IN THE MATTER OF	*	
	*	**BEFORE THE MARYLAND**
ANNE ARUNDEL MEDICAL CENTER	*	
	*	**HEALTH CARE COMMISSION**
DOCKET NO. 13-02-0067 WR	*	

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

I. INTRODUCTION

Anne Arundel Medical Center (AAMC or the "Hospital") is located in Annapolis, Maryland (Anne Arundel County) and has a current licensed acute care bed capacity of 380 beds, including 312 medical/surgical/gynecology/addiction (MSGA) beds and 20 critical care beds as part of the larger MSGA bed inventory.[1] AAMC 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.

AAMC began providing primary percutaneous coronary intervention (pPCI) services in 2002 under a research waiver to participate in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trials, which examined the safety of providing pPCI in hospitals that do not provide cardiac surgery. In 2006, the Hospital was among the first group of non-cardiac surgery hospitals authorized to provide pPCI on a regular basis, subject to ongoing performance requirements and periodic waiver renewal. AAMC's most recent two-year waiver renewal was issued on May 21, 2009.

In order to retain the pPCI waiver, AAMC timely applied to the Commission on February 13, 2013 for renewal of its two-year pPCI waiver. This Report and Recommendation analyzes AAMC'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 2011*, Effective July 1, 2010, pages 3 and 9.

presenting with ST-segment elevation myocardial infarction (STEMI) and for PCI services provided to patients meeting certain eligibility criteria. Since July 1, 2010, all Maryland acute care hospitals providing PCI services have been required to use the American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR) ACTION Registry-GWTG to report quarterly data to the Commission on PCI cases. The hospitals were 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 AAMC renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on data reported by AAMC, at MHCC's request, and ACCF-NCDR 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 AAMC are provided in two cardiac catheterization laboratories (CCL); in addition, the Hospital has two interventional radiology rooms that can be used for cardiac catheterization procedures. Both CCLs have regular hours of operation, Monday-Friday, from 7:00 a.m. to 5:30 p.m. One laboratory (CCL 5) is on-call from 5:30 p.m. to 7:00 a.m. Monday-Friday and all day (24 hours) on Saturday and Sunday. Table 1 below shows cardiac catheterization lab downtime experienced between February 1, 2011 and January 31, 2013.

AAMC reported that cardiac catheterization laboratory services were continually available for the two-year period shown in Table 1. Preventative maintenance and repair were the only causes of down time, and one laboratory was always available. The availability of physicians or other staff was not an issue.

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

- **February 1, 2012-January 31, 2013**

Room	CCL Downtime			
	Date		Duration (Hours)	Reason CCL Unavailable
	Begin	End		
4	4/15/12	4/15/12	6.0	Preventative maintenance
4	4/25/12	4/25/12	3.0	Chiller not working-repaired coolant circulator
4	11/28/12	11/28/12	4.5	Preventative maintenance
5	2/19/12	2/19/12	4.5	Preventative maintenance
5	4/26/12	4/26/12	3.0	Repair table lock to prevent floating of table
5	5/22/12	5/23/12	26.0	Replacement of X-ray tube
5	8/19/12	8/19/12	4.5	Preventative maintenance

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

Room	CCL Downtime			
	Date		Duration (Hours)	Reason CCL Unavailable
	Begin	End		
4	2/20/11	2/21/11	25.0	Repair table lock-unable to move table
4	3/1/11	3/1/11	6.5	Unable to move gantry- repaired
4	4/17/11	4/17/11	4.5	Preventative maintenance
4	12/16/11	12/16/11	12.0	Repair image intensifier
4	10/16/11	10/16/11	4.5	Preventative maintenance
5	2/13/11	2/13/11	4.5	Preventative maintenance
5	6/1/11	6/1/11	4.5	Gantry repair
5	9/6/11	9/6/11	9.0	Tube repair
5	8/21/11	8/21/11	4.5	Preventative maintenance

Source: Anne Arundel Medical Center, Application for Renewal of Waiver, pp. 19-20.

AAMC 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 Staff's analysis of NCDR data for calendar years (CY) 2011 and 2012 (Table 2), AAMC met the required threshold for door-to-balloon time (DTB),

providing pPCI within 90 minutes or less of hospital presentation for 86 percent of patients (172 of 199 patients).

As shown in Table 3, AAMC's analysis of internal data and ACCF-NCDR ACTION Registry-GWTG reports indicate that, during CY 2011 and CY 2012, AAMC provided pPCI within 90 minutes for 91 perecent of patients (184 of 204 patients).

With regard to transfer cases, which sometimes pose a greater challenge for meeting a DTB time of 90 minutes or less, Commission Staff's analysis of NCDR shows that there was only one transfer case in 2012 and two transfer cases in 2011.

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 Anne Arundel Medical Center, 2011 and 2012

Quarter and Year	Primary PCI Volume	Median Door-to-Balloon Time (Minutes)	≤ 90 Minutes (N)	≤90 Minutes (%)
Quarter 4 (Oct-Dec 2012)	21	50.0	19	90
Quarter 3 (Jul-Sept 2012)	25	65.0	20	80
Quarter 2 (Apr-Jun 2012)	23	54.5	21	91
Quarter 1 (Jan-Mar 2012)	25	57.5	22	88
Quarter 4 (Oct-Dec 2011)	28	57.0	27	96
Quarter 3 (Jul-Sept 2011)	24	60.0	20	83
Quarter 2 (Apr-Jun 2011)	24	51.0	23	96
Quarter 1 (Jan-Mar 2011)	29	68.0	20	69
All Quarters	199	Not Calculated	172	86

Source: MHCC staff analysis of NCDR data for calendar years 2011 and 2012; Additional Information, May 5, 2013.

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 applied to patients already hospitalized: the "door" ECG is the first ECG recorded showing STEMI. Cases for each quarter are counted based on the discharge date. However, the NCDR CathPCI Registry data does not capture the ECG date and time for these patients, unless the first ECG was negative.

Table 3. Primary PCI Volume, and Number and Percentage of Patients with DTB ≤ 90 Minutes by Quarter: Internal Data for Anne Arundel Medical Center, 2011 and 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)	23	51.0	22	96
Quarter 3 (Jul-Sep 2012)	23	51.0	20	87
Quarter 2 (Apr-Jun 2012)	24	55.5	22	92
Quarter 1 (Jan-Mar 2012)	23	57.0	22	96
Quarter 4 (Oct-Dec 2011)	28	58.0	26	93
Quarter 3 (Jul-Sept 2011)	27	61.5	24	81
Quarter 2 (Apr-Jun 2011)	23	53.0	22	96
Quarter 1 (Jan-Mar 2011)	32	58.5	26	89
All Quarters	203	Not Reported	184	91

Source: AAMC Application for Renewal of Waiver, February 13, 2013, p. 11; Additional Information, May 5. 2013.
Note: Cases for each quarter are counted based on the procedure date.

AAMC 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 providing pPCI services. Since the previous waiver renewal, staff FTEs for physicians, nurses, and technologists has not changed.

Table 4. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: Anne Arundel Medical Center (as of February 6, 2013)

Staff	Number	Cross-Training (S/C/M)*
Physicians	7	
Nurses	5 (FTE)	C/M
Cardiovascular Technologists	4.6 (FTE)	S/M

Source: AAMC Application for Renewal of Waiver, February 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 5. The total on-call staff of nurses and techs is 3, with a minimum of 1 each.

Table 5. On-Call Primary PCI Team Staffing, Rotation, and Response Time: Anne Arundel Medical Center, February 2013

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	1	0600 to 0600 (24 hr. call) Each physician takes an average of 9 to 10 call days per month. Weekdays are evenly distributed with rotating call on weekends.	5 minute response by telephone; 30 minute arrival from page
Nurses	1 or 2	Rotation varies based on the schedule, with all staff on call 9 to 10 days per month, including 1 to 2 weekends per month. Total of three staff on Call Team with minimum of 1 RN and 1 Tech. Call starts from 1730 on week nights until 0700 and 24 hours on weekends.	5 minute response by telephone; 30 minute arrival from page
Technicians	1 or 2	Rotation varies based on the schedule, with all staff on call 9 to 10 days per month, including 1 to 2 weekends per month. Total of three staff on Call Team with minimum of 1 RN and 1 Tech. Call starts from 1730 on week nights until 0700 and 24 hours on weekend.	5 minute response by telephone; 30 minute arrival from page

Source: AAMC Application for Renewal of Waiver, February 13, 2013, p.9.

*Note: Response time is the time established by the hospital's policy for on-call staff to respond to the call (phone, pager). Response time covers the period from receipt of call to arrival at the hospital.

AAMC does not permit cardiologists to have simultaneous on-call duties at other hospitals. This policy has not changed since the previous renewal waiver. The Hospital requires interventional cardiologists to sign a written statement regarding non-participation in simultaneous call coverage and to abide by AAMC's Medical Staff bylaws, which require that "[a]ll practitioners are responsible for continued coverage of their patients in the Medical Center. They must provide evidence of and maintain appropriate coverage and arrangements (signed out to a practitioner with appropriate privileges who are agreed to assume responsibility for the care of the patient) when not personally promptly available." According to AAMC, the responsible practitioner, or designee, must be able to be physically present at the hospital within 30 minutes, when appropriate, for urgent situations.

AAMC provides post-procedure care for pPCI patients in the Hospital's Critical Care Unit, which is comprised of 20 licensed medical/surgical intensive care beds (Level I Critical Care) and 10 licensed medical/surgical beds (Level II Critical Care). Post-procedure pPCI patients are admitted to a Level I CCU bed; all of the critical care nurses in the unit are educated to care for these patients. During the period from February 1, 2012 to January 31, 2012, the average daily census for the intensive care beds was 12.3. For the entire unit, the average daily census was 22.2 patients. Paid FTEs included 60.7 RNs providing direct nursing care. Patient care technicians (10.8 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]

AAMC stated that its strategy for ensuring intensivist physician coverage 24 hours a day and seven days a week has not changed. AAMC in its previous waiver renewal stated that nine intensivists (four on day shift and one on night shift) provide 24/7 medical coverage of the CCU. In addition, AAMC stated that the admitting cardiologists remain the primary physicians and are notified concerning management of their patients in the CCU by the intensivists.

AAMC 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

AAMC indicated that commitment of support for the primary PCI program has not changed since the previous renewal waiver. For the previous renewal waiver, Victoria W. Bayless, President and Chief Operating Officer of AAMC, submitted a written statement committing to provide the staff, funds, and resources necessary to support the pPCI program.

AAMC 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

Jonathan Altschuler, M.D. continues as the Medical Director of the Cardiac Catheterization Laboratory at AAMC. The Medical Director of the Cardiac Catheterization Laboratory provides appropriate supervision and proper and consistent administration of the laboratory, including necessary control and standardization of procedures performed to enhance overall quality of patient care. AAMC meets this requirement.

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

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

AAMC has identified one body to carry out the case review function and review issues, identify problem areas, and develop solutions related to its pPCI program. During calendar year 2012, this body held ten regularly scheduled monthly meetings. No meetings were held in February, July, or December. However, two meetings were held in March.

AAMC 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

In addition to CCL staff, participants in meetings of AAMC's multiple care area group included: Medical Director, Cardiac Catheterization Laboratory; Medical Director, Cardiac Rehabilitation; Chair of Medicine; internists, cardiologists, and Emergency Department physicians; ED and CCU nurse educators; Cardiac Program Coordinator; Director of the Heart Vascular Institute, Senior Clinical Director, research nurses; and staff from Cardiac Rehab.

AAMC 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 CCU staff over the period from February 2012 to January 2013 included ECG Interpretation, Cardiac Dysfunction, Groin Management, Dysrhythmia Exam, Pacer Management, PA Catheter Management, Intra-Aortic Balloon Pump Training; Angiojet Set-Up In-Service and Demonstration; Perforation Drill, and Transradial Approach for Cardiac Catheterization.

AAMC 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 renewal application states that AAMC maintains current and active agreements with Johns Hopkins Hospital and Washington Hospital Center that were previously submitted to MHCC. In addition, AAMC has an agreement with the University of Maryland Medical Center for unconditional transfer of emergent or elective PCI patients. A copy of this agreement was provided in Attachment A of the renewal application of AAMC.

AAMC 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

As part of the current waiver renewal application, AAMC submitted an updated agreement with MEDSTAR Transport Service for helicopter transport services. In addition, AAMC maintains a compliant agreement with All American Ambulance that guarantees arrival of ground transport within 30 minutes of a request. AAMC 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 AAMC over two 12-month periods, CY 2012 and CY 2011. Based on the data reported by AAMC, each physician met the requirement of performing 75 or more total PCI cases annually during the reporting periods shown below.

AAMC has complied with this requirement.

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

Physician and Reporting Period	Number of pPCI Cases at AAMC	Total PCI Cases-All Hospitals*
CY 2012		
Jonathan A. Altschuler, M.D.	25	131
Robert A. Gallino, M.D.	0	94
Scott M. Katzen, M.D.^	30	109
Robert A. Lager, M.D.	0	86
Kenneth Mong Hung Lee, M.D.	0	85
Marco A. Mejia, M.D.	16	75
Stafford G. Warren, M.D.	22	98
CY 2011		
Jonathan A. Altschuler, M.D.	29	142
Robert A. Gallino, M.D.	0	115
Scott M. Katzen, M.D.^	34	110
Robert A. Lager, M.D.	0	112
Kenneth Mong Hung Lee, M.D.	3	92
Marco A. Mejia, M.D.	22	97
Stafford G. Warren, M.D.	22	81

Source: AAMC Application for Renewal of Waiver, February 13, 2013, pp. 26-33;
^Note: Dr. Katzen completed his fellowship in June 2010;
*Note: The total number of cases at all hospitals includes npPCI cases performed at AAMC as part of the C-PORT E Study.

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

In July 2010, the Hospital granted privileges to Dr. Scott Katzen, who completed fellowship training in interventional cardiology in June 2010. As part of AAMC's prior waiver renewal request, AAMC stated that Dr. Katzen performed 308 PCIs during fellowship training and submitted the requisite documentation.

AAMC has complied with this requirement.

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

Analysis

Each of the physicians currently performing pPCI at AAMC participates in the Hospital's on-call schedule. AAMC has complied with this requirement.

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

Analysis

AAMC submitted the delineation of cardiology privileges granted to each physician. To perform PCI, the physician must meet the Hospital's criteria for initial and ongoing privileging.

AAMC has complied 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.

Data reported by NCDR shows that no patients with a STEMI presentation received thrombolytic therapy. This is consistent with AAMC reporting that no patients received thrombolytic therapy because the cardiac catheterization laboratory was unavailable. Commission staff's review of the NCDR data also suggests that patients undergoing pPCI at AAMC met the above inclusion criteria and were appropriate for primary PCI in settings without on-site cardiac surgery.

AAMC 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 AAMC is located in the metropolitan area of Baltimore, the program is required to perform a minimum of 49 pPCI cases annually. Data reported by AAMC show that AAMC performed 110 pPCI cases during 2011 (Table 7).

Table 7. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Anne Arundel Medical Center, 2011

Quarter and Year	Number of pPCI Cases*
Quarter 1 (Jan-Mar 2011)	32
Quarter 2 (Apr-Jun 2011)	23
Quarter 3 (Jul-Sep 2011)	27
Quarter 4 (Oct-Dec 2011)	28
Calendar Year 2011	***110***

Source: MHCC staff analysis of AAMC Application for Renewal of Waiver, February 13, 2013. pp. 27-33
*Note: 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 AAMC internal data, the Hospital reported performing 93 primary PCI cases during 2012 (Table 8). The Hospital's institutional volume is well above the required minimum number of cases. AAMC meets this requirement.

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

Quarter and Year	Number of pPCI Cases
Quarter 1 (Jan-Mar 2012)	23
Quarter 2 (Apr-Jun 2012)	24
Quarter 3 (Jul-Sep 2012)	23
Quarter 4 (Oct-Dec 2012)	23
Calendar Year 2012	***93***

Source: AAMC Application for Renewal of Waiver, February 13, 2013, pp. 27-33;

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

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

III. RECOMMENDATION

Based on the above analysis and the record in this review, Anne Arundel Medical Center meets the COMAR 10.24.17.05D(1) requirements for institutional resources, physician resources, patient groups suitable for pPCI in settings without on-site cardiac surgery, institutional volume, and process and outcome measures for ongoing quality assessment. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a two-year waiver that permits Anne Arundel Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services.

Table 9. Summary of Analysis: Anne Arundel 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: Victoria W. Bayless
President and COO
Anne Arundel Medical Center
2001 Medical Parkway
Annapolis, Maryland 21401

May 16, 2013
Date

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

13-02-0067 WR
Docket No.

PROJECT DESCRIPTION

On May 19, 2011, the Commission issued a two-year waiver permitting Anne Arundel Medical Center (AAMC 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, AAMC applied to the Commission on February 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 May 16, 2013, that a two-year waiver be issued that permits Anne Arundel Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services under the circumstances and conditions provided in this waiver. The two-year waiver will commence on June 21, 2013 and end on June 21, 2015.

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

CHANGES TO APPROVED WAIVER

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

RENEWAL OF WAIVER

The Hospital must submit an application for renewal of its waiver before its waiver is scheduled to expire on June 21, 2015. The Commission will publish the schedule for the submission of primary PCI waiver renewal applications in the *Maryland Register* and in a posting on the Commission's website.

ACKNOWLEDGEMENT OF RECEIPT OF TWO-YEAR WAIVER

Acknowledgement of your receipt of this two-year waiver permitting Anne Arundel Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery, stating acceptance of its terms and conditions, is required within thirty (30) days.

MARYLAND HEALTH CARE COMMISSION

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Ben Steffen
Executive Director

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