IN THE MATTER OF	*	
	*	**BEFORE THE MARYLAND**
MEDSTAR SOUTHERN MARYLAND	*	
HOSPITAL CENTER	*	
	*	**HEALTH CARE COMMISSION**
DOCKET NO. 13-16-0071 WR	*	

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

I. INTRODUCTION

MedStar Southern Maryland Hospital Center (SMHC or the "Hospital") is located in Clinton, Maryland (Prince George's County) and has a current licensed acute care bed capacity of 239 beds, including 180 medical/surgical/gynecology/addiction (MSGA) beds and 24 critical care beds as part of the larger MSGA bed inventory.[1] SMHC is accredited by the Joint Commission and is a Medicare provider in good standing. The Hospital is also accredited by the Society of Chest Pain Centers as an Accredited Chest Pain Center with PCI.

SMHC began providing primary percutaneous coronary intervention (pPCI) services under the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Registry in January 2002. On June 18, 2009, the Commission approved a two-year waiver for SMHC to continue providing pPCI services without on-site cardiac surgery. The two-year waiver began on July 19, 2009. SMHC subsequently requested and received another two-year waiver valid through July 19, 2013.

In order to retain the waiver, SMHC timely applied to the Commission on March 13, 2013 for renewal of its two-year pPCI waiver. This Report and Recommendation analyzes SMHC'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

[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.

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 SMHC renewal application with the requirements specified in COMAR 10.24.17.05D(1) based SMHC 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

SMHC continues to use two rooms in the cardiac catheterization laboratory (CCL) to perform primary PCI procedures. The routine hours of operation are from 7:00 AM to 6:00 PM, Monday through Friday; on-call coverage is provided from 6:00 PM until 7:00 AM, Monday through Friday. Both rooms now have on-call hours of operation from 7:00 AM until 7:00 AM (24 hours per day) on Saturday and Sunday. Table 1 below shows cardiac catheterization lab downtime experienced between March 2012-February 2013 and March 2011-February 2012.

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

- **January 1, 2012-February 28, 2013**

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
1	1/5/12	1/5/12	0.5	Monitoring system failed requiring reboot
1	1/28/12	1/28/12	4.0	Preventative maintenance
1	2/7/12	2/7/12	2.0	Workstation failure requiring reboot and clearing of cases from system
1	2/8/12	2/8/12	1.5	Volcano crash
1	5/3/12	5/3/12	0.5	Workstation failure requiring reboot
1	6/28/12	6/28/12	4.0	Preventative maintenance
1	7/11/12	7/11/12	1.5	Volcano crash
1	7/12/12	7/12/12	2.0	Injector crash and repair
1	8/6/12	8/6/12	2.0	Workstation failure requiring reboot and clearing of cases from system
1	9/19/12	9/19/12	0.5	Workstation failure requiring reboot
1	11/12/12	11/12/12	0.5	Workstation failure requiring reboot
1	12/01/12	12/01/12	4.0	Preventative maintenance
1	1/13/13	1/13/13	4.0	X-ray equipment maintenance; lubrication & clean; workstation not booting up
2	1/24/12	1/24/12	1.0	Injector crash requiring multiple reboots
2	3/15/12	3/15/12	0.5	Workstation failure requiring reboot
2	3/20/12	3/20/12	4.0	Equipment maintenance; lubrication & clean
2	5/9/12	5/9/12	0.5	Injector crash and repair
2	6/26/12	6/26/12	4.0	Preventative maintenance
2	6/28/12	6/28/12	0.5	Preventative maintenance (afternoon, not at same time of day as CCL#1 down)
2	6/29/12	6/29/12	4.0	Chiller repair
2	7/23/12	7/23/12	5.5	Preventative maintenance
2	10/2/12	10/2/12	0.5	Volcano crash
2	12/19/12	12/19/12	5.5	Preventative maintenance
2	1/4/13	1/4/13	5.0	Preventative maintenance
2	1/13/13	1/13/13	4.0	X-ray equipment maintenance; lubrication & clean; workstation not booting up

Note: On February 16, 2013, both CCLs were available. However, due to accidental release of fire extinguisher and clean up in ED, for 16 hours MSMHC was placed on mini-disaster status.

- **January 1, 2011-December 31, 2012**

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
1	1/6/11	1/6/11	1.0	Volcano crash
1	1/24/11	1/24/11	4.5	Preventative maintenance
1	1/25/11	1/25/11	1.0	Injector crash
1	2/3/11	2/3/11	0.5	WITT system crash
1	3/18/11	3/18/11	0.5	WITT system crash
1	4/5/11	4/5/11	1.5	Volcano crash
1	4/7/11	4/7/11	0.5	WITT system crash
1	5/18/11	5/18/11	0.5	WITT system crash
1	8/17/11	8/17/11	0.5	Volcano crash
1	8/29/11	8/29/11	2.5	Workstation failure requiring reboot
1	9/6/11	9/6/11	1.0	Injector crash
1	10/4/11	10/4/11	4.5	Preventative maintenance
1	10/12/11	10/12/11	0.5	WITT system crash
1	11/28/11	11/28/11	0.5	WITT system crash
2	1/27/11	1/27/11	3.0	Equipment maintenance; lubrication & clean
2	2/15/11	2/15/11	3.5	Injector crash and repaired
2	5/11/11	5/11/11	0.5	WITT system crash
2	5/13/11	5/13/11	5.0	Crash-chiller issue
2	6/2/11	6/2/11	4.0	Preventative maintenance
2	6/27/11	6/27/11	1.0	Injector crash
2	8/3/11	8/3/11	1.0	Injector crash
2	8/11/11	8/11/11	5.5	Crash-chiller issue
2	9/6/11	9/6/11	1.0	Injector crash
2	9/13/11	9/13/11	0.5	WITT system crash
2	9/29/11	9/29/11	0.5	WITT system crash
2	10/12/11	10/12/11	0.5	WITT system crash
2	11/16/11	11/16/11	2.5	Volcano crash
2	11/28/11	11/28/11	0.5	WITT system crash
2	12/8/11	12/8/11	1.0	Volcano crash
2	12/13/11	12/13/11	1.05	Injector crash
2	12/21/11	12/21/11	0.5	WITT system crash

Source: SMHC Application for Renewal of Waiver, pp. 20-23; SMHC Additional Information, June 3, 2013.

SMHC takes one room out of service at a time for maintenance and repair; there were no periods of time when both CCL rooms were unavailable. In addition, NCDR data and monthly reports submitted by SMHC indicate that there were no times in 2011 or 2012 when the lab or staff was unavailable to provide pPCI services to patients. SMHC 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 NCDR data for calendar year (CY) 2011 and CY 2012 combined (Table 2), SMHC met the required threshold for door-to-balloon (DTB) time, providing pPCI in 90 minutes or less of hospital presentation for 80.6 percent of patients (174 of 216 patients). SMHC's performance on this standard was similar for CY 2011 and CY 2012 at 79.8 percent and 81.2 percent respectively.

Table 2. Primary PCI Volume, Median Door-to-Balloon (DTB) Time, and Number and Percentage of Patients by DTB ≤ 90 Minutes by Quarter: NCDR Data for MedStar Southern Maryland Hospital Center, CY 2011 and CY 2012

Quarter and Year	Primary PCI Volume	Median Door-to-Balloon Time (Minutes)	Door-to-Balloon Time	
			≤ 90 Minutes (N)	≤90 Minutes (%)
Quarter 4 (Oct-Dec 2012)	27	66.0	20	74.1
Quarter 3 (July-Sept 2012)	26	59.0	24	92.3
Quarter 2 (Apr-June 2012)	27	79.0	19	70.4
Quarter 1 (Jan-Mar 2012)	37	71.0	32	86.4
Quarter 4 (Oct-Dec 2011)	24	72.5	22	91.7
Quarter 3 (July-Sept 2011)	29	78.0	21	72.4
Quarter 2 (Apr-June 2011)	26	77.0	22	84.6
Quarter 1 (Jan-Mar 2011)	20	78.0	14	70.0
All Quarters	216	Not Calculated	174	80.6

Source: MHCC staff analysis of NCDR data for calendar years 2011 and 2012; SMHC Additional Information, July 8, 2013. For each quarter, the case count is based on the procedure date of the patient.

Note: PCI volume refers to the number of cases where a device was used. DTB time is the difference in minutes between the patient's arrival in the hospital emergency room and the time of first device use. 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 electrocardiogram (ECG). *If and only if* the first ECG is normal/non-diagnostic *and* is noted in the NCDR CathPCI Registry database along with a second ECG showing STEMI, then the date and time of the second (diagnostic) ECG are used as the "door" to calculate DTB time. Historically, for patients already hospitalized: the "door" ECG is the first ECG recorded showing STEMI. However, the NCDR CathPCI Registry does not capture the ECG date and time for these patients, unless the first ECG was negative.

As shown in Table 2, although overall SMHC met the DTB time requirements, in four quarters it fell below the DTB standard of 75 percent of cases within 90 minutes or less. There were a variety of reasons for delays, including a patient's other health conditions, difficulty crossing the lesion, and delays with triage. It does not appear that transfer cases were a significant factor. In 2012, SMHC had only two transfer cases. The average DTB time for these cases was 205 minutes. In 2011, SMHC reported that it had one transfer case, with a DTB of 900 minutes. SMHC attributed the long delay to the patient's condition, which was unstable; the patient had cardiopulmonary resuscitation three times in the intensive care unit prior to transfer to SMHC. The patient was also in cardiogenic shock and intubated. The time between the patient's arrival at SMHC and deployment of a device for the PCI procedure was only 58 minutes.

As a condition of SMHC's previous waiver renewal, SMHC was required to maintain compliance with the DTB time standard because it failed to meet the standard for CY 2010; only 67 percent of its cases had a DTB time of 90 minutes or less in CY 2010. SMHC was required to report to the Commission monthly data on DTB times covering the period from June 1 through December 31, 2011, and provide written notice to the Commission no later than fifteen (15) days after the last day of the calendar year if data covering the period from January 1 through December 31, 2011, or the period from January 1 through December 31, 2012, showed that the Hospital had not attained and maintained compliance. SMHC met these conditions and demonstrated substantial improvement in its DTB times for both CY 2011 and CY 2012. SMHC meets the DTB time standard.

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 currently involved in providing primary PCI services at SMHC. Since SMHC's previous waiver renewal, the Hospital has added two physicians to its roster of interventionalists providing coverage for the pPCI program. The CCL nursing staff has increased from 11 FTEs and 1 additional RN as needed (PRN), to 14.75 FTEs. The number of technical staff also increased from 5 FTE and 1 PRN to 6.25 FTEs. Four radiology technologists and two cardiovascular technologists staff the CCL.

Table 3. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: MedStar Southern Maryland Hospital Center (as of March 1, 2013)

Staff	Number	Cross-Training (S/C/M)*
Physicians	6	
Nurses	14 (1.0 FTE);1 (0.75 FTE) 1 PRN (0)	9 RN (S/C/M); 2 RN (C/M); 3 RN (M)
Technicians	6 (1.0 FTE) 1 (.25 FTE)	4 RT (S/C/M); 2 CVT S/C/M

Source: SMHC Application for Renewal of Waiver, March 13, 2013, p. 9.
*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. The additional members vary depending on the schedule and availability of staff (for example, a second RN or a third technician). SMHC does not permit cardiologists to have simultaneous on-call duties at other hospitals.

Table 4. On-Call Primary PCI Team Staffing, Rotation, and Response Time: MedStar Southern Maryland Hospital Center

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	1	2 days/2 evenings/week; 1 weekend/month	10 minutes call-back; 30 minutes arrival
Nurses	1-2	6 days or evenings/month	10 minutes call-back; 30 minutes arrival
Technicians	2-3	6 days or evenings/month	10 minutes call-back; 30 minutes arrival

Source: SMHC Application for Renewal of Waiver, March 13, 2013, 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.

SMHC provides post-procedure care for pPCI patients in the hospital's Critical Care Department, which has 24 licensed critical care beds and is comprised of a 12-bed intensive care unit and a 12-bed coronary care unit. For the most recent 12-months reported (March 2012-2013), the department's average daily census was 7 patients. The number of paid FTEs providing direct nursing care included 51 hospital RNs and 0.5 agency RN. Certified nursing assistants (2.3 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]

Intensivists provide dedicated 24/7/365 physician coverage in the Critical Care Department. SMHC 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

Michael J. Chiaramonte, M.D., President of the Hospital has stated in writing that the administration fully supports the hospital's primary PCI program and will continue to do so. The

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

renewal application included a copy of this letter, which is dated March 12, 2013. SMHC 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

Roy Leiboff, M.D., an interventional cardiologist, continues as the Medical Director of the Cardiac Catheterization Lab at SMHC. SMHC has indicated that the duties and responsibilities of the Medical Director have not changed since the previous waiver renewal. These responsibilities include organizing and overseeing a Quality Assurance Program; overseeing interventional case review; chairing a committee that reviews primary PCI system issues; overseeing materials and equipment necessary for the program; and reviewing the performance of physicians and providing remedies that include enforced proctorship or loss of privileges. SMHC 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

SMHC provided information concerning dates and attendance at primary PCI case review meetings during the most recent twelve months prior to submission of its waiver renewal application. Meetings were held each month between March of 2012 and March of 2013. SMHC 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

SMHC provided information concerning dates and attendance at meetings of the multiple care area group. The group includes physicians (Interventional Cardiology Director, interventional cardiologists, ICU/CCU Director, ED Director and physician); nurses (IR/CCL Manager, CCL nurses, Vice President for Cardiovascular Services, PCI coordinators, Chest Pain

Center Coordinator, ED Nursing Director, and CC Nursing Educator); and other staff (hospital CEO, Chief Nursing Officer, Vice President for Quality and Risk, Vice President General Counsel, EMS Liaison, and Vice President for Radiology). Between March 2012 and February 2013, the group met monthly. SMHC 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

SMHC supplied examples of educational activities provided for the CCL and critical care staffs during the period from March 2012 to March 2013. Topics included the NCDR Update (2012), Trends in Critical Care Nursing; Care of the Patient with Cardiovascular Disorders; Cardiovascular Assessment and Hemodynamics; Spotlight in Critical Care; Applied Clinical Excellence in Electrophysiology and Intra-Cardiac Cartosound Acunav, Cath Tech Training; Atrial Fibrillation; Cardiovascular Care Coordinator Bootcamp; Ultra AngioJet Rheolytic Thrombectomy System; IMPACT Coding and Documentation Update. SMHC meets this requirement.

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

Analysis

The Patient Transfer Agreement and Addendum executed by Washington Hospital Center and Southern Maryland Hospital, Inc., remains in effect. SMHC 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

SMHC stated that its transport agreements remain in effect. A Helicopter Transport Agreement between SMHC and MedSTAR Transport service commenced on April 1, 2006, and meets the requirement. SMHC also has a compliant Ground Ambulance Services Agreement with LifeStar Response of Maryland. SMHC 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 5 provides the total PCI cases performed by the hospital's interventionalists.

Table 5. Total Number of PCI Cases Performed by Physician: MedStar Southern Maryland Hospital Center, 2011 and 2012

Physicians for Reporting Period: 1/1/12-12/31/12	Number of pPCI Cases at SMHC	Total PCI Cases-All Hospitals*
Srinivas Addala, M.D.	18	84
Muhammad Ashraf, M.D.	34	88
Vivek Bahl, M.D.	0	75
Nicholas Balaji, M.D.	26	77
Roy H. Leiboff, M.D.	32	96
Rajendra R. Shetty, M.D.	7	99
Physicians for Reporting Period: 1/1/11-12/31/11		
Srinivas Addala, M.D.	28	97
Muhammad Ashraf, M.D.	25	77
Vivek Bahl, M.D.	0	100
Nicholas Balaji, M.D.	13	197
Roy H. Leiboff, M.D.	26	113
Rajendra R. Shetty, M.D.	7	105

*The total number of cases at all hospitals includes npPCI cases performed at SMHC as part of the C-PORT E Study.
Source: SMHC Application for Renewal of Waiver, March 13, 2013, pp. 30-35; Additional Information, June 5, 2013.

Each physician was in compliance with the ACC/AHA criteria for competency in CY 2011 and CY 2012. SMHC is consistent 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

There is one physician newly out of fellowship, Nicholas Balaji, M.D. SMHC provided a copy of a letter from the program director where Dr. Balaji completed his fellowship training confirming that he participated as first operator in over 50 PCI procedures for myocardial infarction. SMHC meets this requirement.

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

Analysis

Each of the physicians participates in the hospital's on-call schedule. SMHC is consistent with this requirement.

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

Analysis

The credentialing criteria include the above-listed ACC/AHA criteria. SMHC renewed the clinical privileges of each physician in 2012. SMHC is consistent 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.

SMHC stated that no patients received thrombolytic therapy as primary reperfusion therapy or received PCI after primary thrombolytic therapy failed. Data from the Commission staff's analysis of the NCDR data confirm that, during the CY 2012 and CY 2011, there were no patients who received thrombolytic therapy as primary reperfusion therapy. The patients undergoing primary PCI at SGAH met the above inclusion criteria and were appropriate for primary PCI in settings without on-site cardiac surgery. SMHC 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 SMHC is located in the metropolitan area of Washington, the program is required to perform a minimum of 49 pPCI cases annually. Data from SMHC show that interventionalists at the Hospital performed 117 pPCI cases during 2012 (Table 6).

Table 6. Number of Patients Who Had Primary Percutaneous Coronary Intervention by Quarter: MedStar Southern Maryland Hospital Center, 2012

Quarter and Year	Number of pPCI Cases*
Quarter 1 (Jan-Mar 2012)	37
Quarter 2 (Apr-Jun 2012)	27
Quarter 3 (Jul-Sep 2012)	26
Quarter 4 (Oct-Dec 2012)	27
Calendar Year 2012	***117***

Source: SMHC Application for Renewal of Waiver, 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 SMHC internal data, the hospital reported performing 99 primary PCI cases during 2011 (Table 7).

Table 7. Number of Patients Who Had Primary Percutaneous Coronary Intervention by Quarter: MedStar Southern Maryland Hospital Center, 2011

Quarter and Year	Number of pPCI Cases
Quarter 1 (Jan-Mar 2011)	20
Quarter 2 (Apr-Jun 2011)	26
Quarter 3 (Jul-Sep 2011)	29
Quarter 4 (Oct-Dec 2011)	24
Calendar Year 2011	***99***

Source: SMHC Application for Renewal of Waiver, March 13, 2013, p. 30-35; Additional Information, June 5, 2013.

The hospital's institutional volume is well above the required minimum number of cases. SMHC 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

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

III. RECOMMENDATION

Based on the above analysis and the record in this review, Southern Maryland Hospital Center meets the COMAR 10.24.17.05D(1) requirements for 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 Southern Maryland Hospital Center to continue providing primary percutaneous coronary intervention services without on-site cardiac surgery services.

Table 8. Summary of Analysis: MedStar Southern Maryland Hospital 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	Yes
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: Michael J. Chiaramonte
Chief Executive Officer
Southern Maryland Hospital Center
7503 Surratts Road
Clinton, Maryland 20735

July 18, 2013
Date

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

13-16-0071 WR
Docket No.

PROJECT DESCRIPTION

On June 16, 2011, the Commission issued a two-year waiver permitting MedStar Southern Maryland Hospital Center (SMHC 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, SMHC applied to the Commission on March 13, 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 July 18, 2013, that a two-year waiver be issued that permits Southern Maryland Hospital Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services. The two-year waiver will commence on July 19, 2013 and end on July 19, 2015.

In order for the Hospital to retain the waiver, MedStar Southern Maryland Hospital 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, MedStar Southern Maryland Hospital 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 July 19, 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 Southern Maryland Hospital 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
Pamela Creekmur, Health Officer, Prince George's County
Robert Bass, M.D., FACEP, Executive Director, MIEMSS