

IN THE MATTER OF \*  
\*  
CARROLL HOSPITAL CENTER \*  
\* BEFORE THE  
AND UNIVERSITY OF MARYLAND \*  
\*  
UPPER CHESAPEAKE MEDICAL \* MARYLAND HEALTH  
\*  
CENTER \*  
\* CARE COMMISSION  
CERTIFICATE OF CONFORMANCE \*  
\*  
ELECTIVE PCI SERVICES \*  
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**Staff Report and Recommendation**

**December 18, 2014**

# **I. INTRODUCTION**

## **A. Background**

In 2012, Maryland established a new regulatory model for percutaneous coronary intervention (PCI) and cardiac surgery services. PCI is a procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve narrowing of the artery and includes rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents, and other catheter devices for treatment of coronary atherosclerosis.

Under the 2012 law, PCI became a service explicitly regulated by the Maryland Health Care Commission (MHCC) rather than indirectly regulated through regulation of “open heart surgery.” Establishment of new PCI programs are now considered through a process called Certificate of Conformance (CoC) review, with all providers of PCI services now subject to revalidation and authorization through periodic on-going performance reviews.

Two categories of PCI programs are addressed in the Certificate of Conformance regulations found in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Coronary Intervention Services chapter (Chapter) of the State Health Plan, which became effective August 18, 2014: (1) emergency, or primary, PCI programs, that provide only emergent PCI intervention in a heart attack shortly after it begins, and; (2) programs that provide both emergency pPCI and elective, or non-primary, PCI cases, which are non-emergent and involve interventions to revascularize coronary arteries that are substantially blocked but have not resulted in an immediate cardiac event requiring emergency treatment.

Most PCI cases in Maryland are performed in the ten hospitals that provide cardiac surgery and both types of PCI services. However, in the last two decades, research studies have shown that both emergency and elective PCI services can be provided in hospitals without on-site cardiac surgery and achieve levels of patient safety, with respect to mortality and complication rates, comparable to the performance achieved in cardiac surgery hospitals. The initial research study, in which Maryland hospitals participated, showed that in hospitals without cardiac surgery on site (SOS), the provision of primary PCI to certain heart attack patients provided better outcomes than thrombolytic therapy, which previously had been standard care for heart attack patients in non-SOS hospitals. For this reason, the Commission permitted non-SOS hospitals that could meet certain volume and quality standards to provide primary PCI services.. Ultimately, 13 such programs were established, more than doubling the number of Maryland sites at which primary PCI can be performed, with the benefit of enabling better emergency interventions to occur more quickly following the onset of a heart attack, Early intervention is a critical factor in preserving life and minimizing the damage to heart muscle, improving the recovery potential for the patient.

More recently, the changing science in heart disease treatment showed that the provision of elective PCI in non-SOS hospitals was not inferior to the provision of elective PCI in hospitals with cardiac surgery on-site. As a result, the Commission granted authority to provide elective PCI

services to eight of the 13 non-SOS hospitals that were providing primary PCI. The potential benefit of allowing a hospital with only primary PCI services to provide elective PCI programming is that a more active program with more PCI cases may support the sustainability of the hospital's provision of needed primary PCI services, a life-saving procedure. These eight hospitals all experienced a regulated and monitored sequence of first operating their elective PCI programs as research "waiver"<sup>1</sup> hospitals, graduating to "registry waiver"<sup>2</sup> status at the conclusion of the active research phase and now, through the 2012 legislation and resulting MHCC action, as regular clinical providers of both primary and elective PCI, subject to on-going performance reviews by MHCC.

Five Maryland hospitals are only authorized to provide emergency PCI services. Two of those hospitals, Carroll Hospital Center (CHC) and University of Maryland Upper Chesapeake Medical Center (UMC), both located approximately one hour apart in north central Maryland, are the first two applicants for Certificates of Conformance to initiate elective PCI programs.

Additional background on the evolution of PCI regulation in Maryland can be found in Section .02 of the Chapter, which can be accessed through the following link:  
<http://www.dsd.state.md.us/artwork/10241701.pdf>

## **B. Applicants**

### **Carroll Hospital Center (CHC)**

Carroll Hospital Center is a 147-bed general acute care hospital located in Westminster, the county seat of Carroll County, and is the only hospital located within this jurisdiction. It is an independent hospital but recently announced an affiliation with LifeBridge Health, a multi-facility health care system with two general acute care hospitals, Sinai Hospital of Baltimore, located in northwest Baltimore City, and Northwest Hospital, located in Randallstown, in Baltimore County. CHC may eventually become a member hospital of the LifeBridge system. Sinai Hospital, the largest LifeBridge general hospital, provides both cardiac surgery and the full spectrum of PCI services.

To implement this project, CHC proposes to purchase an Intravascular Ultrasound with Fractional Flow Reserve at an estimated cost of \$170,000. This equipment will be used to measure the way in which coronary artery blockages impede oxygen delivery to the heart muscle, providing additional diagnostic information for use in determining the appropriate approach to treating a particular patient's disease condition. It is the only expenditure CHC has proposed in association with this project.

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<sup>1</sup> Authorized to provide the service under the control and protocols of a clinical trial examining the safety of elective PCI in hospitals without cardiac surgery back-up.

<sup>2</sup> Authorized to provide the service with mandatory National Cardiac Data Registry (NCDR) reporting requirements for performance monitoring.

## University of Maryland Upper Chesapeake Medical Center (UCMC)

University of Maryland (UM) Upper Chesapeake Medical Center is a 183-bed general acute care hospital located in Bel Air, the county seat of Harford County. Historically, it was part of a two-hospital system composed of the two Harford County general hospitals, UCMC and Harford Memorial Hospital in Havre de Grace. In 2013, after an evolutionary affiliation, the two-hospital Upper Chesapeake Health System was merged into the University of Maryland Medical System (UMMS), which operates 11 general hospitals in the State. Two UMMS hospitals provide cardiac surgery and PCI, the University of Maryland Medical Center in Baltimore City and UM St. Joseph Medical Center in Towson, Baltimore County. Two other UMMS hospitals, UM Baltimore Washington Medical Center in Glen Burnie (Anne Arundel County) and UCMC provide emergency PCI without on-site cardiac surgery backup and BWMC also provides elective PCI services. BWMC submitted a letter of intent in December 2014 to establish a cardiac surgery program.

UCMC has stated that no capital expenditure by the hospital will be required add elective PCI services.

### Service Area Population Characteristics

The most recent population forecast of the Maryland Department of Planning indicates that Carroll County’s population will increase about five percent between 2010 and 2020, and the population of Harford and Cecil County will grow slightly faster during this ten-year period, six to seven percent. Population growth in these three jurisdictions is slightly slower than that for Maryland overall, a projected eight percent between 2010 and 2020. All three jurisdictions will see growth in the current decade in their elderly population of 45 to 50 percent, slightly higher than projected growth statewide (39 percent).

Cecil County is relevant to consider with respect to primary and elective PCI at because it borders Harford County on the north, at greater distance from the hospital facilities concentrated in Baltimore City and County, and is connected to Harford County via an interstate highway. UCMC identified six Cecil County zip code areas<sup>3</sup> in which it has a majority market share position and included these in its service area definition when projecting elective PCI demand. These same six areas accounted for 30 percent of the total population of the 17 Cecil County zip code areas in 2010 and are identified by UCMC as having a shorter driving distance to UCMC than the nearest Delaware hospital providing primary PCI, Christiana Hospital in Newark.<sup>4</sup>

**Table 1: Population and Population Change: Carroll, Cecil, and Harford County, 2010-2020**

Jurisdiction	2010 Total	2010 Aged 65+	2020 Total	2020 65+
Carroll	167,134	21,809	175,898	32,236
Cecil	101,108	11,875	108,596	17,568
Harford	244,826	30,564	258,648	44,441

Source: Maryland Dept. of Planning, July 2014 population projection series

<sup>3</sup> Perry Point, Perryville, Port Deposit, Rising Sun, Colora, and Conowingo.

<sup>4</sup> Google Maps

## Compliance With Primary PCI Waiver Requirements

Both Carroll Hospital Center and UCMC obtained their initial one-year waivers to provide primary PCI services in 2008. Thus, both qualify to submit CoC applications to add elective PCI by virtue of providing primary PCI in accordance with established standards for more than two years, as provided in Health-General 19-120.1(g)(2)(vii) and COMAR 10.24.17.04A(2)(b). Both have received three “waiver” renewals of two years duration, reflecting compliance with the performance standards used by MHCC for emergency PCI waivers prior to the 2012 law. The waiver for UCMC was last renewed in March of 2013 and that of CHC was last renewed in September of 2013.

Both hospitals were asked to address their current compliance with the standards for emergency PCI in this review. Their filings indicate that each hospital continues to meet the standards for primary PCI. All of the required confirmations and affirmations have been made. The following information highlights the recent experience of the hospitals with respect to the primary PCI standards in the Chapter.

Each hospital maintains the necessary on-call facilities and staffing to be able to perform primary PCI 24 hours per day, seven days per week on short notice with acceptable levels of downtime for cardiac catheterization laboratories. CHC reports one fewer physician performing primary PCI services at the hospital, compared to the staffing level at its 2013 waiver renewal, but still exceeds the minimum requirement.

**Table 2: Total Number of Cardiac Catheterization Laboratory Physicians, Nurses, and Technical Staff, August 2014**

	Full-Time Equivalents	Cross-Training
<b>CHC</b>		
Physicians	4	
Nurses	6.2	circulate/monitoring
Technical Staff	5.8	scrub/circulate/monitoring
<b>UCMC</b>		
Physicians	4	
Nurses*	11	circulate/monitoring
Technical Staff*	8	scrub/circulate/monitoring

Source: CoC Applications, CHC & UCMC, Sept, 2014

\*UCMC also report four “as necessary” staff; one nursing and three techs

Each hospital is achieving acceptable case volume and door-to-balloon (DTB) times for primary PCI cases. In the twelve months preceding these CoC applications, the following tables show what the applicants reported. Each had one quarter in the past year in which it fell below the target DTB time of less than 90 minutes for at least 75% of primary PCI cases. However, for the fiscal year covered, CHC provided PCI with a DTB time of 90 minutes or less 88% of the time and UCMC met this performance standard in 78% of cases. Both programs show improvement in DTB times reported in the last waiver renewals of 2013, but a new standard for measuring DTB times was adopted for use by MHCC in 2014, in order to better align the standard with the National Cardiac Data Registry (NCDR) definition. As shown in Table 3, at 82 and 128 emergency PCI cases, respectively, both also exceeded the highest minimum program volume level standard in the

Chapter, 49 cases. In 2012 and 2013, CHC reported annual case volumes of 73. In 2011-2012, UCMC reported 116 and 130 cases.

**Table 3: Door-to-Balloon Time, Carroll Hospital Center, 2013-14**

	STEMI Patients	STEMI Patients Receiving Primary PCI	STEMI Patients with DTB Times < 90 Minutes	
			Number	%
Third Qtr. 2013	38	27	25	93
Fourth Qtr. 2013	21	17	11	65
First Qtr. 2014	22	18	16	89
Second Qtr. 2014	26	20	20	100
<b>TOTAL</b>	<b>107</b>	<b>82</b>	<b>72</b>	<b>88</b>

Source: CoC Applications, CHC, Sept, 2014

**Table 4: Door-to-Balloon Time, UM Upper Chesapeake Medical Center, 2013-14**

	STEMI Patients	STEMI Patients Receiving Primary PCI	STEMI Patients with DTB Times < 90 Minutes	
			Number	%
Third Qtr. 2013	52	26	24	92
Fourth Qtr. 2013	53	29	22	76
First Qtr. 2014	61	37	27	73
Second Qtr. 2014	51	36	27	75
<b>TOTAL</b>	<b>217</b>	<b>128</b>	<b>100</b>	<b>78</b>

Source: CoC Applications, UCMC, Sept, 2014

The cardiologists at both facilities report PCI caseloads that are well above the minimum requirement of 50 PCI procedures annually averaged over a 24-month period. The average annual caseloads reported for the CHC cardiologists ranged from 93 to 161 cases; for UCMC, the range was 176 to 274 cases.

As a matter of form, the applicant hospitals were also asked to address the three general review standards that are posed to all general hospitals filing Certificate of Need applications for any type of project, under COMAR 10.24.10. These standards address information regarding charges, the hospital's charity care policy, and quality of care.

Both hospitals demonstrated that they complied with the charge information standard. This standard requires availability of a defined "representative list of charges" that is updated at least quarterly and made available on the hospital's website. Both hospitals have complying charity care policies and both fell within the third quartile in the most recent ranking of Maryland hospitals by level of charity care provided (charity care as a percentage of total expenses). Both hospitals also complied with the quality of care standard. They have all necessary licenses, certifications, and accreditations and neither hospital has any quality measures that had a measure value that fell below 90% in the most recent update of the Hospital Performance Evaluation Guide at the time these applications were submitted.

## II. PROCEDURAL HISTORY

Both applicant hospitals filed CoC applications in September 2014. Subsequently, in response to requests for additional information and clarification, both hospitals submitted two additional filings; in the case of CHC, on September 26 and October 13, 2014 and, in the case of UCMC, on September 29 and October 29, 2014.

## III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

### A. Commission Program Policies, COMAR 10.24.17.04A(2)

#### Consideration of New Programs.

##### *(2) Elective Percutaneous Intervention*

*(a) A hospital shall obtain a Certificate of Conformance to establish elective PCI services, unless the hospital is exempt from this requirement under Health General §19-120.1(d).*

Neither of these hospitals is exempt from CoC requirements.

*(b) A hospital shall have been providing primary PCI services for at least two years before seeking a Certificate of Conformance to provide elective PCI services, unless the hospital is located in a part of Maryland that does not have sufficient access to emergency PCI services. In such cases, sufficiency of access will be evaluated by the Commission based on a review of evidence presented by the applicant and collected by Commission staff. An applicant shall show that the population in the service area of the proposed program is receiving suboptimal therapy for STEMI. This review shall include an analysis of emergency transport data and patient-level outcome data.*

Each hospital has been providing primary PCI services for more than two years.

*(c) A review schedule for the establishment of elective PCI programs will be published in the Maryland Register at least annually for each health planning region where there is at least one hospital that provides only primary PCI services. An application to establish primary PCI and elective PCI services based on insufficient access pursuant to .04A(2)(b) of this regulation may be filed at any time.*

All five of the hospitals that currently provide only primary PCI were eligible to file in this first CoC review cycle for elective PCI. Only CHC and UCMC did so.

### Certificate of Conformance Review Standards, COMAR 10.24.17.06

#### B. Elective PCI Services.

*A hospital issued a Certificate of Conformance to establish an elective PCI service shall agree to voluntarily relinquish its authority to provide elective PCI services if it fails to meet the*

***applicable standards for a Certificate of Conformance.***

Acknowledgment of this agreement was part of each applicant's affidavit concluding the CoC applications, which were signed by Robert White, Vice President of Operations for CHC and by Lyle Sheldon, President and CEO of UCMC.

***An applicant seeking to establish elective PCI services shall meet all applicable criteria for a Certificate of Conformance for a primary PCI program<sup>5</sup>, and shall meet the following additional requirements***

***(1) Need***

***The hospital shall demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.***

**CHC**

CHC initially reported that, prior to the implementation of its primary PCI program, it was taking "many" of the patients in need of emergency PCI arriving at its emergency department as "walk-ins" or by ambulance transport, in excess of three hours to "get out of" its emergency department to providers of primary PCI services. In response to staff questions, CHC reported that, prior to establishment of its primary PCI program, a "comprehensive study of the arrival and transfer time for patients requiring primary PCI showed a median arrival to transfer time of 1 hour 54 minutes" and a delay in initiating transfer "primarily due to the need to locate an accepting facility and arrange transfer." CHC also stated that processing of primary PCI patients in its emergency department had been improved, with electrocardiograms (ECGs) administered within eight minutes for walk-ins from the time of registration and, in the case of EMS transport, use of field ECGs with direct communication from the field coming to the hospital ED to expedite initiation of the emergency PCI when the patient arrives. CHC states that expected door-to-door time in the ED is less than 60 minutes.

In supplemental filings where each hospital was asked to expand on its initial responses to this standard, CHC noted the "fixed cost burden" of the emergency PCI program primarily related to the inefficiency and low productivity of "stand-by coverage" costs. It stated that its ability to continue to provide primary PCI services at "close to break-even" is predicated on successfully maintaining its fixed cost investment at current levels through the growth in case volume associated with elective PCI. The hospital stated that, if it is granted authority to provide elective PCI, its currently unproductive stand-by costs will be converted to productive elective PCI activity. Without this additional service, the current "thin margins" will erode.

**UCMC**

UCMC identifies itself as the principal primary PCI provider for residents of Harford County and most of Cecil County and notes that travel time for ambulances is negatively affected

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<sup>5</sup> This requirement was addressed in the preceding Section I.B. of this report.



by the condition of some roadways in this service area and the Susquehanna River, with limited crossing points for vehicles coming from Cecil County to UCMC. UCMC reports that travel times can be as long as 30 minutes from northeast Harford County to UCMC and up to 40 minutes from central Cecil County. The hospital states that traveling to the closest alternative Maryland primary PCI site beyond Bel Air, Franklin Square Hospital in northeast Baltimore County adds 20 minutes to the transit time. UCMC believes that the absence of its primary PCI service in Bel Air would “severely limit” the ability to reach the “potential target of 90 minutes from first medical contact to balloon time” for many patients from this service area.

UCMC pointed out that the new hospital payment model is one in which additional volume may not equate to enhanced financial sustainability. It believes that, in the absence of elective PCI capabilities, “patients will seek programs that can provide these services (diagnostic and interventional cardiac catheterization) seamlessly,” placing the interventional program at risk as physicians channel patients in greater numbers to facilities with “robust PCI services.” The hospital states that this scenario will make it harder to attract cardiologists to work at UCMC and harder to maintain on-call coverage. Payors will also prefer to channel patients to other facilities to avoid duplicative costs, and the reduced level of diagnostic cardiac catheterizations resulting from this migration of patients will increase the unit cost of CCL services. UCMC also notes that as a primary PCI provider it is probably limited to reaching a total of approximately 150 pPCIs but will be unable to achieve the 200 to 250 case volume level, associated with improved performance and better outcomes. As will be noted, UCMC believes that it can almost certainly reach these volumes with the addition of elective PCI.

Estimated driving mileage from the CoC applicant hospitals to the nearest alternative hospitals providing emergency PCI services are shown in the following table.

**Table 5: Estimated Driving Miles from CHC and UCMC to Nearest Alternative Emergency PCI Hospitals in Central and Western Maryland and in Delaware**

Hospital	Location	CHC	UCMC
<b>BALTIMORE COUNTY</b>			
University of Maryland St. Joseph	Towson	31	20
MedStar Franklin Square	Rosedale	39	19
<b>BALTIMORE CITY</b>			
<b>Sinai</b>	<b>Baltimore City</b>	<b>30</b>	<b>34</b>
St. Agnes	Baltimore City	31	33
MedStar Union Memorial	Baltimore City	33	30
University of Maryland	Baltimore City	36	31
Johns Hopkins	Baltimore City	36	26
Johns Hopkins Bayview	Baltimore City	41	24
<b>FREDERICK COUNTY</b>			
Frederick Memorial	Frederick	30	78
<b>OTHER</b>			
Meritus	Hagerstown, Washington Co.	56	-
Christiana	Newark, Newcastle Co., Delaware	-	50

Source: Google Maps (Mileage shown is for route with lowest number of driving miles)

## **Recommendation**

The locations of these hospitals, in State-designated rural counties lying beyond the suburbs of Baltimore (and, in northeast Maryland, lying beyond the suburbs of Wilmington, Delaware, and Philadelphia) lend themselves to the more timely access rationale underlying the planned de-concentration of PCI services over the last ten years. Unlike the situation in the urban centers of Baltimore and the District of Columbia, losing one of these primary PCI centers would substantially result in reduced timely access to PCI facilities for the populations residing in the immediate area of the hospital and the northern sectors of the hospitals' service areas.

Each hospital, although currently showing a positive account of revenue and expenses, predicts that its PCI program will erode unless it is granted authority to perform elective PCI. Each hospital believes that there will be inevitable marginalization of PCI programs that are limited to emergency PCI relative to the 18 existing Maryland hospitals with both elective and primary PCI capabilities.

Staff concludes that the preferable course of action for the Commission, in this situation where an alternative for primary PCI is not within a close driving distance of many points in the program's home county and some adjoining areas, is to authorize CHC and UCMC to provide elective PCI and thereby improve the productivity of their PCI facilities and staff.

For these reasons, Staff recommends that the Commission find that CHC and UCMC each has demonstrated that its proposed elective PCI program is needed to preserve timely access to primary PCI services for the population to be served.

### ***(2) Volume***

***The hospital shall demonstrate its proposed elective PCI program will achieve a volume of 200 or more total PCI cases (elective and emergency) by the end of the second year of providing elective PCI services.***

### **CHC**

The hospital described a twelve-city (zip code area) primary service area and identified 413 elective PCI cases in that area in 2013. CHC assumes that its proposed elective PCI program will be able to draw 25% of this market and increase that share to 35% within three years. This will yield, with no change in PCI volume generated from the service area, 105 to 147 elective PCI cases in the first three years of operation. At the approximate average emergency PCI case count of 80, this forecast yields a total of 206 PCI cases by the second year and 227 by the third year, just above the minimum volume target.

Using NCDR data sets, MHCC staff examined the overlap, at the zip code area-level, between the complete 20-zip code service area defined by the origin of primary PCI cases at CHC in 2013 and the patient origin of primary and elective PCI cases from the other 22 Maryland hospitals, two Delaware hospitals, and MedStar Washington Hospital Center in D.C., in that same year. This approach yields an elective PCI case pool of 610 cases originating from the zip codes

associated with CHC's primary PCI cases, substantially larger than the pool of primary PCI cases from the service area identified by CHC. Assuming an emergency PCI case load of 80, CHC would only need to capture about 20% of this larger market definition to reach the minimum 200 case volume. The data set indicates that CHC performed just over half of the primary PCI cases originating in its complete service area, as defined by primary PCI patient origin.

## UCMC

UCMC notes that reaching a case volume of 200 for all PCI cases at UCMC would only require about 50 elective PCI cases per year, given its recent average annual primary PCI volume of 150 cases. By comparison, UCMC notes that over 300 cardiac patients per year are being transferred to the University of Maryland Medical Center<sup>6</sup> from Harford County physician practices and facilities, many of whom obtain an elective PCI. The current Medical Director of the UCMC primary PCI program performed 129 PCI cases at UMMC in FY2014.

In a supplemental filing, UCMC identified a 31-zip code service area based on inpatient volume. Twenty-three of the zip code areas are Harford zips, six are Cecil County zips, and two Baltimore County zips are included. UCMC stated that it had a majority of market share in each of these zip code areas. UCMC assumed that it would be able to capture 40% of the elective PCI market in these areas and indicated that it had a 23% share of the primary PCI cases in the service area. UCMC projects 100 elective PCI cases in its first year of offering this service, increasing to 160 elective PCI cases by the fourth year of operation. Coupled with an average of 150 emergency PCI cases, this yields a forecast of 250 total PCI cases in the first year and 310 by the fourth year.

MHCC staff applied the same total service area analysis using the NCDR data sets and, as with CHC, found that relatively modest market share assumptions can be used to forecast an elective PCI caseload at UCMC that would top 200 cases per year. The data set indicates that UCMC accounted for just over 60% of the primary PCI cases originating in its complete service area, as defined by primary PCI patient origin.

Implicit in consideration of this standard is the impact that these proposed projects are likely to have on existing program volume. The following table profiles Maryland hospitals' PCI program activity in 2013.

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<sup>6</sup> UCMC notes that patients are also referred to UM St. Joseph Medical Center, Johns Hopkins Hospital, MedStar Union Memorial Hospital, and other hospitals.

**Table 6: CY 2013 PCI Program Case Volume, Maryland Hospitals**

<b>Central Maryland Hospitals</b>	<b>Primary</b>	<b>Elective</b>	<b>Total</b>
<b>Cardiac Surgery/PCI Centers</b>			
MedStar Union Memorial (Baltimore City)	98	1,005	1,103
UM St. Joseph (Baltimore County)	114	947	1,061
Sinai of Baltimore (Baltimore City)	83	746	829
Johns Hopkins (Baltimore City)	43	749	792
University of Maryland (UM) (Baltimore City)	67	587	654
<b>PCI Centers – Emergency and Elective</b>			
St. Agnes (Baltimore City)	117	358	475
Anne Arundel (Anne Arundel)	127	221	348
UM Baltimore Washington (Anne Arundel)	115	177	292
Johns Hopkins Bayview (Baltimore City)	57	142	199
<b>PCI Centers – Emergency Only</b>			
UM Upper Chesapeake (Harford)	131	-	131
MedStar Franklin Square (Baltimore County)	112	-	112
Carroll (Carroll)	84	-	84
Howard General (Howard)	81	-	81
<b>Washington, DC Area Hospitals</b>			
<b>Cardiac Surgery/PCI Centers</b>			
MedStar Washington (District of Columbia)	241	1,561	1,802
Washington Adventist (Montgomery)	67	634	701
Suburban (Montgomery)	69	428	497
Prince George's (Prince George's)	56	189	245
<b>PCI Centers – Emergency and Elective</b>			
MedStar Southern Maryland (Prince George's)	111	179	290
Shady Grove Adventist (Montgomery)	114	145	259
<b>PCI Centers – Emergency Only</b>			
Holy Cross (Montgomery)	81	-	81
<b>Western Maryland Hospitals</b>			
<b>Cardiac Surgery/PCI Centers</b>			
Western Maryland Regional (Allegany)	53	270	323
<b>PCI Centers – Emergency and Elective</b>			
Frederick (Frederick)	112	219	331
Meritus (Washington)	86	209	295
<b>Eastern Shore Hospital</b>			
<b>Cardiac Surgery/PCI Centers</b>			
Peninsula Regional (Wicomico)	121	526	647

Source: MHCC staff analysis of NCDR CathPCI registry data, CY 2013.

The service area overlap analysis previously noted indicates that four hospitals are most likely to experience some loss of elective PCI case volume through the addition of this service at CHC. Listed in order with respect to the number of cases originating from zip code areas in the CHC primary PCI service area, they are UM St. Joseph Medical Center, Sinai Hospital, University of Maryland Medical Center, and Meritus Medical Center. The level of likely individual impact on these programs would not reduce the volume of any existing PCI program to levels inconsistent with the State Health Plan requirements. The “maximum potential impact” is an unlikely “worst

case” impact (from the perspective of the affected hospital) assuming that CHC would be able to capture 100% of the elective PCI caseload of the affected hospital in zip code areas that are included in CHC’s complete emergency PCI service area.

**Table 7: Impact Analysis – Addition of Elective PCI at CHC**

Hospital	Projected Range of Impact	Maximum Potential Impact	2013 Adjusted Cases		
			Projected Impact Range	Maximum Potential Impact	Total PCI Cases (primary and non-primary)
UM St. Joseph	85	177	885	770	884- 999
Sinai	41	117	705	629	705- 788
Meritus	25	70	184	139	225- 270
UMMC	21	61	566	526	593- 633

Source: NCDR and CHC CoC Application, Sept 2014

The fact that the interventional cardiologists staffing the CHC emergency PCI program are affiliated with the University of Maryland Medical Center suggests that the service area overlap analysis probably overstates the likely impact of elective PCI at CHC on non-UMMS facilities and, correspondingly, understates that on UMMS hospitals. The service area analysis indicates that the two UMMS hospitals have existing elective PCI program volumes large enough to withstand the worst case impact resulting from the addition of an elective PCI program at CHC, without raising questions with respect to proficiency or viability of the UMMS hospitals’ programs.

The service area overlap analysis indicates that four hospitals are most likely to experience some loss of elective PCI case volume through the addition of this service at UCMC, and three are the same hospitals potentially affected by the addition of the CHC program. Listed in order with respect to the number of cases originating from zip code areas in the UCMC primary PCI service area, they are Sinai, UM St. Joseph Medical Center, University of Maryland Medical Center, and Union Memorial Hospital. As with the previous table, the “maximum potential impact” is an unlikely “worst case” impact scenario assuming that UCMC would be able to capture 100% of the elective PCI caseload of the affected hospital in zip code areas that are included in UCMC’s complete emergency PCI service area.

**Table 8: Impact Analysis – Addition of Elective PCI at UCMC**

Hospital	Projected Range of Impact	Maximum Potential Impact	2013 Adjusted Cases		
			Projected Impact Range	Maximum Potential Impact	Total PCI Cases (primary and non-primary)
Sinai	84	211	662	535	618-745
UM St. Joseph	72	181	875	766	880- 989
UMMC	69	173	518	414	481- 585
Union Memorial	36	90	969	915	1,013- 1,067

Source: NCDR and UCMC CoC Application, Sept 2014

Combining the service area overlap analyses to account for projected and maximum potential impact yields the following scenarios.

**Table 9: Impact Analysis – Addition of Elective PCI at CHC and UCMC**

Hospital	Projected Range of Impact	Maximum Potential Impact	2013 Adjusted Cases		
			Projected Impact Range	Maximum Potential Impact	Total PCI Cases (primary and non-primary)
UM St. Joseph	134	358	813	585	699- 927
Sinai	125	328	621	418	501- 704
UMMC	90	234	497	353	420- 564

Source: NCDR and CHC and UCMC CoC Application, Sept 2014

In its application, UCMC stated that it expected the existing elective PCI program at the University of Maryland Medical Center would experience the greatest level of impact, in terms of “market share volume,” as a result of its proposed introduction of this service, citing the case volume (129 cases in FY 2014) of Dr. Michael Drosser, Medical Director of its Interventional Cardiology program, at UMMC and noting that these patients “live in our service area.”

### **Recommendation**

Staff recommends that the Commission find that CHC and UCMC has each demonstrated that its proposed elective PCI program is likely to achieve a volume of 200 or more total PCI cases (elective and emergency) by the end of the second year of providing elective PCI services. This case volume can be achieved without reducing the volume at existing elective PCI programs unacceptably.

#### ***(3) Financial Viability***

***The Commission may waive the volume requirement in subsection (2) if the applicant demonstrates that adding an elective PCI program to its existing primary PCI program at its likely projected annual case volume will permit the hospital’s overall PCI services to achieve financial viability.***

Neither applicant hospital is seeking a waiver of the volume requirement in subsection (2) to demonstrate that the additional service will permit PCI to achieve financial viability at the hospital as a service line. And, as noted, staff believes that both facilities can reach the minimum volume level of 200 total cases per year by shifting achievable levels of market share from the service areas they have established for primary PCI.

Each hospital provided financial schedules of revenues and expenses that show income generation from delivery of primary PCI. The hospitals took different approaches to reporting and modeling revenues and expenses and this can be seen in the financial schedules they provided. CHC took a broad approach, looking at revenues and expenses throughout its full range of diagnostic and treatment services and allocating revenues and expenses for all these services for each primary PCI patient that received primary PCI at CHC.

**Table 10: Revenues and Expenses (\$000s), Primary PCI Services at Carroll Hospital Center**

	<b>FY 2013</b>	<b>FY 2014</b>
Gross Patient Services Revenue	\$1,854	\$1,891
Bad Debt	40	58
Contractual Allowances	182	225
Charity Care	45	25
Net Patient Services Revenue	\$1,587	\$1,583
<b>Operating Expenses</b>		
Salaries, Wages, and Benefits	\$1,070	\$1,065
Contractual Services	13	14
Current Depreciation	64	64
Supplies	343	353
Total Operating Expenses	\$1,490	\$1,496
<b>Income from Operations</b>		
	\$98	\$87

Source: CHC CON Application, Sept 2014

UCMC more narrowly focused on its cardiac catheterization laboratory operation in constructing its financial schedule. The revenue side reflects charges for primary PCI and does not attempt to pull in additional revenue generated by primary PCI patients either pre or post PCI. Similarly, in reporting and projecting expenses, it focused on staffing and supplying its CCL and allocated costs just to account for primary PCI cases (excluding, e.g., diagnostic cardiac catheterization, electrophysiology studies, and other services).

**Table 11: Revenues and Expenses (\$000s), Primary PCI Services at Upper Chesapeake Medical Center**

	<b>CY 2012</b>	<b>CY 2013</b>
Gross Patient Services Revenue	\$2,583	\$2,658
Bad Debt	155	160
Contractual Allowances	155	160
Charity Care	77	80
Net Patient Services Revenue	\$2,196	\$2,260
<b>Operating Expenses</b>		
Salaries, Wages, and Benefits	\$140	\$138
Contractual Services	47	46
Current Depreciation	5	5
Supplies	878	904
Total Operating Expenses	\$1,070	\$1,093
<b>Income from Operations</b>		
	\$1,126	\$1,167

Source: UCMC CON Application, Sept 2014

Each hospital projects that it will profitably provide the expanded PCI service range, if approval is granted by the Commission.

**Table 12: Revenues and Expenses, Primary PCI Services at Carroll Hospital Center**

	FY 2015	FY 2016	FY 2017
Gross Patient Services Revenue	\$2,351	\$2,939	\$3,106
Bad Debt	61	76	80
Contractual Allowances	280	350	370
Charity Care	42	53	56
Net Patient Services Revenue	\$1,968	\$2,460	\$2,600
<b>Operating Expenses</b>			
Salaries, Wages, and Benefits	\$1,220	\$1,402	\$1,457
Contractual Services	17	22	24
Current Depreciation	64	64	64
Project Depreciation	12	24	24
Supplies	568	863	945
Total Operating Expenses	\$1,883	\$2,375	\$2,514
<b>Income from Operations</b>			
Income from Operations	\$85	\$85	\$85

Source: CHC CON Application, Sept 2014

**Table 13: Revenues and Expenses, Primary PCI Services at Upper Chesapeake Medical Center**

	CY 2015	CY 2016	CY 2017
Gross Patient Services Revenue	\$4,714	\$5,505	\$5,656
Bad Debt	283	330	339
Contractual Allowances	283	330	339
Charity Care	141	165	170
Net Patient Services Revenue	\$4,006	\$4,680	\$4,808
<b>Operating Expenses</b>			
Salaries, Wages, and Benefits	\$339	\$575	\$575
Contractual Services	46	46	46
Current Depreciation	5	5	5
Supplies	1,603	1,872	1,923
Total Operating Expenses	\$1,992	\$2,498	\$2,549
<b>Income from Operations</b>			
Income from Operations	\$2,014	\$2,181	\$2,258

Source: UCMC CON Application, Sept 2014

### **Recommendation**

This standard is inapplicable to the review of these CoC requests, since neither hospital seeks relief from the minimum volume standard on the basis of trying to achieve financial viability through the addition of elective PCI. Based on our review of the financial performance information provided, staff believes that both CHC and UCMC can provide primary and elective PCI services on a financially viable basis.

#### **(4) Quality**

***A hospital shall demonstrate that it provided high quality emergency PCI services over a period of two years or longer, unless the hospital is not required to obtain a Certificate of Conformance to establish emergency PCI services before establishing elective PCI services.***

As previously noted, both of these hospitals were authorized to provide primary PCI services in 2008 and have received three renewals of their “waivers” to continue providing the



service. Before issuing the waiver renewals, the Commission found that the programs met the applicable quality standards. Each hospital has updated its information on compliance with primary PCI standards (each obtained two-year waiver renewals in 2013) and both continue to be compliant with those standards. It is anticipated that the meaning of “high quality emergency PCI services” may evolve under the new regulatory oversight structure put in place this year by MHCC and this consideration will come into play as the performance of these two hospitals and others are subjected to on-going performance review.

***(5) Preference***

***A hospital that was providing primary PCI services on January 1, 2012 will be given preference over another hospital that was not providing primary PCI services on January 1, 2012, when the two hospitals have service areas that overlap and only one additional PCI program is needed to provide adequate geographic access for the population in the service areas of both hospitals.***

Both hospitals provided primary PCI services on January 1, 2012. Neither is in a simultaneous review with a hospital seeking to establish elective PCI services that was not providing primary PCI services on January 1, 2012. Thus, this standard is not applicable in this review.

***(6) Patient Selection***

***The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:***

***(a) Patients described as appropriate for elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of Patients with Acute Myocardial Infarction or in the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.***

***(b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk are not suitable for elective PCI, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.***

Each hospital provided the required commitment, in writing, in its CoC application filings.

#### **IV. SUMMARY AND RECOMMENDATION**

The information considered in this review indicates that each of these hospitals provides a distinct advantage for geographic accessibility to primary PCI services in north central Maryland and each has successfully established and maintained a primary PCI program in conformance with the standards established by MHCC for primary PCI in the non-cardiac surgery hospital setting. It also is likely that each can add elective PCI services in a manner consistent with MHCC’s regulatory expectations and that this will improve the chances for preservation of primary PCI programs at these hospitals, reducing the fixed unit cost of their CCL operations and making the hospitals more attractive venues for interventional cardiologists.

Staff recommends that the Commission award Certificates of Conformance for the provision of elective PCI services by Carroll Hospital Center and University of Maryland Upper Chesapeake Medical Center. Each has demonstrated its compliance with the applicable review criteria and standards.

IN THE MATTER OF \*  
CARROLL HOSPITAL CENTER \* BEFORE THE  
CERTIFICATE OF CONFORMANCE \* MARYLAND HEALTH  
ELECTIVE PCI SERVICES \* CARE COMMISSION  
\*

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**FINAL ORDER**

Based on the analysis and recommendations in the Staff Report and the record in this review, it is, this 18th day of December, 2014, **ORDERED**:

That the application filed by Carroll Hospital Center for a Certificate of Conformance that authorizes it to provide elective, or non-primary, PCI services is hereby **APPROVED**, in accordance with and subject to the applicable requirements in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Intervention Services Chapter of the State Health Plan.

**MARYLAND HEALTH CARE COMMISSION**

IN THE MATTER OF	*	
	*	
UNIVERSITY OF MARYLAND	*	BEFORE THE
	*	
UPPER CHESAPEAKE	*	
	*	MARYLAND HEALTH
MEDICAL CENTER	*	
	*	
CERTIFICATE OF CONFORMANCE	*	CARE COMMISSION
	*	
ELECTIVE PCI SERVICES	*	
*****		

**FINAL ORDER**

Based on the analysis and recommendations in the Staff Report and the record in this review, it is, this 18th day of December, 2014, **ORDERED**:

That the application filed by University of Maryland Upper Chesapeake Medical Center for a Certificate of Conformance that authorizes it to provide elective, or non-primary, PCI services is hereby **APPROVED**, in accordance with and subject to the applicable requirements in COMAR 10.24.17, the Cardiac Surgery and Percutaneous Intervention Services Chapter of the State Health Plan.

**MARYLAND HEALTH CARE COMMISSION**