STATE OF MARYLAND

MARYLAND HEALTH CARE COMMISSION

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MEMORANDUM

To: Commissioners

From: Eileen Fleck, Acting Chief EF.
Specialized Services Policy and Planning

Date: March 21, 2013

Re: Renewal of Primary Percutaneous Coronary Intervention (PCI) Waiver
Upper Chesapeake Medical Center
Docket No. 13-12-0066 WR

Enclosed is a staff report and recommendation on the request by Upper Chesapeake Medical Center (UCMC) for renewal of its authorization to provide primary PCI services. The report reviews the performance of UCMC in providing this service during two years that have elapsed since its last renewal and evaluates this performance against the standards adopted by the Commission for the provision of primary PCI in hospitals that do not provide cardiac surgery services.

Staff recommends the Commission authorize renewal of this waiver. While our review of the hospital's performance indicates that it has fallen short of the door-to-balloon time target established in 2010 for primary PCI, it has shown progress in improving its performance in this important process measure over the renewal period being examined, achieving the target DTB time in calendar year 2012. The hospital clearly meets all of the other 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.

IN THE MATTER OF	*	
	*	**BEFORE THE MARYLAND**
UPPER CHESAPEAKE	*	
MEDICAL CENTER	*	**HEALTH CARE COMMISSION**
DOCKET NO. 13-12-0066 WR	*	

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

I. INTRODUCTION

Upper Chesapeake Medical Center (UCMC or the Hospital) is located in Bel Air, Maryland (Harford County) and has a current licensed acute care bed capacity of 181 beds, including 166 medica l/surgical/gynecology/addictions be ds, including 1 4 c ritical care beds.[1] UCMC is part of Upper Chesapeake Health, a health system that also includes Harford Memorial Hospital (HMH) in Havre de Grace, Maryland. Harford Memorial Hospital is licensed to operate 89 beds. UCMC is accredited by the Joint Commission and a Medicare Provider in good standing.

UCMC began providing primary percutaneous coronary intervention (pPCI) services on April 4, 2008. This approval authorized UCMC to provide pPCI services for a one-year period. On March 19, 2009, the Commission approved a two-year waiver for UCMC to provide pPCI services without on-site cardiac surgery. UCMC subsequently received a second two-year waiver to provide pPCI services on March 17, 2011.

In order to retain the waiver, UCMC applied to the Commission on December 10, 2012 for renewal of its two-year pPCI waiver. This Report and Recommendation analyzes UCMC'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 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

[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 9.

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 UCMC renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on reported experience, UCMC 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

Primary PCI services at UCMC are provided in two cardiac catheterization laboratories (CCL). Both laboratories have regular hours of operation, Monday-Friday, from 7:00 a.m. to 5:00 p.m., and are on-call Monday-Friday 5:00 p.m.-7:00 a.m. and Saturday-Sunday, 24 hours per day. Table 1 shows the downtime experienced by the CCL rooms at UCMC between December 2010 and November 2012. During the time that the primary CCL Room No. 1 was unavailable, services were still available in the Interventional Angiography/Cath Lab (hybrid lab) in Room No. 2.

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

- **December 1, 2011-November 30, 2012**

Room	Cardiac Catheterization Laboratory Services Unavailable			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
2	12/13/11	12/13/11	4.2	Preventative Maintenance
1	1/10/12	1/10/12	3.8	Preventative Maintenance
2	6/27/12	6/27/12	4.5	Preventative Maintenance
1	7/10/12	7/10/12	4.6	Preventative Maintenance
1	7/19/12	7/19/12	.25	System would not boot up. Called GE. Remote access found chiller did not start up properly and signaled the generator. Rebooted the system and unit operated properly.
2	11/18/12	11/18/12	6.4	Preventative Maintenance

- **December 1, 2010-November 30, 2011**

Room	Cardiac Catheterization Laboratory Services Unavailable			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
2	12/29/10	12/29/10	4.3	Preventative Maintenance
1	1/11/11	1/11/11	4.3	Preventative Maintenance
2	6/10/11	6/10/11	4.3	Preventative Maintenance
1	7/26/11	7/26/11	4.3	Preventative Maintenance

Source: Upper Chesapeake Medical Center, Application for Renewal of Waiver, pages 18-19; Additional Information, March 12, 2013.

These data show that at no time did UCMC fail to provide pPCI services due to downtime or equipment maintenance. Upgrades are not performed during regularly scheduled Vascular Surgery or Cardiology block time.

UCMC 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 NCDR data for the period October 2010 to September 2012 (Table 2), UCMC met the required threshold for door-to-balloon (DTB) time, providing pPCI within 90 minutes or less of hospital presentation for 73.9 percent of patients (181 of 245 patients). Internal data reported by UCMC indicate slightly fewer patients received pPCI within 90 minutes or less, 71.5 percent of patients (176 of 246 patients), as shown in Table 3. UCMC used the admission date of patients rather than the procedure date for defining quarters resulting in slight differences in the counts of patients in some quarters.

Included in UCMC's internal data are 50 STEMI patients, who were transferred from Harford Memorial Hospital (HMH), which is located about 22 miles from UCMC. A total of 30 of the 50 STEMI patients transferred from HMH received pPCI therapy. Total DTB time (the time from presentation at the first facility to the time of PCI at the receiving institution) for these transferred patients was longer, with the median for each of nine quarters of data ranging from 97.8 minutes to 168 minutes, as shown in Table 4. However, for some of the quarters where UCMC fell short of the D2B standard, even after excluding the transfer cases.

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

Quarter Ending	STEMI patients receiving pPCI	Median DTB Time	STEMI Patients with DTB of 90 minutes or less	
			Number	Percent
Dec 2010	22	83.0	13	59.1%
Mar 2011	38	52.5	28	73.7%
Jun 2011	23	64.0	18	78.3%
Sep 2011	35	70.0	27	77.1%
Dec 2011	40	79.5	26	65.0%
Mar 2012	30	71.5	23	76.7%
Jun 2012	29	59.5	22	75.9%
Sep 2012	28	47.0	24	85.7%
All Quarters	245	--	181	73.9%

Source: MHCC staff analysis of NCDR CathPCI Registry Data and Additional Information 3/13/13.
*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 –the difference in minutes between the patient's arrival at any 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 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. This same algorithm is applied to patients already hospitalized: the "door" ECG is the first ECG recorded showing STEMI.

Table 3. Primary PCI Volume, and Number and Percentage of Patients with DTB ≤ 90 minutes by Quarter: Internal Data for Upper Chesapeake Medical Center, January-September 2010

Quarter Ending	STEMI patients receiving pPCI	Median DTB Time	STEMI Patients with DTB of 90 minutes or less	
			Number	Percent
Dec 2010	22	89.5	13	59.1%
Mar 2011	40	71	28	70.0%
Jun 2011	19	56	17	89.5%
Sep 2011	35	95.6	24	68.6%
Dec 2011	40	89.9	24	60.0%
Mar 2012	29	79.4	22	75.9%
Jun 2012	31	77.5	23	74.2%
Sep 2012	30	60.8	25	83.3%
All Quarters	246	Not reported	176	71.5%

Source: UCMC Application, December 10, 2012, p.11; Additional Information, January 30, 2013.

Table 4: Primary PCI Volume, Median Door-to-Balloon (DTB) Time, and Number and Percentage of Patients With DTB ≤ 120 minutes by Quarter for Patients Transferred to Upper Chesapeake Medical Center

Quarter Ending	Number of STEMI patients	STEMI patients receiving pPCI	Median DTB Time	STEMI Patients with DTB of 120 minutes or less	
				Number	Percent
Dec 2010	8	4	97.8	4	100.0%
Mar 2011	12	8	111.1	5	62.5%
Jun 2011	3	0	NA	NA	NA
Sep 2011	4	4	104.8	4	100.0%
Dec 2011	7	5	168	2	40.0%
Mar 2012	6	4	114.5	3	75.0%
Jun 2012	7	4	150.3	1	25.0%
Sep 2012	3	1	99	1	100.0%
All Quarters	57	36	Not reported	26	72.2%

Source: Additional Information from UCMC, January 30, 2013.

UCMC explained that one reason for its mixed performance in meeting the door-to-balloon standard for the review period is that between August and November 2011, the data coordinator position was vacant. As a result, UCMC states that it did not have solid feedback on its performance. UCMC reports that it has developed a plan to avoid this problem in the future by monitoring data closely regardless of staff turnover. UCMC states that data entry is now faster and problems are identified and reviewed within a week of their occurrence.

UCMC explained that it has taken steps to reduce its door to balloon times, such as purchasing LIFENET modems for all EMS units in Harford and Cecil counties and public education efforts to call 911. These changes were also noted in the waiver renewal two years ago. UCMC also reported that it has recently implemented a method to scan and send encrypted EKGs performed in the emergency department to the interventional cardiologists' cell phones for cases requiring collaborative review. Previously, a cardiologist had to be near a fax machine to receive the information. UCMC stated that this change has decreased decision time in identification of equivocal EKG results.

Although UCMC had a door-to-balloon time of 90 minutes or less for only about 70 percent of its STEMI patients over 24 months, UCMC has taken steps to improve the percentage of patients that meet the door-to-balloon time standard, and the Hospital has maintained a substantial level of compliance. The most recent 12 months of data suggest that progress has been made. Based on MHCC calculations from the NCDR data for the first three quarters of 2012 and data reported by the applicant for the last quarter of 2012, for this twelve-month period, UCMC achieved a DTB time of 90 minutes or less for 83 percent of patients..

On this basis, Staff recommends that UCMC be found to have met 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 5 shows the total number of staff currently involved in providing primary PCI services at UCMC. Since December 2010, the hospital has increased the CCL nursing staff from 9.0 to 10.0 FTEs, and there are slightly fewer pro re nata (PRN) nurses (five instead of six). The number of technicians has increased from 5.0 to 6.0 FTEs and the hospital has added added two PRN technologists. The pPCI program is now staffed by four physicians instead of 10.

Table 5. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: Upper Chesapeake Medical Center (as of 12/01/12)

Staff	Number	Cross-Training (S/C/M)*
Physicians	4	Not applicable
Nurses	10.0 FTEs; 5.0 PRN RNs**	9 C/M; 1 S/C/M C/M
Cardiovascular Technologists	6.0 FTEs 2 PRN**	C/M

Source: UCMC Application for Renewal of Waiver, December 10, 2012, p. 9;
*Staff are cross-trained to scrub (S), circulate (C), and monitor (M).
**Nurses and technologists are retained when necessary (PRN).

The number of physicians, nurses, and technicians who make up each on-call team is shown in Table 6. UCMC permits cardiologists to have simultaneous on-call duties at other hospitals. If the on-call interventional cardiologist is not available or cannot respond to the cardiac cath lab in a timely fashion, the patient is transferred to a tertiary facility. UCMC indicated that its policies and procedures when the on-call physician is unavailable have not changed since they were last submitted to the Commission.

Table 6. On-Call Primary PCI Team Staffing, Rotation, and Response Time: Upper Chesapeake Medical Center, December 2012

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	1	5:00 p.m. to 7:00 a.m. Mon-Fri; 24 hours Sat-Sun. Four interventional cardiologists provide 1 weekend of call every 4 weeks and 1 weekend of backup on call coverage. Night shift call during the week is divided equally among the four cardiologists.	30 minutes
Nurses	2	5:00 p.m. to 7:00 a.m. Mon-Fri; 24 hours Sat-Sun. Two weekends and 9 weekdays in a 6-week period.	30 minutes
Cardiovascular Technologists	2	5:00 p.m. to 7:00 a.m. Mon-Fri; 24 hours Sat-Sun. Two weekends and 9 weekdays in a 6-week period.	30 minutes

Source: UCMC Application for Renewal of Waiver, December 10, 2012, p. 10.
*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.

UCMC provides post-procedure care for pPCI patients in the hospital's 14-bed Intensive Care Unit (ICU) and 25-bed intermediate care unit (IMC). During the period from November 1, 2011 to October 30, 2012, the ICU's average daily census was 11.4 patients, and the IMC's average daily census was 21.3 patients. Paid FTEs included 33.7 RNs providing direct nursing care. Nursing Technicians (5.1 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] This appears to be the approximate ratio at UCMC.

There are dedicated physicians that provide 24/7 medical coverage of the ICU.

UCMC 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

Lyle E. Sheldon, President and Chief Executive Officer of Upper Chesapeake Health, submitted a written statement committing to support the pPCI program as part of the original pPCI waiver application. The renewal application includes a letter from Mr. Sheldon, stating that Upper Chesapeake Health remains 100 percent committed to the pPCI program as a key component of the system's Cardiovascular Service Line. UCMC 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

Michael N. Drossner, M.D. continues to be the Medical Director of the Cardiac Catheterization Laboratories at UCMC. The Medical Director is responsible for defining and implementing credentialing criteria, delivery of care and services in the Cardiac Catheterization

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

Laboratory consistent with ACC/AHA/MHCC requirements, and other tasks as required by COMAR 10.24.17.05D(1). UCMC indicates that no changes have been made in the position description since the last waiver renewal.

UCMC 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

UCMC stated that the hospital currently reviews all STEMI cases. Meetings were held about twice a month, on average, between December 2011 and November 2012. However, there were no meetings held in April, May, or June of 2012. An interventional cardiologist along with authorized staff, review cases performed by other interventional cardiologists. If a case does not meet all requirements, then the interventional cardiologist reviewing the case or the Quality Health Information Management staff may seek further review. In addition to these case reviews, the hospital holds two peer review meetings per year. Case review records that require further review are held for the peer review process.

UCMC 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 November 2011 to October 2012, UCMC held ten regularly scheduled meetings of its multiple area care group (no meeting was held in March or July 2012). In addition to CCL staff, participants included: Director, Cardiac Catheterization Laboratory; Director, Echo Lab; Emergency Medicine physicians; STEMI Data Coordinator; Quality Management Specialist; Nurse Manager of the ICU; STEMI Data Coordinator; Nursing Educators; Directors of the Emergency Departments at HMH and UCMC; representatives from Maryland ExpressCare (transportation service); and representatives of Harford County EMS and Cecil County EMS.

UCMC 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

Educational activities attended by CCL and critical care unit staff over the period from November 2011 to October 2012 included vendor-sponsored Intra-Aortic Balloon Pump training; instruction regarding Zoll© Life Vest (wearable cardioverter defibrillator) by a company representative; radiation safety training, intravascular ultrasound training, training on radial artery management post-cardiac catheterization, and capnography.

UCMC 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

UCMC has a patient transfer agreement with the University of Maryland Medical Center. This agreement for unconditional transfer of pPCI patients became effective February 15, 2011 and renews automatically for additional one-year terms, if neither party terminates the agreement.

UCMC 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

UCMC stated that the applicable agreements previously submitted are still active. In May 2009, UCMC executed an agreement with STAT MedEvac (STAT) for air ambulance transport services. Executed in May 2009, the agreement with STAT states that STAT may be unavailable at times due to high demand or emergencies or other unforeseen circumstances; UCMC is responsible to obtain substitute air ambulance transport services.

The current waiver renewal application also includes an Ambulance Service Agreement that Upper Chesapeake Health System executed in June 2009 and amended on February 1, 2011, in which Hart to Heart Ambulance Service agrees to arrive within thirty (30) minutes of receipt of call for all requests to transport STEMI patients enrolled in the primary PCI program.

UCMC 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 7 provides the total PCI cases performed by the physicians with privileges at UCMC during the period from October 2010 to September 2012. At the time of application, all but four of the physicians were no longer performing primary PCI at UCMC. The other eight physicians stopped working in the laboratory between April and June 2011.

Table 7. Total Number of PCI Cases Performed by Physician: Upper Chesapeake Medical Center, October 1, 2010-September 30, 2012

Physician	Number of pPCI Cases at UCMC	Total PCI Cases-All Hospitals
Reporting Period (10/1/11-09/30/12)		
Martin A. Albornoz, M.D.	21	248
Michael N. Drossner, M.D.	59	200
Raymond H. Plack, M.D.	26	222
Matthew R. Voss, M.D.	25	120
Reporting Period (10/1/10-09/30/11)		
Martin A. Albornoz, M.D.	1	173
Michael N. Drossner, M.D.	61	205
Benjamin V. DuBois, M.D.	3	104
Anuj Gupta, M.D.	1	133
Kourosh Mastali, M.D.	10	146
Henry Meilman, M.D.	4	51
Raymond H. Plack, M.D.	12	182
Henry S. Sun, M.D.^	13	122
Matthew R. Voss, M.D.	9	190

Source: UCMC Application, December 10, 2012, pp. 25-36 and Additional Information, January 30, 2013.
Note: For eight physicians not currently practicing at UCMC, UCMC did not attempt to report their PCI case volumes since leaving UCMC's roster.

The above data show that all four of the physicians currently practicing at UCMC, Martin A. Albornoz, M.D., Michael N. Drossner, M.D, Raymond H. Plack, M.D., and Matthew R. Voss, M.D., performed at least 75 PCI cases during the most recent 12 months at the time of the application.

UCMC complies 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

UCMC has not granted privileges to any physician less than three years out of fellowship training. UCMC complies with this requirement.

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 UCMC participate in the on-call schedule. UCMC complies with this requirement.

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

Analysis

UCMC submitted the delineation of cardiology privileges granted to each physician. The hospital requires that interventional cardiologists perform a minimum of 75 coronary interventional procedures per year in order to maintain privileges.

UCMC complies 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.

UCMC reports that no patients received thrombolytic therapy either adjunctively or as primary reperfusion therapy. NCDR data reviewed by Commission staff confirm this report.

UCMC 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 UCMC is located in the metropolitan area of Baltimore, the program is required to perform a minimum of 49 pPCI cases annually. UCMC reported that, based on internal data, its cardiac interventionalists performed 130 pPCI cases between October 1, 2011 and September 30, 2012 (Table 8).

Table 8. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Upper Chesapeake Medical Center, October 2011-September 2012

Quarter and Year	Number of pPCI Cases*
Quarter 1 (Oct-Dec 2011)	40
Quarter 2 (Jan-Mar 2012)	29
Quarter 3 (Apr-Jun 2012)	31
Quarter 4 (Jul-Sep 2012)	30
October 2011-September 2012	***130***

Source: MHCC staff analysis of UCMC Application, December 10, 2012, p.11; Additional Information, March 13, 2013.
*PCI volume refers to the number of cases where a device was used. All patients undergoing PCI were appropriate for pPCI in settings without on-site cardiac surgery.

Based on UCMC internal data, the hospital reported performing 116 primary PCI cases during the period from October 1, 2010 to September 30, 2011 (Table 9). The hospital's institutional volume is well above the required minimum number of cases.

Table 9. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Upper Chesapeake Medical Center, October 2010-September 2011

Quarter and Year	Number of pPCI Cases
Quarter 1 (Oct-Dec 2010)	22
Quarter 2 (Jan-Mar 2011)	40
Quarter 3 (Apr-Jun 2011)	19
Quarter 4 (Jul-Sep 2011)	35
October 2010-September 2011	***116***

Source: MHCC staff analysis of UCMC Application, December 10, 2012, p11; Additional Information, March 13, 2013.

UCMC's performance 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

UCMC 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. UCMC meets this requirement.

III. RECOMMENDATION

Based on the above analysis and the record in this review, Upper Chesapeake 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. While this review indicates that UCMC has fallen short of the door-to-balloon time target established in 2010 for primary PCI, it has shown progress in improving its performance over the renewal period being examined, achieving the target DTB time in calendar year 2012. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a

two-year waiver that permits Upper Chesapeake Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services.

Table 9. Summary of Analysis: Upper Chesapeake 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.	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: Lyle E. Sheldon, FACHE
President and CEO
Upper Chesapeake Health
520 Upper Chesapeake Drive, Suite 405
Bel Air, Maryland 21014-4324

March 21, 2013
Date

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

13-12-0066 WR
Docket No.

PROJECT DESCRIPTION

On March 17, 2011, the Commission issued a two-year waiver permitting Upper Chesapeake Medical Center (UCMC 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, UCMC applied to the Commission on December 10, 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 March 21, 2013, that a two-year waiver be issued that permits Upper Chesapeake 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 April 4, 2013 and end on April 4, 2015.[3]

In order for the Hospital to retain the waiver, Upper Chesapeake 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.

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[3] Based on 2012 statutory amendments, this time frame is subject to changes currently in process that will transform the current primary PCI waiver program to a regulatory oversight process involving periodic renewals of Certificates of Continuing Conformance.

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, Upper Chesapeake 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 April 4, 2015.[4] 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 Upper Chesapeake 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
Susan C. Kelly, Health Officer, Harford County
Robert Bass, M.D., FACEP, Executive Director, MIEMSS

[4] Ibid.