

IN THE MATTER OF
SHADY GROVE ADVENTIST
HOSPITAL
DOCKET NO. 13-15-0070 WR

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BEFORE THE MARYLAND
HEALTH CARE COMMISSION

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

I. INTRODUCTION

Shady Grove Adventist Hospital (SGAH or the “Hospital”) is located in Rockville, Maryland (Montgomery County) and has a current licensed acute care bed capacity of 331 beds, including 250 medical/surgical/gynecology/addiction (MSGA) beds and 28 adult critical care beds as part of the larger MSGA bed inventory.¹ SGAH 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.

SGAH began providing primary percutaneous coronary intervention (pPCI) services in 1996, under a research waiver granted to the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT). On June 18, 2009, the Commission approved a two-year waiver for SGAH to continue providing pPCI services without on-site cardiac surgery. In 2011, SGAH subsequently applied for and received renewal of its two-year waiver. In order to retain its current waiver, SGAH applied to the Commission on March 12, 2013 for renewal of its two-year pPCI waiver. This Report and Recommendation analyzes SGAH’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, 2013, 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 SGAH renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on reported experience, SGAH internal data, and ACCF-NCDR CathPCI Registry and ACTION Registry-GWTG 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

SGAH has three cardiac catheterization laboratory (CCL) procedure rooms in which to perform primary PCI procedures (Labs 1, Lab 2, and Lab B). The routine hours of cath lab operation are 7:00 a.m. to 6:00 p.m., Monday through Friday. On-call hours are 6:00 p.m. to 7:00 a.m., Monday through Friday, and 24 hours per day on weekends. Table 1 shows the downtime experienced by the CCL rooms at SGAH between January 2011 and December 2012.

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

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

Room	Cardiac Catheterization Laboratory Services Unavailable			
	Date		Duration	Reason Unavailable
	Begin	End		
2	2/15/12	2/15/12	2 hours	Hemo screen interference #7731102
2	2/29/12	2/29/12	2 hours	Cables pinched causing interference with monitoring/cautery
1	3/22/12	3/22/12	4 hours	Imaging module control wires showing C#7845976
2	5/31/12	5/31/12	3 hours	Fluoro exposure failed #8045196
1	7/20/12	7/20/12	5 hours	Unable to cine/fluoro only Phillips #8220605
2	8/16/12	8/16/12	3 hours	Hemo monitor bracket on the boom
B	10/31/12	10/31/12	6 hours	Gravity movement unavailable #0040002440

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

Room	Cardiac Catheterization Laboratory Services Unavailable			
	Date		Duration	Reason Unavailable
	Begin	End		
1	3/31/11	3/31/11	10 minutes	Work list was not showing up C#6800775
1	6/2/11	6/2/11	None	Ghost image on monitor
B	7/14/11	7/14/11	1 hour	DLX not working
B	7/21/11	7/21/11	15 minutes	Had to shut down and restart 3 times
2	10/12/11	10/12/11	1 hour	Cine not working
1	10/12/11	10/12/11	6 hours	Procedure table free floating
B	10/18/11	10/18/11	6 hours	Image degrading
1	11/7/11	11/7/11	4 hours	Image intensifier not working and stays in landscape position

Source: SGAH Application for Renewal of Waiver, March 12, 2013, Attachment B.

These data show that at no time did SGAH fail to provide cardiac catheterization laboratory services because a lab room was unavailable or staff was unavailable.

SGAH 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 Commission staff’s review of the NCDR data for calendar year (CY) 2011 and CY 2012 (Table 2), SGAH met the required threshold for door-to-balloon time, providing pPCI within 90 minutes or less of hospital presentation for 83 percent of patients (175 of 210 patients) over the two year period. SGAH also met this standard in seven of the eight quarters, just missing the standard in the fourth quarter of 2011. One reason hospitals may find it challenging to meet the DTB time standard is transfer cases. During calendar year CY 2012, SGAH received eight transfers; six of these cases had a DTB time of less than 90 minutes. In CY 2011, SGAH had seven transfer cases and all but one of these cases had a DTB time of over 90 minutes.

As shown in Table 3, SGAH internal data and ACCF-NCDR CathPCI Registry and ACTION Registry-GWTG reports indicate that, during CY 2010 and CY 2011, SGAH provided pPCI within 90 minutes to 85 percent of patients (180 of 211 patients). This is consistent with Commission staff’s analysis of the NCDR data for the same period.

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 Shady Grove Adventist Hospital, CY 2011- 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)	28	71.5	21	86
Quarter 3 (July-Sept 2012)	21	74.0	20	95
Quarter 2 (Apr-June 2012)	28	75.5	24	85
Quarter 1 (Jan-Mar 2012)	35	68.0	32	91
Quarter 4 (Oct-Dec 2011)	23	67.0	17	74
Quarter 3 (July-Sept 2011)	21	65.0	19	90
Quarter 2 (Apr-June 2011)	24	55.0	18	75
Quarter 1 (Jan-Mar 2011)	30	59.0	24	80
All Quarters	210	Not Calculated	175	83%

Source: MHCC staff analysis of NCDR CathPCI data for calendar years 2011 and 2012 and NCDR Action data for January-March 2011;

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

Table 3. Primary PCI Volume, and Number and Percentage of Patients With DTB ≤ 90 minutes by Quarter: Internal Data for Shady Grove Adventist Hospital, CY 2011- 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)	29	71	25	86
Quarter 3 (July-Sept 2012)	20	73	19	95
Quarter 2 (Apr-June 2012)	26	76	22	85
Quarter 1 (Jan-Mar 2012)	34	69	31	91
Quarter 4 (Oct-Dec 2011)	25	72	19	76
Quarter 3 (July-Sept 2011)	22	60	18	82
Quarter 2 (Apr-June 2011)	24	70	18	75
Quarter 1 (Jan-Mar 2011)	31	60	28	90
All Quarters	211	Not Calculated	180	85

Source: SGAH Application for Renewal of Waiver, March 12, 2013, p. 9.

SGAH meets this requirement.

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

Analysis

Table 4 shows the total number of staff currently involved in providing primary PCI services at SGAH. The number of cardiac interventionalists engaged by SGAH for its pPCI program has remained the same since its previous waiver renewal.

Table 4. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: Shady Grove Adventist Hospital (as of March 3, 2013)

Staff	Number	Cross-Training (S/C/M)*
Physicians	5	
Nurses	8 FTE	C/M
Cardiovascular Technologists	6 FTE	S/C/M

Source: SGAH Application for Renewal of Waiver, March 12, 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. SGAH 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: Shady Grove Adventist Hospital Center

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	1	Every 4 th day Monday - Thursday, Every 4 th weekend Friday - Sunday	30 Minutes
Nurses	2	Self-scheduling with one weekend a month required and a minimum of 8 total days per month required; no more than 3 consecutive days. Holidays are assigned.	30 Minutes
Technicians	2	Self-scheduling with one weekend a month required and a minimum of 8 total days per month required; no more than 3 consecutive days. Holidays are assigned.	30 Minutes
Physicians	1	Cardiac Associates provides a back up interventional cardiologist 24 hours a day, 7 days a week in the event of 2 primary PCIs	30 Minutes

Source: SGAH Application for Renewal of Waiver, March 12, 2013, pp. 7-8.

*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.

SGAH provides post-procedure care for pPCI patients in the hospital's 28-bed Medical/Surgical Intensive Care Unit (ACCU). Intensivists provide physician coverage of the hospital's critical care services. In 2012, the ACCU's average daily census was 18.3 patients. The number of paid FTEs providing direct nursing care included 51.8 hospital RNs. Patient care technicians (6.9 paid FTEs) support the unit, as well as unit support coordinators (4.4 paid FTEs). 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

SGAH meets this requirement.

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

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

Analysis

Dennis Hansen, President of Shady Grove Adventist Hospital at the time the Hospital submitted its renewal application, previously has submitted a written statement committing to support the pPCI program. The renewal application states that the commitment letter remains in effect. SGAH 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

Dennis Friedman, M.D., F.A.C.C. continues as the Medical Director of Cardiology and Research Services at SGAH. The Hospital previously provided a position description for the Medical Director of Cardiology and Research Services, whose primary function is to manage the clinical, administrative, and educational components of invasive cardiac services. The responsibilities of the physician director address the requirements of COMAR 10.24.17.

SGAH 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

SGAH provided information concerning dates and attendance at ten interventional case review meetings held during calendar year 2012. There was no meeting in September or November.

SGAH 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 SGAH includes physicians (Medical Director of Cardiac and Research Services; Chair of Emergency Medicine; Director of Chest Pain Center; and EMS Liason; nurses (ED Manager, Director of ED, Chest Pain Center Coordinator, Director of the Adult Critical Care Unit (ACCU), ACCU Educator, Manager CVIR, Director Cardiovascular Services, Quality Improvement representative, Cardiology and Cardiovascular Research Manager, Cardiovascular Educator, Research Nurse, Vice President of Operations); and others (physician assistant, Pharmacy Director, and EMS representative). The multiple care area group met on a monthly basis, with the exception of the month of August, during calendar year 2012.

SGAH 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 ACCU staff during CY 2012 included 12 lead EKG and STEMI recognition, Intra-Aortic Balloon Pump (IABP) counterpulsation therapy, workshop on caring for primary PCI patients, CRT Symposium, and Brilinta in-service training. There was also iSTAT and ACT in-service and competency validation.

SGAH 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

SGAH has stated that the term of the Hospital's transfer agreement with Washington Adventist Hospital, which provides for the unconditional transfer of primary PCI and non-primary PCI patients, was extended an additional five (5) years effective February 1, 2010.

SGAH 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

SGAH stated that its agreement for emergency transport remains in effect. It has an agreement with Washington Hospital Center's MedSTAR Transport Service that states helicopter transport of critically ill patients will be provided by MedSTAR. On behalf of SGAH and other facilities in the health system, Adventist HealthCare has executed a ground transport agreement with LifeStar Response of Maryland. SGAH maintains a compliant agreement with All American Ambulance and Transport that guarantees arrival of a ground ACLS ambulance within 30 minutes of a request. SGAH therefore 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 SGAH over CY 2012 and CY 2013. Each physician met the requirement to perform 75 or more total PCI cases annually.

**Table 6. Total Number of PCI Cases Performed
by Physician: Shady Grove Adventist Hospital, CY 2012 and CY 2011**

Physician and Reporting Period	Number of pPCI Cases at SGAH	Total PCI Cases-All Hospitals*
1/1/12-12/31/12		
Michael R. Castine, M.D.	24	78
Michael S. Chen, M.D.	18	114
Gregory H. Fisher, M.D.	4	81
Dennis C. Friedman, M.D.	38	110
Thomas H. Wang, M.D.	15	90
1/1/11-12/31/11		
Michael R. Castine, M.D.	26	90
Michael S. Chen, M.D.	31	115
Gregory H. Fisher, M.D.	12	64
Dennis C. Friedman, M.D.	19	108
Thomas H. Wang, M.D.	16	132

Source: SGAH Application for Renewal of Waiver, March 12, 2013.

*The total number of cases at all hospitals includes npPCI cases performed at SGAH as part of the C-PORT E Study.

SGAH 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

The waiver renewal application filed by SGAH states that no physicians are less than three years out of fellowship. SGAH is consistent with this requirement.

- 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 SGAH participates in the hospital's on-call schedule. SGAH is consistent with this requirement.

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

Analysis

The hospital's criteria for granting supplemental cardiology privileges in percutaneous coronary intervention have not changed since the previous waiver renewal. SGAH renewed privileges for all five interventionalists in either 2011 or 2012.

SGAH 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.

SGAH 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.

SGAH 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 SGAH is located in the Metropolitan Washington area, the program is required to perform a minimum of 49 pPCI cases annually. Data from the Commission’s STEMI Registry show that SGAH performed 99 PCI cases during 2012 (Table 7).

Table 7. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Shady Grove Adventist Hospital, 2012

Quarter and Year	Number of pPCI Cases*
Quarter 1 (Jan-Mar 2012)	33
Quarter 2 (Apr-Jun 2012)	17
Quarter 3 (Jul-Sep 2012)	20
Quarter 4 (Oct-Dec 2012)	29
Calendar Year 2012	99

Source: SGAH Application for Renewal of Waiver, March 12, 2013, Attachment G.

*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 SGAH internal data, the Hospital reported performing 104 primary PCI cases during 2011(Table 8).

Table 8. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Shady Grove Adventist Hospital, 2011

Quarter and Year	Number of pPCI Cases
Quarter 1 (Jan-Mar 2011)	32
Quarter 2 (Apr-Jun 2011)	24
Quarter 3 (Jul-Sep 2011)	22
Quarter 4 (Oct-Dec 2011)	26
<i>Calendar Year 2011</i>	<i>104</i>

Source: SGAH Application for Renewal of Waiver, March 12, 2013, Attachment G.

The Hospital’s institutional volume is well above the required minimum number of cases for both CY 2012 and CY 2011.

SGAH 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

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

III. RECOMMENDATION

Based on the above analysis and the record in this review, Shady Grove Adventist Hospital meets the COMAR 10.24.17.05D(1) requirements for institutional resources, physician resources, patient groups suitable for pPCI in settings without on-site cardiac surgery, institutional volume, and process and outcome measures for ongoing quality assessment. The Executive Director of the Maryland Health Care Commission recommends that the Commission

issue a two-year waiver that permits Shady Grove Adventist Hospital to provide primary percutaneous coronary intervention services without on-site cardiac surgery services.

Table 9. Summary of Analysis: Shady Grove Adventist Hospital

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

MARYLAND HEALTH CARE COMMISSION

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

TO: John Sackett
President
Shady Grove Adventist Hospital
9901 Medical Center Drive
Rockville, Maryland 20850

June 20, 2013
Date

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

13-15-0070 WR
Docket No.

PROJECT DESCRIPTION

On June 16, 2011, the Commission issued a two-year waiver permitting Shady Grove Adventist Hospital (SGAH 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, SGAH applied to the Commission on March 12, 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 June 20, 2013, that a two-year waiver be issued that permits Shady Grove Adventist Hospital to provide primary percutaneous coronary intervention services without on-site cardiac surgery services under the circumstances and conditions provided in this waiver. The two-year waiver will commence on July 19, 2013 and end on July 19, 2015.

In order for the Hospital to retain the waiver, Shady Grove Adventist Hospital must maintain compliance with the requirements for primary PCI programs found in COMAR 10.24.17, Table A-1. Table A-1 is attached to, and incorporated in, this two-year waiver.

CHANGES TO APPROVED WAIVER

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

RENEWAL OF WAIVER

The Hospital must submit an application for renewal of its waiver before its waiver is scheduled to expire on 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 Shady Grove Adventist Hospital to provide primary percutaneous coronary intervention services without on-site cardiac surgery, stating acceptance of its terms and conditions, is required within thirty (30) days.

MARYLAND HEALTH CARE COMMISSION

Ben Steffen
Executive Director

cc: Patricia Nay, M.D. Acting Director, Office of Health Care Quality
Ulder Tillman M.D., M.P.H., Health Officer, Montgomery County
Robert Bass, M.D., FACEP, Executive Director, MIEMSS