IN THE MATTER OF	*	
	*	**BEFORE THE MARYLAND**
BALTIMORE WASHINGTON	*	
MEDICAL CENTER	*	**HEALTH CARE COMMISSION**
	*	
DOCKET NO. 13-02-0068 WR	*	

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

I. INTRODUCTION

Baltimore Washington Medical Center (BWMC or the "Hospital") is located in Glen Burnie, Maryland (Anne Arundel County) and has a current licensed acute care bed capacity of 307 beds, including 265 medical/surgical/gynecology/addiction (MSGA) beds and 24 critical care beds as part of the larger MSGA bed inventory.[1] BWMC is accredited by the Joint Commission and is a Medicare provider in good standing. The hospital is part of the University of Maryland Medical System.

BWMC began providing primary percutaneous coronary intervention (pPCI) services under a research waiver as a participating hospital in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials, investigating the ability to safely provide pPCI in hospitals without cardiac surgery programs, in February, 2001. In 2006, the hospital was among the first group of non-cardiac surgery hospitals authorized to provide pPCI on a regular basis, subject to ongoing performance requirements and periodic waiver renewal. BWMC's most recent two-year waiver renewal was issued in 2011, and this renewal expires June 21, 2013.

BWMC timely applied to the Commission on February 4, 2013 for renewal of its two-year pPCI waiver. This Report and Recommendation analyzes BWMC'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 requirements for primary PCI programs without on-site cardiac surgery. From January 2006 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.

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 providing 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 use the CathPCI Registry to report quarterly data to the Commission. Staff analyzed the consistency of the BWMC renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on reported experience and data submitted by the Hospital to the ACCF-NCDR CathPCI Registry ("NCDR").

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

Since August 2010, BWMC has operated two cardiac catheterization laboratories (CCLs) used in provision of pPCI services. Both CCLs have regular hours of operation, Monday-Friday, from 6:30 a.m. to 5:00 p.m.; on-call hours of operation are from 5:00 p.m. to 6:30 a.m. Monday-Friday, and both operate 24 hours per day on Saturday and Sunday.

Table 1 below shows cardiac catheterization lab downtime experienced during calendar years 2011 and 2012. During the time that the primary CCL (Room 1) was unavailable because of equipment maintenance or repair, the backup, Room 2, was available. BWMC reported that at no time were both CCLs unavailable. BWMC also reported that no STEMI patients received thrombolytics because of a lack of pPCI availability. Data from the NCDR are consistent with the information reported by BWMC; the NCDR data show that no patients with a STEMI presentation received thrombolytics.

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

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

	CCL Downtime			
	Date		**Duration (Hours)**	
Room	**Begin**	**End**		**Reason CCL Unavailable**
1	1/31/12	1/31/12	6.0	UPS battery change
1	6/28/12	6/28/12	4.5	Preventive maintenance
1	9/25/12	9/25/12	0.5	FRU batter change
1	10/11/12	10/11/12	1.0	LS# relay replacement
1	11/17/12	11/17/12	6.0	Chiller hose repair
1	12/11/12	12/11/12	4.5	Preventive maintenance and chiller hose replacement
2	2/16/12	2/16/12	10.0	Preventive maintenance
2	7/30/12	7/30/12	6.0	Preventive maintenance
2	10/16/12	10/16/12	6.0	Preventive maintenance

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

	CCL Downtime			
	Date		**Duration (Hours)**	
Room	**Begin**	**End**		**Reason CCL Unavailable**
1	6/2011	6/2011	3.5	Preventive maintenance
1	12/7/11	12/7/11	2.5	Preventive maintenance
1	10/17/11	10/17/11	6.0	Preventive maintenance
2	4/19/11	4/19/11	10.0	Preventive maintenance
2	5/17/11	5/17/11	2.5	Table adjustment
2	7/13/11	7/13/11	6.0	Preventive maintenance
2	8/31/11	8/31/11	4.0	Part install table

Source: Baltimore Washington Medical Center, Application for Renewal of Waiver, pp. 16-17; Additional Information, April 30, 2013.

BWMC 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

Based on the Commission's analysis of NCDR data for the combined calendar years 2011 and 2012 (Table 2), BWMC met the required threshold for door-to-balloon time, providing pPCI within 90 minutes or less of hospital presentation for 88 percent of patients (185 of 211 patients). BWMC also exceeded the required standard in COMAR 10.24.17 that at least 75 percent of STEMI patients receiving primary PCI have a door to balloon time of 90 minutes or less in seven of the eight quarters and performed just below the standard, 73.7%, in the other quarter.

As shown in Table 3, BWMC internal data reports indicate that, during calendar years 2011 and 2012, BWMC provided pPCI within 90 minutes to 90.5 percent of patients (191 of 211 patients).

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 Baltimore Washington Medical Center, 2011 and 2012

Quarter and Year	Primary PCI Volume	Median Door-to-Balloon Time (Minutes)	≤ 90 Minutes (N)	≤90 Minutes (%)
Quarter 4 (Oct-Dec 2012)	27	62.0	24	88.9
Quarter 3 (Jul-Sept 2012)	34	60.0	30	88.2
Quarter 2 (Apr-Jun 2012)	35	62.0	30	85.7
Quarter 1 (Jan-Mar 2012)	24	62.0	23	95.8
Quarter 4 (Oct-Dec 2011)	19	69.0	17	89.5
Quarter 3 (Jul-Sept 2011)	29	57.5	25	86.2
Quarter 2 (Apr-Jun 2011)	19	68.0	14	73.7
Quarter 1 (Jan-Mar 2011)	24	59.0	22	91.7
All Quarters	211	Not Calculated	185	87.7

Source: MHCC staff analysis of NCDR data for calendar years 2011 and 2012.
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 applied to patients already hospitalized: the "door" ECG is the first ECG recorded showing STEMI. However, NCDR CathPCI Registry data does not capture the ECG date and time for these patients, unless the first ECG was negative.

Table 3. Primary PCI Volume, Median Door-to-Balloon (DTB) Time, and Number and Percentage of Patients with DTB ≤ 90 minutes by Quarter: Internal Data for Baltimore Washington 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)	27	60.0	25	92.6
Quarter 3 (Jul-Sept 2012)	31	54.5	26	83.8
Quarter 2 (Apr-Jun 2012)	36	62	33	91.6
Quarter 1 (Jan-Mar 2012)	26	61.0	24	92.3
Quarter 4 (Oct-Dec 2011)	19	65.0	18	94.7
Quarter 3 (Jul-Sept 2011)	30	57.5	28	93.3
Quarter 2 (Apr-Jun 2011)	19	67.0	15	78.9
Quarter 1 (Jan-Mar 2011)	23	60.0	22	95.6
All Quarters	211	Not Reported	191	90.5

Source: BWMC Application for Renewal of Waiver, February 4, 2013, p. 9.

BWMC 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.

<u>Analysis</u>

Table 4 shows the total number of staff currently involved in providing primary PCI services at BWMC. The pPCI program is currently staffed by 4 physicians, 5 FTE nurses, one supplemental RN, and 4 FTE cardiovascular technologists. BWMC noted that it is seeking to recruit a fifth technologist.

Table 4. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: Baltimore Washington Medical Center (as of February 4, 2013)

Staff	Number	Cross-Training (S/C/M)*
Physicians	4	
Nurses	5.0 staff (FTE), 1.0 Manager, and 1 SSP RN	S/C/M
Cardiovascular Technologists	4.0 (FTE) and 1.0 FTE posted	S/M

Source: BWMC Application for Renewal of Waiver, February 4, 2013, p.7.
*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. BWMC does not permit cardiologists to have simultaneous on-call duties at other hospitals.

Table 5. On-Call Primary PCI Team Staffing, Rotation, and Response Time: Baltimore Washington Medical Center

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	1	Evenly divided each month among 4 physicians	3-5 minute pager response; < 30 minute arrival
Nurses	2-3	2-3 days per week and every other weekend	3-5 minute pager response; < 30 minute arrival
Cardiovascular Technologists	2-3	2-3 days per week and every other weekend	3-5 minute pager response; < 30 minute arrival

Source: BWMC Application for Renewal of Waiver, February 4, 2014, p.8.
*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.

BWMC provides post-procedure care for pPCI patients in the Hospital's Critical Care Unit (CCU/ICU), which has 36 licensed beds. During calendar year 2012, the average daily census for the critical care beds was 22 patients. Paid FTEs included 74.5 RNs providing direct nursing care. Patient care technicians (13.2 paid FTEs) 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]

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

Intensivists are responsible for providing clinical care in the CCU. Intensivists provide physician coverage 24 hours a day, seven days a week.

BWMC 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

As part of a previous waiver renewal application, Karen E. Olscamp, FACHE, President and Chief Executive Officer of BWMC, submitted a letter, dated February 4, 2009, confirming support for the pPCI program. BWMC has indicated that the Hospital President's commitment to support the pPCI program has not changed. BWMC 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

Samuel Yoon, M.D. continues as the Medical Director of the Cardiac Catheterization Laboratory at BWMC. BWMC has indicated that the previously submitted position description for the Medical Director remains in effect. BWMC 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

BWMC held clinical case review meetings almost weekly, with a few exceptions, during calendar year 2012.

BWMC 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 BWMC met on a monthly basis with the exception of July, 2012. The membership of the multiple care area group was consistent with COMAR 10.24.17 requirements and included physicians, nurses, and other appropriate staff.

BWMC 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

BWMC provided a list of continuing educational activities in which staff in the Cardiac Catheterization Laboratory and the Coronary Care Unit participated. Educational activities encompassed the following topics: Advanced Cardiac Life Support; Moderate Sedation; vendor-sponsored in-service training on pharmaceuticals and devices; and Skills Day (ISTAT, Glucometer, IABP, ACT, Pleurovac, and Phlebotomy).

BWMC 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

BWMC has indicated that the Collaboration Agreement between University of Maryland Medical Center (UMMC) and BWMC remains in effect. BWMC 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

BWMC has indicated that the agreement for interfacility transport of both primary angioplasty and non-primary angioplasty patients between University of Maryland ExpressCare and BWMC, previously reviewed by MHCC, remains in effect. BWMC 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

Table 6 provides the total PCI cases performed by the physicians with privileges at BWMC over two 12-month periods, CY 2012 and CY 2011. Each physician met the requirement to perform 75 or more total PCI cases annually, with the exception of Dr. Miller in 2011 and Dr. Schaeffer in 2012. Dr. Miller's lower case volume in 2011 was due to taking maternity leave. In 2011, BWMC accepted that in order to remain compliant with its waiver Dr. Miller had to stop performing PCI at BWMC until the Commission received acceptable documentation of compliance with the ACC/AHA Criteria for Competency of 75 or more total PCI cases for the most recent 12-month period. This documentation was provided prior to Dr. Miller's return to BWMC, as required. Dr. Schaeffer's low case volume in 2012 resulted from his decision to retire in early September.

Table 6. Total Number of PCI Cases Performed by Physician: Baltimore Washington Medical Center, 2011 and 2012

Physicians for Reporting Period CY2012	Number of pPCI Cases at BWMC	Total PCI Cases-All Hospitals
Samuel C. Yoon, M.D.	29	92
Ratnakar Mukherjee, M.D.	37	111
Kelly L. Miller, M.D.	30	100
Allen Schaeffer, M.D.	29	49
Stafford Warren, M.D.	0	98
Physicians for Reporting Period CY2011		
Samuel C. Yoon, M.D.	19	102
Ratnakar Mukherjee, M.D.	36	89
Kelly L. Miller, M.D.	12	51
Allen Schaeffer, M.D.	26	80
Stafford Warren, M.D.	0	81

Source: BWMC Application for Renewal of Waiver, February 4, 2013, Tab 7; Additional Information, May 9, 2013.
Note: Allen Schaeffer, M.D. retired September 3, 2012.

BWMC has complied with this requirement.

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

BWMC reported that none of the above physicians is newly out of fellowship. This requirement does not apply.

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

Analysis

Each of the physicians with privileges to perform pPCI at BWMC participates in the hospital's on-call schedule. One physician, Allen Schaeffer, M.D., retired in September 2012. He was replaced by Dr. Stafford Warren in late November 2012, which is why Dr. Warren did not perform any PCI cases at BWMC for the reporting period. BWMC is in compliance with this requirement.

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

Analysis

Each physician is currently in good standing. In July 2102, BWMC renewed the privileges of three of the four interventionalists, and BWMC renewed privileges of the fourth interventionalist in October 2012.

BWMC 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.

BWMC reported that there was no time in 2011 or 2012 that a cardiac catheterization laboratory was not available for pPCI. BWMC also reported that no patients received thrombolytic therapy as a primary mode of reperfusion therapy due to a lack of lab availability. This is consistent with NCDR data that shows no patients with a STEMI presentation received thrombolytic therapy.

BWMC 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 BWMC is located in the metropolitan area of Baltimore, the program is required to perform a minimum of 49 pPCI cases annually. Staff analysis of NCDR data shows that BWMC performed 120 pPCI cases during 2012 (Table 7).

Table 7. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Baltimore Washington Medical Center, 2012

Quarter and Year	Number of pPCI Cases
Quarter 1 (Jan-Mar 2012)	24
Quarter 2 (Apr-Jun 2012)	35
Quarter 3 (Jul-Sep 2012)	34
Quarter 4 (Oct-Dec 2012)	27
Calendar Year 2012	***120***

Source: MHCC staff analysis of NCDR data for calendar year 2011.
Notes: PCI volume refers to the number of cases where a device was used.

BWMC's internal data for individual physicians' caseloads also shows a total of 120 primary PCI cases during 2012 (Table 8), which is consistent with Commission Staff's analysis of NCDR data.

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

Quarter and Year	Number of pPCI Cases
Quarter 1 (Jan-Mar 2012)	27
Quarter 2 (Apr-Jun 2012)	31
Quarter 3 (Jul-Sep 2012)	36
Quarter 4 (Oct-Dec 2012)	26
Calendar Year 2012	***120***

Source: BWMC Application for Renewal of Waiver, February 12, 2013, p. 9.

The Hospital's institutional pPCI volume is well above the required minimum number of cases. BWMC 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

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

III. RECOMMENDATION

Based on the above analysis and the record in this review, Baltimore Washington Medical Center 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 renewal of the waiver that permits Baltimore Washington Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services.

Table 9. Summary of Analysis: Baltimore Washington 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:	Karen E. Olscamp, FACHE President and CEO Baltimore Washington Medical Center 301 Hospital Drive Glen Burnie, Maryland 21061	May 16, 2013 Date
RE:	Provision of Primary Percutaneous Coronary Intervention Services Without On-Site Cardiac Surgery	13-02-0068 WR Docket No.

PROJECT DESCRIPTION

On May 19, 2011, the Commission issued a two-year waiver permitting Baltimore Washington Medical Center (BWMC 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, BWMC 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 Baltimore Washington 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, Baltimore Washington 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.

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, Baltimore Washington 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 Baltimore Washington 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

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Ben Steffen
Executive Director

cc: Patricia Nay, M.D., Acting Director, Office of Health Care Quality, DHMH
Jinlene Chan, MD, MPH, Acting Health Officer, Anne Arundel County
Robert Bass, M.D., FACEP, Executive Director, MIEMSS
Steve Ports, Acting Executive Director, HSCRC