:00 p.m.; on-call hours are from 5:00 p.m. to 7:00 a.m. Monday-Friday, and 7:00 a.m. to 7:00 a.m. (24 hours per day) on Saturday-Sunday.

Table 1 below shows the downtime experienced by the cardiac catheterization laboratories from October 1, 2011 until September 30, 2012. These data show that at no time did FMH fail to have a cardiac catheterization laboratory available to provide pPCI services due to downtime or equipment maintenance.

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

- **October 1, 2011-September 30, 2012**

Room	Cardiac Catheterization Laboratory Down Time			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
1	8/14/2012	8/14/2012	4	Equipment maintenance
2	7/18/2012	7/18/2012	4	Equipment maintenance
1	7/17/2012	7/17/2012	3	Equipment repair
2	7/18/2012	7/18/2012	2	Equipment repair
1	7/2/2012	7/2/2012	6.5	Equipment repair
1	6/28/2012	6/28/2012	6	Equipment repair
2	6/18/2012	6/18/2012	1.5	Equipment repair
1	6/15/2012	6/15/2012	1	Equipment repair
2	2/26/2012	2/26/2012	12	Equipment repair
1	11/2/2011	11/2/2011	1	Equipment maintenance
2	11/2/2011	11/2/2011	1	Equipment maintenance

*On 11/2/2011, Cath Lab Room #1 and Cath Lab Room #2 were out of service at different times, allowing one room to be available for STEMI/pPCI at all times.

- **October 1, 2010-September 30, 2011**

Room	Cardiac Catheterization Laboratory Down Time			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
2	12/23/2010	12/23/2010	1.0	Equipment failure/repair
1	1/16/2011	1/16/2011	2.5	Equipment maintenance
2	1/24/2011	1/24/2011	2.5	Equipment maintenance
1	2/18/2011	2/18/2011	2.0	Equipment maintenance
2	2/18/2011	2/18/2011	2.0	Equipment maintenance
1	3/02/2011	3/02/2011	1.5	Equipment failure/repair
1	5/18/2011	5/18/2011	0.5	Equipment failure/repair
2	6/13/2011	06/14/2011	22.0	Equipment failure/repair
1	9/26/2011	09/26/2011	0.5	Equipment failure/repair

*On 2/18/2011, Cath Lab Room #1 and Cath Lab Room #2 were out of service at different times, allowing one room to be available for STEMI/pPCI at all times.

Source: Frederick Memorial Hospital, Application for Renewal of Waiver, November 14, 2012, pp. 17-18.

FMH meets this requirement.

- 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.**

Analysis

As shown in Table 2, FMH internal data indicates that FMH met the current pPCI door-to-balloon time standards that 80 percent of patients have a door-to-balloon time of less than 120 minutes and 75 percent of patients have a door-to-balloon time of 90 minutes or less. As shown in Table 2, FMH met these standards for all eight quarters between October 2010 and September 2012. Overall, approximately 89 percent of patients had a door-to-balloon time of 90 minutes or less for this period.

Table 2: Primary PCI Volume, and Number and Percentage of Patients with DTB ≤ 90 minutes: Frederick Memorial Hospital, October 2010-September 2012

Quarter and Year	Primary PCI Volume	Door-to-Balloon Time	
		≤ 90 Minutes (N)	≤ 90 Minutes (%)
Quarter 1 (Jul-Sept. 2012)	20	20	100
Quarter 2 (Apr-Jun 2012)	27	25	92.6
Quarter 3 (Jan-Mar 2012)	30	28	93.3
Quarter 4 (Oct-Dec 2011)	28	26	92.9
Quarter 5 (Jul-Sept 2011)	31	26	83.9
Quarter 6 (Apr-Jun 2011)	27	23	85.2
Quarter 7 (Jan-Mar 2011)	42	35	83.3
Quarter 8 (Oct-Dec 2010)	19	16	84.2

Source: FMH Application for Renewal of Waiver, November 14, 2012, p. 9.

FMH meets this requirement.

- 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 3 shows the total number of staff involved in providing primary PCI services at FMH as of September 30, 2012. Since the prior waiver request, the CCL nursing staff increased from 4.75 to 7.5, and technical staff increased from 5.7 to 6.8. The number of physicians providing pPCI coverage at FMH has remained unchanged, at 11.

Table 3. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: Frederick Memorial Hospital (as of 9/30/2012)

Staff (1)	Number	Cross-Training (S/C/M)*
Physician	11	Not Applicable
Nurse	7.5 FTEs;	S/C/M
Cardiovascular Technologist	6.8 FTEs	S/C/M

Source: FMH Application for Renewal of Waiver, November 14, 2012, p. 20.

*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 4. FMH does not permit the primary interventional cardiologist to have simultaneous on-call duties at other hospitals.

Table 4. On-Call Primary PCI Team Staffing, Rotation, and Response Time: Frederick Memorial Hospital, September 2012

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	11	6:30 am-6:30 am Changes on a daily basis	30 minutes
Nurses	2	5:00 pm-7:00 am weekdays, starting Monday 5:00 pm and ending Saturday 7:00 am 7:00 am- 7:00 am weekends and holidays	30 minutes
Cardiovascular Technologists	2	5:00 pm-7:00 am weekdays, starting Monday 5:00 pm and ending Saturday 7:00 am 7:00 am- 7:00 am weekends and holidays	30 minutes

Source: FMH Application for Renewal of Waiver, November 14, 2013, p. 7.

*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.

FMH provides post-procedure care for pPCI patients in the Hospital's Intensive Care Unit. During the period from July 1, 2011 to June 30, 2012, the ICU's average daily census was 7.8 patients. Paid FTEs during the most recent 12 months (October 1, 2011 to September 30, 2012) included 27.9 ICU RNs and technical staff comprised of 3.6 ICU Monitor Technicians. The Society of Critical Care Medicine has provided a basic measure of nurse staffing as 14 to 17 nurse care hours per patient or a ratio of about 1:1.² FMH staffing exceeds that level.

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

Physician coverage of the ICU is provided in-house 24 hours a day/seven days a week. FMH's response indicates that its policies for physician coverage have not changed since the last waiver renewal.

FMH 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

Thomas A. Kleinhanzl, President and Chief Executive Officer of Frederick Memorial Healthcare System, has submitted a written statement committing to support the pPCI program. The renewal application states that the commitment from FMH and Mr. Kleinhanzl remains in effect.

FMH 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

The Co-Medical Directors of the FMH Interventional Cardiology program are David Brill, M.D., FACC, FSCAI and Stephen Williams, M.D., FACC, FSCAI. The directors are responsible for the professional management of the Hospital's Cardiac Catheterization Laboratory, including overall pPCI program management. Dr. Brill was the medical director at the time of FMH's last waiver renewal application. FMH's response indicates that the duties and responsibilities for the medical director position have not changed since the last waiver renewal.

FMH 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

During the period from September 1, 2011 to September 30, 2012, physicians (including interventional cardiologists, a general cardiologist, and an emergency department physician), CCL nursing and technician staff, performance improvement staff, and the Director of Cardiac and Vascular Services attended meetings. These meetings were held each month with the exception of January 2012.

FMH 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

During the period from September 1, 2011 to September 30, 2012, FMH held regularly scheduled monthly operations meetings with the exception of January 2012. Participants included: catheterization lab staff; interventional cardiologists; emergency department physician; Director of Cardiac and Vascular Services; Vice President of Nursing; Vice President for Service Line Development and Operations; and Director of Critical Care. The Battalion Chief of the Frederick County Bureau of Emergency Medical Services and Training attended five of the monthly meetings.

FMH 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

FMH provided examples of educational activities between November 2011 and September 2012. Staff from both the CCL and ICU attended a Intra-Aortic Balloon Pump (IABP) class in February 2012 and a critical care course in April 2012. Other activities included monthly Competency Reviews, Cardiovascular Class, and an Intravascular Ultrasound (IVUS) Review. The activities included programs that were approved for continuing education credits. As required, the target audiences for these programs were catheterization laboratory staff (nurses and technologists) and ICU nurses.

FMH 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

FMH's response indicates that its written agreement with a tertiary institution that provides for unconditional transfer of patients has not changed since the last waiver renewal. It has a written agreement for unconditional transfer of patients with Washington Adventist Hospital and Johns Hopkins Hospital, both of which provide cardiac surgery.

FMH 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.**

Analysis

FMH's response indicates that its transport agreement has not changed since its last waiver renewal. It has a written transport agreement with Butler Medical Transport guaranteeing arrival of a ground ambulance within 30 minutes of request. Butler is to provide the back-up to air transport for pPCI and npPCI patients. FMH has an agreement with STAT MedEvac (STAT) for air ambulance transport services. The agreement with STAT states that there may be occasions when STAT will be unable to respond within 30 minutes of a request (weather limitations, aircraft maintenance, or multiple flight requests). The helicopter transport agreement between FMH and MedSTAR Transport Service remains in effect; that agreement also states that there may be occasions when MedSTAR will be unable to respond within 30 minutes. FMH stated that Butler Medical Transport has an ambulance located in the Hospital's area 24/7 to respond to requests for ground transport.

FMH meets this requirement.

Category: Physician Resources

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

Analysis

FMH did not add any new physicians to the roster of physicians for the pPCI program at FMH since its previous waiver renewal. Table 6 provides the total PCI cases performed by the physicians with privileges at FMH over the four most recent calendar-year quarters, the period between October 1, 2011 and September 30, 2012. As shown in Table 5, all physicians met the required minimum number of annual PCI cases (75). FMH is consistent with this requirement.

**Table 5. Total Number of PCI Cases Performed by Physician:
Frederick Memorial Hospital, October 1, 2011-September 30, 2012**

Physician	Number of pPCI Cases at FMH^	Other Hospitals			Total PCI Cases-All Hospitals*
		Number of pPCI Cases	Number of npPCI Cases	Total PCI Cases	
David Brill, M.D.	8	9	97	106	120
Michael R. Castine, M.D.	0	23	62	85	85
Matthews Chacko, M.D.	6	14	104	118	125
Michael S. Chen, M.D.	0	26	87	113	113
Dennis Friedman, M.D.	0	38	76	114	114
Chao Wei Hwang, M.D.	43	3	14	17	128
Laurence Kelley, M.D.	0	20	60	80	80
Julie M. Miller, M.D.	0	26	74	100	100
Jon R. Resar, M.D.	0	20	161	181	181
Thomas H. Wang, M.D.	16	17	22	39	95
Stephen Williams, M.D.	32	1	8	9	141

*The total number of cases at all hospitals includes npPCI cases performed at FMH.

Source: FMH Application for Renewal of Waiver, November 14, 2012, pp. 23-35.

- 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

FMH reported that Dr. Chao Wei Hwang is newly out of fellowship. He first obtained privileges at FMH June 11, 2010. FMH previously provided the required documentation that Dr. Hwang completed a minimum of 50 acute MIs during his fellowship training.

FMH is consistent with this requirement.

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

Analysis

The physicians who currently perform primary PCI at FMH participate in the Hospital's on-call schedule. FMH is consistent with this requirement.

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

Analysis

FMH provided the form for delineation of privileges that each physician requesting privileges in the cardiac catheterization laboratory is required to complete. Each physician performing primary PCI has been credentialed by FMH.

FMH meets 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.

Data from FMH show that zero patients received thrombolytic therapy during each of the most recent calendar-year quarters between October 1, 2010 and September 30, 2012. In addition, FMH conducted a voluntary external review of PCI cases performed in calendar year 2011. According to FMH, the results of the review, conducted through The American Medical Foundation for Peer Review and Education, demonstrated appropriate use of both pPCI and npPCI cases.

Data from the ACCF-NCDR CathPCI Registry regarding thrombolytic therapy is consistent with the data reported by FMH. The patients undergoing primary PCI at MMC met the above inclusion criteria and were appropriate for primary PCI in settings without on-site cardiac surgery.

FMH 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 FMH is located outside the metropolitan areas of Washington and Baltimore, the program is required to perform a minimum of 36 pPCI cases annually. Data reported by FMH show that FMH performed well above the required minimum number of cases during the previous four quarters between October 1, 2011 and September 31, 2012. FMH reported performing 105 pPCI cases, as shown in Table 6. Based on ACCF-NCDR CathPCI Registry data, FMH reported performing 102 primary PCI cases during the period October 2011 to September 2012 (Table 7).

Table 6. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Frederick Memorial Hospital, October 1, 2011 to September 31, 2012

Quarter Date and Year	Number of pPCI Cases*
Quarter 1 (Oct-Dec 2011)	28
Quarter 2 (Jan-Mar 2012)	30
Quarter 3 (Apr-June 2012)	27
Quarter 4 (Jul-Sept 2012)	20
<i>All Four Quarters</i>	<i>105</i>

Source: FMH Application for Renewal of Waiver, November 14, 2012, pp.25-35.

*PCI volume refers to the number of cases where a device was used.

Table 7. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Frederick Memorial Hospital, October 1, 2011 to September 31, 2012

Quarter Date and Year	Number of pPCI Cases*
Quarter 1 (Oct-Dec 2011)	27
Quarter 2 (Jan-Mar 2012)	29
Quarter 3 (Apr-June 2012)	24
Quarter 4 (Jul-Sept 2012)	22
<i>All Four Quarters</i>	<i>102</i>

Source: MHCC staff analysis of ACCF-NCDR CathPCI Registry data.

FMH 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

FMH is a current participant in the American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR) ACTION Registry-GWTG and the NCDR CathPCI Registry. FMH also provided a copy of its outline of policies and procedures for cardiac catheterization laboratory case reviews. In addition, FMH stated that it intends to annually conduct external peer review.

FMH meets this requirement.

III. RECOMMENDATION

Based on the above analysis and the record in this review, Frederick Memorial Hospital meets 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. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a two-year waiver that permits Frederick Memorial Hospital to provide primary percutaneous coronary intervention services without on-site cardiac surgery services.

Table 8. Summary of Analysis: Frederick Memorial Hospital

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 \leq 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 \leq 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.	Yes
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: Thomas Kleinhanzl
President and CEO
Frederick Memorial Hospital
400 West Seventh Street
Frederick, Maryland 21701

February 21, 2013
Date

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

13-10-00642 WR
Docket No.

PROJECT DESCRIPTION

On February 17, 2011, the Commission issued a two-year waiver permitting Frederick Memorial Hospital (FMH 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, FMH applied to the Commission on November 14, 2012 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 February 21, 2013, that a two-year waiver be issued that permits Frederick Memorial Hospital 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 March 14, 2013 and end on March 14, 2015.

In order for the Hospital to retain the waiver, Frederick Memorial Hospital 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.

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, Frederick Memorial Hospital 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 March 14, 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 Frederick Memorial Hospital 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
Barbara Brookmyer, M.D., M.P.H., Frederick County Health Officer
Robert Bass, M.D., FACEP, Executive Director, MIEMSS