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| **IN THE MATTER OF** | * | |
| | * | **BEFORE THE MARYLAND** |
| **MERITUS MEDICAL CENTER** | * | |
| | * | |
| **DOCKET NO. 13-21-0065 WR** | * | **HEALTH CARE COMMISSION** |
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**REPORT AND RECOMMENDATION ON REQUEST TO RENEW WAIVER TO PROVIDE PRIMARY PCI WITHOUT CARDIAC SURGERY ON-SITE**

## I. INTRODUCTION

Located in Hagerstown, Maryland (Washington County), Meritus Medical Center (MMC) opened on December 11, 2010 as a replacement hospital for the former Washington County Hospital (WCH).[1] The acute care bed capacities for Meritus Medical Center are as follows: 203 medical/surgical beds, 24 critical care beds, 6 pediatric beds, 18 obstetric beds, and 18 acute psychiatric beds.[2] The hospital is accredited by the Joint Commission and is a Medicare provider in good standing.

MMC provides both primary percutaneous coronary intervention (pPCI) and non-primary percutaneous coronary interventions (npPCI). Staff recently reviewed MMC's compliance with the requirements of the C-PORT E Registry and COMAR 10.24.05 and 10.24.17, Table A-1. On December 20, 2012, the Commission concluded that MMC meets these requirements, thereby allowing MMC to continue providing npPCI services without obtaining a Certificate of Conformance, a new requirement resulting from legislation passed in 2012.

The hospital began providing (pPCI) services on March 15, 2008. This approval authorized WCH to provide pPCI services for a one-year period. On February 19, 2009, the Commission approved a two-year waiver for WCH to provide pPCI services without on-site cardiac surgery. The Commission renewed the waiver for two years on February 17, 2011.

MMC applied to the Commission on October 11, 2012 for renewal of its waiver. This Report and Recommendation analyzes the hospital's compliance with the requirements for pPCI services without on-site cardiac surgery.

[1] The Articles of Incorporation of Washington County Health System, Inc. have been amended to change the legal name of the corporation to Meritus Health, Inc., which operates Meritus Medical Center. The ownership of the hospital has not changed.

[2] Maryland Health Care Commission, *Annual Report on Selected Maryland Acute Care and Special Hospital Services, Fiscal Year 2013*, Effective July 1, 2012, pages 3 and 12.

## II. STAFF REVIEW AND ANALYSIS OF WAIVER RENEWAL

### Background

Under *COMAR 10.24.17 State Health Plan for Cardiac Surgery and PCI Services* (Chapter), 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 services without on-site cardiac surgery as specified in Table A-1 of the Chapter. 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 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 MMC renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on the hospital's internal data and data submitted by the Hospital to the ACCF-NCDR CathPCI Registry.

### 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**

MMC provides primary PCI services in four cardiac catheterization laboratory (CCL) rooms. Routine availability of cath lab services includes regular hours of operation from 6:00 a.m. to 5:30 p.m., Monday-Friday; on-call hours are from 5:30 p.m. to 6:00 a.m. Monday-Friday, and 6:00 a.m. to 6:00 a.m. (24 hours) on Saturday-Sunday.

Table 1 below shows the downtime experienced by the four CCL rooms at MMC between October 2011-September 2012 and October 2010-September 2011. Based on data reported by MMC, one patient was not taken emergently to the cardiac catheterization laboratory in 2012 because of physician unavailability. The patient was transported by helicopter to a tertiary hospital. MMC also noted that four CCL rooms were unavailable for a four hour block that began January 19, 2011. MMC explained that this was one month after the move from

Washington County Hospital to MMC, and the CCL rooms had to be connected to the backup generator system. MMC notified the emergency department of this planned downtime in advance as well as surrounding ambulance companies. On a second occasion, all four CCL rooms were unavailable for a six hour block that began on June 26, 2012. This was necessary in order to install special outlets that enable computers to maintain power in the event of a power failure. MMC again provided advance notification of the anticipated downtown to its emergency department and surrounding ambulance companies. Except for these two periods of downtime, , MMC maintained compliance with the requirement to provide pPCI services 24 hours per day, seven days per week during the reporting period.

MMC meets this requirement.

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

- **October 1, 2011-September 30, 2012**

| Room | Cardiac Catheterization Laboratory Services Down Time | | | |
|---|---|---|---|---|
| | Date | | Duration (Hours) | Reason Unavailable |
| | Begin | End | | |
| 4 | 1/23/12 | 1/24/12 | 25.5 | Fluoroscopy stopped working |
| 2 | 4/13/12 | 4/19/12 | 140 | Tube failure (new tube ordered, installed) |
| 1,2,3,4 | 6/26/12 | 6/27/12 | 4.0 | Electrical upgrades |
| 3 | 7/13/12 | 7/16/12 | 82.5 | Tube failure (new tube ordered, installed) |
| 4 | 8/7/12 | 8/8/12 | 20 | Hard drive failure |
| 4 | 9/11/12 | 9/12/12 | 23 | x-ray down |
| 4 | 9/16/12 | 9/17/12 | 29 | Video board failure |
| 2 | 9/25/12 | 9/25/12 | 1.3 | 2 STEMI patients arrived in ED 11 minutes apart; 2nd patient transported by helicopter to tertiary hospital due to physician unavailability |

- **October 1, 2010-September 30, 2011**

| Room | Cardiac Catheterization Laboratory Services Down Time | | | |
|---|---|---|---|---|
| | Date | | Duration (Hours) | Reason Unavailable |
| | Begin | End | | |
| 4 | 12/29/10 | 12/29/10 | 2.0 | Pedestal locked up |
| 1,2,3,4 | 1/19/11 | 1/20/11 | 6.0 | UPS installation power up |
| 3 | 5/19/11 | 5/19/11 | .25 | Software not synced-rebooted and functional |

Source: Meritus Medical Center, Application for Renewal of Waiver, October 11, 2012, Attachment 5.

**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 data in the ACCF-NCDR CathPCI Registry, reported by MMC for the prior eight quarters between October 1, 2010 and September 30, 2012 (Table 2), MMC met the required threshold for door-to-balloon time, providing pPCI with a DTB time of 90 minutes or less for 89 percent of patients (148 of 159). MMC initially submitted internal data for pPCI volume and DTB time to demonstrate compliance with the standards. However, MMHC subsequently realized that the data required corrections.

MMC meets this requirement.

**Table 2. Primary PCI Volume, and Number and Percentage of Patients with DTB ≤ 90 minutes by Quarter: Meritus Medical Center, October 2011-September 2012**

| Quarter and Year | Primary PCI Volume | Door-to-Balloon Time | |
|---|---|---|---|
| | | ≤ 90 Minutes (N) | ≤ 90 Minutes (%) |
| Quarter 1 (Jul-Sept 2012) | 22 | 14 | 64% |
| Quarter 2 (Apr-Jun 2012) | 27 | 26 | 96% |
| Quarter 3 (Jan-Mar 2012) | 26 | 24 | 92% |
| Quarter 4 (Oct-Dec 2011) | 18 | 18 | 100% |
| Quarter 5 (Jul-Sept 2011) | 24 | 21 | 88% |
| Quarter 6 (Apr-Jun 2011) | 22 | 15 | 68% |
| Quarter 7 (Jan-Mar 2011) | 11 | 11 | 100% |
| Quarter 8 (Oct-Dec 2010) | 17 | 18 | 100% |

Source: MHCC Staff analysis of ACCF-NCDR CathPCI Registry data.
Note: If a case was included in the volume of primary PCI cases, then it was included in the denominator for calculating the percentage of cases with a D2B time of 90 minutes or less.

**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 involved in providing primary PCI services at MMC as of September 30, 2012. MMC has seven physicians on its roster of interventionalists, which is a decline from the number reported in its last waiver renewal request (11). The CCL nursing staff increased from 5.6 to 8.7 FTEs, and the technical staff decreased from 6.0 to 5.0 FTEs.

**Table 3. Total Number of Physician, Nursing, and Technical Staff Providing Primary PCI Services: Meritus Medical Center (as of 9/30/2012)**

| Staff | Number | Cross-Training (S/C/M)* |
|---|---|---|
| Physicians | 7 | Not applicable |
| Nurses | 8.7 FTEs | 2.0 S/CM and 6.7 (C/M) |
| Cardiovascular Technologists | 5.0 FTEs | S/CM |

Source: MMC Application for Renewal of Waiver, October 11, 2012, 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 entire team consists of a physician and four staff members, including at least one nurse and one technologist. The other two members may be either nurses or technologists.

The Hospital's policy of not permitting the primary interventional cardiologist to have simultaneous on-call duties at other hospitals remains in effect.

**Table 4. On-Call Primary PCI Team Staffing, Rotation, and Response Time: Meritus Medical Center, September 2012**

| Type of Clinical Staff on Team | Number of Staff | Call Rotation | Response Time* |
|---|---|---|---|
| Physicians | 1 | 8:00 a.m. – 8:00 a.m.<br>Average of 2-10 days per month | 30 minutes |
| Nurses | 1-2 | 5:30 p.m. to 6:00 a.m. Mon-Fri and 24 hours on weekends<br>2 nights/week and every other weekend | 30 minutes |
| Cardiovascular Technologists | 1-2 | 5:30 p.m. to 6:00 a.m. Mon-Fri and 24 hours on weekends<br>2-3 days/week and one weekend a month, with the weekend being defined as Friday, Saturday, and Sunday | 30 minutes |

Source: MMC Application for Renewal of Waiver, October 11, 2012, pp. 9-10.
*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.

During the period from October 1, 2011 to September 30, 2012, MMC provided post-procedure care for pPCI patients in the Hospital's Critical Care Unit (CCU), a unit of 24 licensed beds. The CCU's average daily census was 18 patients during this time. Paid FTEs included 55.3 RNs and 9.2 LPN providing direct nursing care. The Society of Critical Care Medicine has

provided a basic measure of nurse staffing as 14 to 17 nurse care hours or a ratio of about 1:1.[3] MMC exceeds this requirement. The interventional cardiologist is on call for emergent procedures and the post-procedure care of any primary PCI patient.

MMC 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**

Joseph P. Ross became the President and CEO of Meritus Health, Inc. in February 2011. Mr. Ross submitted a written statement that the hospital administration of Meritus Medical Center will provide "whatever resources necessary for the continued support of both the pPCI and npPCI services."

MMC 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**

Robert Marshall, M.D. continues to be the Medical Director of Interventional Cardiology at the Hospital. MMC's response indicates that the responsibilities of this position also have not changed since the last waiver renewal.

MMC 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**

In the renewal application, the Hospital reported that interventional case reviews are held every other month. During the 14 months from June 2011 to August 2012, MMC held seven

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

meetings to review interventional cases, except for February 2012. Attendance at those meetings has included: emergency department staff (physicians, including chair; nurses including director, research care specialist, and educator); manager of critical care; and emergency medical services (EMS) coordinator.

MMC also reported that weekly meeting are held with CCL staff. There were 34 meetings held between October 2011 and September 2012. According to MMC, processes related to door-to-balloon times, team activation times, field transmission of EKGs ED, intra-catheterization and post-procedure care are reviewed on all STEMI patients prior to each meeting by the Medical Director and CCL lab staff members. Specific patient cases are pulled and reviewed if any issues related to patient care arose. MMC reports that door-to-balloon times have improved as well as field transmission of EKGs and door-to-EKG times have improved because of collaboration within the group.

MMC 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 Hospital reported that the Strategy of Care (multiple care area group) meetings are held monthly. In addition to CCL staff, attendance at the strategy meetings has included: RN research specialists and the hospital's cardiac rehabilitation/congestive heart failure (CHF) specialist; nurses representing cardiac rehabilitation and ED education; Administrative Director of Medical Surgical Services; and clinical managers. Participants in the strategy meetings have also included representation from the pharmacy, laboratory, and social work departments.

MMC 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**

MMC provided a list of internal and external continuing education for CCL and CCU staff over the period, October 1, 2011-September 30, 2012. Activities held over this time period included topics such as therapeutic hypothermia, cardiac medications, groin management and intra-aortic balloon pump. There were also mock events for coronary dissection and air embolism.

MMC 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**

MMC's response indicates that its written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care has not changed since its last waiver renewal. MMC has the required agreement with both Johns Hopkins Hospital, in Baltimore, and Suburban Hospital, in Bethesda. MMC 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**

Washington County Hospital Association (WCHA), now known as MMC, has a written transport agreement with Butler Medical Transport guaranteeing arrival of a ground ambulance within 30 minutes of request. Butler is to provide transport for pPCI and npPCI patients. This agreement was signed in July 2009 and remains in effect for seven years.

MMC 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 physicians with privileges at MMC over 12-month periods from October 2010 to September 2012.

**Table 5. Total Number of PCI Cases Performed by Physician: Meritus Medical Center, October 2010-September 2011 and October 2011-September 2012**

| Physician and Reporting Period 10/1/10-9/30/11 | Number of pPCI Cases at MMC | Other Hospitals | | | Total PCI Cases-All Hospitals |
|---|---|---|---|---|---|
| | | Number of pPCI Cases | Number of npPCI Cases | Total PCI Cases | |
| Payam Fallahi, M.D. | 51 | 0 | 0 | 0 | 120 |
| Jack Flyer, M.D. | 2 | 23 | 52 | 75 | 77 |
| Robert Marshall, M.D. | 22 | 18 | 20 | 38 | 80 |
| Salman Mehboob, M.D. | 15 | 0 | 42 | 42 | 80 |
| Feroz Padder, M.D. | 23 | 20 | 21 | 41 | 87 |
| Joseph A. Quash, Jr., M.D. | 0 | 2 | 79 | 81 | 81 |
| Khalid Zirvi, M.D. | 18 | 0 | 31 | 31 | 91 |
| | | | | | |
| **Physician and Reporting Period 10/1/11-9/30/12** | **Number of pPCI Cases at MMC** | **Other Hospitals** | | | **Total PCI Cases-All Hospitals** |
| | | **Number of pPCI Cases** | **Number of npPCI Cases** | **Total PCI Cases** | |
| Payam Fallahi, M.D. | 20 | 0 | 17 | 17 | 144 |
| Jack Flyer, M.D. | 0 | 27 | 76 | 103 | 103 |
| Robert Marshall, M.D. | 20 | 24 | 29 | 53 | 89 |
| Salman Mehboob, M.D. | 21 | 5 | 32 | 37 | 78 |
| Feroz Padder, M.D. | 13 | 21 | 27 | 48 | 80 |
| Joseph A. Quash, Jr., M.D. | 0 | 7 | 63 | 70 | 70 |
| Khalid Zirvi, M.D. | 21 | 12 | 14 | 26 | 70 |

Source: MMC Application for Renewal of Waiver, October 11, 2012, Attachment 10;

Dr. Zirvi and Dr. Quash's case volumes fell slightly below the requirement of 75 or more total PCI cases annually for the period October 1, 2011 to September 30, 2012. However, over the two-year period of MMC's most recent waiver renewal, the case volumes for these two physicians were in compliance for every other continuous block of four quarters. For this reason, Staff recommends that MMC be found to be in compliance with this standard and will monitor case volumes on a quarterly basis going forward to assure continued compliance 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 application filed by MMC states that two physicians are less than three years out of fellowship training. Dr. Mehboob completed his interventional cardiology fellowship in September 2010; Dr. Fallahi completed his training in June 2010. The Hospital provided

documentation that each physician completed a minimum of 50 acute MIs during his fellowship training.

MMC is consistent with this requirement.

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

**Analysis**

The physicians who currently perform primary PCI at MMC participate in the Hospital's on-call schedule. MMC is consistent with this requirement.

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

**Analysis**

MMC's response indicates that the credentialing criteria have not changed since the last waiver renewal. Each physician performing primary PCI has been credentialed by MMC.

MMC 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.

For the period October 1, 2010 to September 30, 2012, MMC reports that no patients received thrombolytic therapy as primary reperfusion therapy, and no patients who received primary thrombolytic therapy after receiving PCI. Data from the ACCF-NCDR CathPCI Registry is consistent with the data reported by MMC. The patients undergoing primary PCI at MMC met the above inclusion criteria and were appropriate for primary PCI in settings without on-site cardiac surgery.

MMC 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 MMC is located outside the metropolitan areas of Washington and Baltimore, the program is required to perform a minimum of 36 pPCI cases annually. Data from the ACCF-NCDR CathPCI Registry confirm that MMC performed above the required minimum number of cases during the period from October 1, 2011 to September 30, 2012. MMC reported performing 93 pPCI cases (Table 6). MMC initially reported performing a greater volume of cases based on internal data. However, MMC subsequently realized the data were erroneous.

MMC meets this requirement.

**Table 6. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Meritus Medical Center, October 2011-September 2012**

| Quarter and Year | Number of pPCI Cases |
|---|---|
| Quarter 1 (Oct-Dec 2011) | 18 |
| Quarter 2 (Jan-Mar 2012) | 26 |
| Quarter 3 (Apr-June 2012) | 27 |
| Quarter 4 (Jul-Sept 2012) | 22 |
| ***All Quarters*** | ***93*** |

Source: MHCC staff analysis of ACCF-NCDR CathPCI Registry data.

**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**

MMC is a current participant in the American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR) ACTION Registry-GWTG and the NCDR CathPCI Registry.

MMC meets this requirement.

## III. RECOMMENDATION

Based on the above analysis and the record in this review, Meritus Medical Center meets the 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 on-going quality assessment in COMAR 10.24.17.05D(1). The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a two-year waiver that permits Meritus Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services.

**Table 7. Summary of Analysis: Meritus 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<br>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:** Joseph P. Ross
President and CEO
Meritus Medical Center
1116 Medical Campus Road
Hagerstown, Maryland 21742

February 21, 2013
Date

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

13-21-0065 WR
Docket No.

## PROJECT DESCRIPTION

On February 17, 2011, the Commission issued a two-year waiver permitting Washington County Hospital (WCH), now Meritus Medical Center (MMC 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, WCH/MMC applied to the Commission on October 11, 2012 for renewal of its two-year pPCI waiver.

## WAIVER

The Maryland Health Care Commission has reviewed the Report and Recommendation in this matter and, based on that analysis and the record in this review, ordered on February 21, 2013, that a two-year waiver be issued that permits Meritus 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 March 14, 2013 and end on March 14, 2015.

In order for the Hospital to retain the waiver, Meritus Medical Center must maintain compliance with the requirements for primary PCI services 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, Meritus 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 current waiver is scheduled to expire on March 14, 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 Meritus Medical Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery, stating acceptance of its terms and conditions, is required within thirty (30) days.

**MARYLAND HEALTH CARE COMMISSION**

_____

Ben Steffen, M.D.
Executive Director

cc: Patricia Nay, M.D., Acting Director, Office of Health Care Quality
Earl E. Stoner, MPH, Health Officer, Washington County
Robert Bass, M.D., FACEP, Executive Director, MIEMSS