IN THE MATTER OF	*	
	*	**BEFORE THE MARYLAND**
CARROLL HOSPITAL CENTER	*	
	*	**HEALTH CARE COMMISSION**
DOCKET NO. 13-06-0072 WR	*	

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

I. INTRODUCTION

Carroll Hospital Center (CHC) is located in Westminster, Maryland (Carroll County) and has a current licensed acute care bed capacity of 158 beds, including 111 medical/surgical/gynecology/addiction (MSGA) beds and 12 critical care beds as part of the larger MSGA bed inventory.[1] CHC is accredited by the Joint Commission and is a Medicare provider in good standing.

CHC initiated primary percutaneous coronary intervention (pPCI) services on October 13, 2008. On September 17, 2009, the Commission approved a two-year waiver for CHC to continue providing pPCI services without on-site cardiac surgery. The two-year waiver began on October 13, 2009. In 2011, the Commission renewed the hospital's waiver for an additional two years through October 13, 2013.

In order to retain the pPCI waiver, CHC applied to the Commission on June 11, 2013 for renewal of its two-year pPCI waiver. This Report and Recommendation analyzes CHC'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, the State Health Plan Chapter for Cardiac Surgery and PCI Services ("Chapter"), the Commission may waive any of the policies in Regulations .04 or .05 of the Chapter for a specified time period if the hospital requesting the waiver can demonstrate the ability to comply with all requirements for a primary (emergency) PCI program without on-site cardiac surgery, as specified in Table A-1. Following development of the hospital's pPCI program, the Commission may issue a waiver for a two-year period provided that the hospital has met and demonstrates that it 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

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

eligibility criteria. Effective July 1, 2010, each Maryland acute care hospital with a waiver from the Commission to provide pPCI is 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. Each hospital with a waiver is also required to enroll in the ACCF-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 CHC renewal application with the requirements specified in COMAR 10.24.17.05D(1) based on CHC's internal data and ACCF-NCDR CathPCI Registry data.

Compliance with COMAR 10.24.17.05D(1) Waiver from Policies. Primary Percutaneous Coronary Intervention in Hospitals without On-Site Cardiac Surgery.

Category: Institutional Resources

1) All institutions should provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week.

Analysis

Primary PCI services at CHC are provided in three cardiac catheterization laboratory (CCL) rooms. All rooms have regular hours of operation, Monday-Friday, from 7:00 a.m. to 4:30 p.m. Room 1 is available on-call from 4:30 p.m. to 7:00 a.m. on Monday-Friday, and 24 hours per day on Saturday-Sunday. Based on the information shown in Table 1, CCL services were available in at least one room, 24 hours per day seven days a week over the entire two-year reporting period.

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

- **June 1, 2012-May 31, 2013**

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
1	9/25/12	9/25/12	4	Preventive maintenance
1	11/8/12	11/18/12	1	Intercom system repair
1	12/12/12	12/12/12	4	Preventive maintenance
1	1/8/13	1/10/13	24	Toshiba's National Service Team on site to improve image quality. Room 3 or Dual Plane room used for STEMI cases while work was done during the day.
1	4/25/13	4/25/13	4	Preventive maintenance
2	11/6/12	11/6/12	4	Tube water flow not detected. Room not used for STEMI
2	4/1/13	4/1/13	4	Preventive maintenance. Room not used for STEMI
3	8/12/12	8/12/12	4	Preventive maintenance
3	9/18/12	9/18/12	0.5	No image to fluoro monitor
3	11/27/12	11/27/12	4	Preventive maintenance
3	12/17/12	12/17/12	1	Reattach power cables to overhead fluoro monitor
3	1/4/13	1/4/13	4	Preventive maintenance
3	5/1/13	5/1/13	4	Preventive maintenance

Table 1. CCL Services Unavailable by Date and Room (continued)

- **June 1, 2011-May 31, 2012**

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
1	6/1/11	6/1/11	4.0	Preventive maintenance
1	7/1/11	7/1/11	5.0	Room down for replacement of equipment. Utilized room 3 for STEMI cases.
1	8/10/11	8/10/11	8.0	Software upgrade. Utilized room 3 for STEMI cases.
1	9/1/11	9/1/11	4.0	Preventive maintenance
1	11/17/11	11/17/11	4.0	Table not operating. Utilized room 3 for STEMI cases.
1	12/1/11	12/1/11	4.0	Preventive maintenance
1	3/1/12	3/1/12	4.0	Preventive maintenance
1	6/1/12	6/1/12	4.0	Preventive maintenance
2	6/16/11	6/16/11	3.5	Calibration of C-Arm
2	8/24/11	8/24/11	0.5	Monitor not functioning
2	10/26/11	10/26/11	0.5	Image "burn out"
2	11/4/11	11/4/11	1.25	Continued image "burn out"
2	1/13/12	1/13/12	4.75	Non- diagnostic images room
2	4/1/12	4/1/12	4.0	Preventive maintenance
2	5/2/12	5/2/12	13.75	Image quality poor
3	6/1/11	6/1/11	2.0	Collimator failure
3	8/1/11	8/1/11	4.0	Preventive maintenance
3	11/1/11	11/1/11	4.0	Preventive maintenance
3	11/4/11	11/4/11	1.25	Monitor not working
3	1/25/12	1/25/12	1.0	Table malfunctioning
3	2/1/12	2/1/12	4.0	Preventive maintenance
3	2/15/12	2/15/12	1.0	Unable to acquire live fluoro
3	5/1/12	2/1/12	4.9	Preventive maintenance

Source: Carroll Hospital Center, Application for Renewal of Waiver, pages 17-18.

During the reporting period, CHC always had at least one backup room available to provide pPCI services for STEMI patients.

CHC 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 the ACCF-NCDR CathPCI Registry data for the period July 2011-March 2013 and data reported by the applicant for the second quarter of 2013 (Table 2), CHC met the required threshold for door-to-balloon (DTB) time, providing pPCI within 90 minutes or less of hospital presentation for 81 percent of patients over this period (118 of 146 patients). On a quarterly basis, CHC met the DTB standard in six of the eight quarters reviewed and was just below the standard (74 percent of cases) in one of the two non-conforming quarters. Staff notes that CHC had no transfer patients for the entire review period.

CHC's internal data and ACCF-NCDR ACTION Registry-GWTG reports for the period July 2011-June 2013 were fully consistent with Staff's analysis of the ACCF-NCDR CathPCI Registry data, following a small number of corrections to the initial data submission. Therefore, a separate table with information reported by CHC to accompany the following Table 2 is unnecessary and has not been included in this report.

Table 2. Primary PCI Volume, Median Door-to-Balloon (DTB) Time, and Number and Percentage of Patients by DTB ≤ 90 minutes by Quarter: Data Reported by Carroll Hospital Center, July 2011- June 2013

Quarter and Year	Primary PCI Volume	Median Door-to-Balloon Time (Minutes)	Door-to-Balloon Time	
			≤ 90 Minutes (N)	≤90 Minutes (%)
Quarter 3 (July-Sept 2011)	12	74.5	10	83
Quarter 4 (Oct-Dec 2011)	19	78.0	14	74
Quarter 1 (Jan-Mar 2012)	19	75.0	16	84
Quarter 2 (Apr-June 2012)	23	67.0	19	83
Quarter 3 (July-Sept 2012)	19	86.0	15	79
Quarter 4 (Oct-Dec 2012)	16	70.0	14	88
Quarter 1 (Jan-Mar 2013)	19	82.0	13	68
Quarter 2 (Apr-June 2013)*	19	Not Calculated	18	95
All Quarters	146	Not Calculated	118	81

Source: MHCC staff analysis of NCDR data for July 2011-March 2013and Additional Information August 19-21, 2013.

Notes: *NCDR data is not available yet for the period April-June 2013; values shown in the table were reported by the applicant. 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 insertion of the first device (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 procedure date for the patient.

CHC 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 3 shows the total number of staff currently involved in providing primary PCI services at CHC. The nursing staff remains at 5.2 FTEs, and the FTEs for cardiovascular

technicians and nursing technicians also remain the same, at 5.0 FTEs and one FTE, respectively. CHC increased the number of physicians on staff from four to five.

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

Staff	Number	Cross-Training (S/C/M)*
Physicians	5	
Nurses	5.2 (FTE)	C/M
Cardiovascular Technicians	5.0 (FTE)	S/C/M
Nursing Technician	1.0 (FTE)	C

Source: CHC Application for Renewal of Waiver, June 11, 2013, pp. 8-9.
*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. CHC does not permit cardiologists to have simultaneous on-call duties at other hospitals.

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

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time*
Physicians	1	Every 5th night and every 5th weekend	45 minutes
Nurses	2	Weekly 1630-0700 hours Monday-Friday, 24 hours on weekends	30 minutes
Cardiovascular Technicians	1	Weekly 1630-0700 hours Monday-Friday, 24 hours on weekends	30 minutes
Nursing Technician	1	Weekly 1630-0700 hours Monday-Friday, 24 hours on weekends	30 minutes

Source: CHC Application for Renewal of Waiver, June 11, 2013, p. 9;
*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.

CHC provides post-procedure care for pPCI patients in the hospital's Coronary Care Unit (CCU), which has 12 licensed beds. During the period from June 2012 to May 2013, the average daily census for the CCU beds was 7.0 patients. CHC has hired full- and part-time credentialed intensivists to cover the hospital's critical care services 24/7. The hospital uses a locum agency to cover the intensivists' vacations and time off as needed. The number of paid FTEs providing direct nursing care included 30.2 hospital RNs. A nursing technician who also functions as a unit secretary (1.8 paid FTEs) supports 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]

CHC 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

John Sernulka, President and CEO of CHC, submitted a written statement committing to support the pPCI program as part of the original pPCI waiver application. The renewal application states that the original commitment letter remains in effect. CHC 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

David Zimrin, M.D. continues as the Medical Director of Interventional Cardiology at CHC. The previously submitted position description for the Medical Director remains in effect. CHC 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

CHC has one group that carries out the case review function, reviews issues, identifies problem areas, and develops solutions related to its pPCI program. The Emergent PCI Quality and Case Review group meets regularly each month.

CHC meets this requirement.

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

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

CHC held meetings of the multiple care area group on a monthly basis (except December 2012); the hospital provided information concerning dates and attendance at the meetings held from June 2012 to June 2013. In addition to the Medical Director of Interventional Cardiology, interventionalists, and CCL staff, participants included: ED physicians; ED Registered Nurse; Executive Director of the ED Service Line; Critical Care Unit Manager and Critical Care Educator; other nurses; Quality Manager; Executive Director of the Cardiovascular Service Line; Assistant Vice President of Service Lines; Pharmacist; and EMS Liaison.

CHC 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

CHC provided a list of continuing educational activities in which staff in the CCL and the Coronary Care Unit participated from June 1, 2012 to May 31, 2013. Educational activities encompassed the following topics: Pacemaker Lead; Pradaxa®; tissue plasminogen activator; Alaris® Pump; Critical Stenosis Intervention; Stents; Intra-Aortic Balloon Pump; and LifeVest®.

CHC 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

Prior to the last waiver renewal, CHC executed an amendment to extend its Collaboration Agreement with the University of Maryland Medical Center (UMMC) that provides for the unconditional transfer of pPCI patients to UMMC. CHC meets this requirement. CHC indicated that this amended agreement has not been terminated, amended, modified, or replaced since its previous waiver renewal.

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

CHC indicated its written agreements have not changed since the previous waiver renewal. The Hospital previously executed an interfacility transport agreement with University of Maryland ExpressCare that guarantees arrival within 30 minutes if an air ambulance is available and able to fly. The ground transport agreement between CHC and Butler Medical Transport is compliant and remains in effect. Butler Medical Transport provides an ambulance on site at Carroll Hospital Center. CHC 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 pPCI privileges at CHC over two 12-month periods, July 1, 2011-June 30, 2012, and July 1, 2012-June 30, 2013.

Table 5. Total Number of PCI Cases Performed by Physician: Carroll Hospital Center, July 1, 2011 – June 30, 2013

Physician and Reporting Period	Number of pPCI Cases at CHC	Total PCI Cases-All Hospitals
7/1/12-6/30/13		
Anuj Gupta, M.D.	8	101
Barry Reicher, M.D.	15	92
Mukta Srivastava, M.D.	22	156
James L. Stafford, M.D.	0	78
Mark R. Vesely, M.D.	13	120
David A. Zimrin, M.D.	16	77
7/1/11-6/30/12		
Anuj Gupta, M.D.	25	140
Barry Reicher, M.D.	4	45
James L. Stafford, M.D.	0	129
Mark R. Vesely, M.D.	17	126
David A. Zimrin, M.D.	27	131

Source: CHC Application for Renewal of Waiver, June 11, 2013, pp. 22-27; Additional Information, August 19, 2013.

As shown in Table 5, all but one of the physicians, Barry Reicher, M.D., met the performance standard of 75 or more PCI cases annually for the two reporting periods shown. The medical director for CHC's PCI program indicated that he was aware that Dr. Reicher would be reducing his work schedule to pursue additional education and followed his case volume closely. The medical director stated that he believed the standard was applied on a calendar year basis, noting that in both CY 2011 and CY 2012 Dr. Reicher met the standard. Commission staff confirmed this assessment. However, CHC should not have permitted Dr. Reicher to perform pPCI upon realizing that his case volume was not sufficient, based on the waiver renewal period. During the third and fourth quarters of 2011, Dr. Reicher's PCI volume was only 13 cases. In the next two quarters (January-June 2012) Dr. Reicher performed a much greater number of cases (32 total). However, this increase was not sufficient to reach the performance standard of 75 or more PCI cases. In the following year, Dr. Reicher performed a total of 92 cases, well over the performance standard of 75 PCI cases.

Given that Dr. Reicher is currently meeting the physician volume standard, it is acceptable for Dr. Reicher to continue providing PCI services at CHC. It is important that CHC make certain that each of its interventionalists remains in compliance with this regulatory requirement based on the renewal period for the waiver. CHC has assured Commission staff that it will comply with the physician volume performance standard.

The substantial level of compliance achieved by CHC on this standard and CHC's assurances merit strong consideration in this case, despite Dr. Reicher's lack of compliance with the case volume standard in FY 2012. Staff does not recommend denial or conditioning of the waiver renewal on the basis of this issue.

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

CHC reported that none of the above physicians is newly out of fellowship. This requirement does not apply.

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

Analysis

Five physicians currently participate in CHC's on-call schedule: Drs. Zimrin, Gupta, Vesely, Srivastava, and Reicher. Dr. Stafford did not perform pPCI at CHC during the reporting period. CHC is consistent with this requirement.

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

Analysis

Each of the physicians is currently in good standing. In May 2013, CHC renewed the privileges of Drs. Zimrin, Vesely, Reicher, and Stafford. The hospital renewed the privileges of Dr. Gupta in May 2012, and Dr. Srivastava gained privileges for the first time in July 2012.

CHC 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.

CHC reported that at no time did it fail to take a STEMI patient emergently to the cardiac catheterization laboratory because the staff or lab was unavailable. Data from the ACCF CathPCI Registry confirms that at no time between July 2011 and March 2013 did CHC provide thrombolytic therapy. Commission staff's review of the ACCF CathPCI Registry data also suggests that patients undergoing pPCI at CHC met the above inclusion criteria and were appropriate for primary PCI in settings without on-site cardiac surgery.

CHC 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 CHC is located in the metropolitan area of Baltimore, the program is required to perform a minimum of 49 pPCI cases annually. Data reported by the applicant show that CHC performed 73 pPCI cases between July 2011 and June 2012 (Table 6). This information is consistent with Commission staff's analysis of the ACCF NCDR CathPCI Registry data.

Table 6. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Carroll Hospital Center, July 2011- June 2012

Quarter and Year	Number of pPCI Cases*
Quarter 3 (Jul-Sep 2011)	12
Quarter 4 (Oct-Dec 2011)	19
Quarter 1 (Jan-Mar 2012)	19
Quarter 2 (Apr-June 2012)	23
Total	***73***

Source: CHC Additional Information, August 19, 2013.
*PCI volume refers to the number of cases where a device was used. All patients undergoing PCI were appropriate for pPCI in settings without on-site cardiac surgery.

Based on CHC internal data and ACCF NCDR Action Registry data, the hospital reported performing 74 primary PCI cases between July 2012 and June 2013 (Table 7). This information is consistent with Commission staff's analysis of the ACCF NCDR CathPCI Registry data between July 2012 and March 2013; Registry data for April-June 2013 is not yet available.

Table 7. Number of Patients Who Had Primary Percutaneous Coronary Intervention (pPCI) by Quarter: Carroll Hospital Center, July 2012-June 2013

Quarter and Year	Number of pPCI Cases
Quarter 3 (Jul-Sep 2012)	19
Quarter 4 (Oct-Dec 2012)	17
Quarter 1 (Jan-Mar 2013)	19
Quarter 2 (Apr-Jun 2013)	19
Total	***74***

Source: CHC Additional Information, August 19, 2013.

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

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

III. RECOMMENDATION

Based on the above analysis and the record in this review, Carroll Hospital Center meets the COMAR 10.24.17.05D(1) requirements for institutional resources, patient groups suitable for pPCI in settings without on-site cardiac surgery, institutional volume, and process and outcome measures for ongoing quality assessment. In addition, Carroll Hospital Center substantially meets the requirements for physician resources, with the exception of one physician performing fewer than 75 PCI cases over the first four quarters of data reviewed as part of Carroll Hospital Center's waiver renewal. Therefore, the Executive Director of the Maryland Health Care Commission recommends that the Commission issue a two-year waiver that permits Carroll Hospital Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery services.

Table 8. Summary of Analysis: Carroll Hospital Center

COMAR 10.24.17.05D(1) Requirement	Compliance
Provision of primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week	Yes
Provision of primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients 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.	No*
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

*One physician did not perform 75 cases for the first four quarters of data reviewed for the waiver renewal. However, the physician did perform over 75 cases for the most recent four quarters of data reported.

MARYLAND HEALTH CARE COMMISSION

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

TO: John Sernulka, FACHE
President and CEO
Carroll Hospital Center
200 Memorial Avenue
Westminster, Maryland 21157

September 19, 2013
Date

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

13-06-0072 WR
Docket No.

PROJECT DESCRIPTION

On September 15, 2011, the Commission issued a two-year waiver permitting Carroll Hospital Center (CHC 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, CHC applied to the Commission on June 11, 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 September 19, 2013, that a two-year waiver be issued that permits Carroll Hospital 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 October 13, 2013 and end on October 13, 2015.

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

CHANGES TO APPROVED WAIVER

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

RENEWAL OF WAIVER

The Hospital must submit an application for renewal of its waiver before its waiver is scheduled to expire on October 13, 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 Carroll Hospital Center to provide primary percutaneous coronary intervention services without on-site cardiac surgery, stating acceptance of its terms and conditions, is required within thirty (30) days.

MARYLAND HEALTH CARE COMMISSION

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Ben Steffen
Executive Director

cc: Patricia Nay, M.D., Director, Office of Health Care Quality
Larry L. Leitch, M.A., M.P.A., Health Officer, Carroll County
Robert Bass, M.D., FACEP, Executive Director, MIEMSS