IN THE MATTER OF	*	**BEFORE THE**
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UNIVERSITY OF MARYLAND	*	**MARYLAND HEALTH**
SHORE MEDICAL CENTER	*	
AT EASTON	*	**CARE COMMISSION**
	*	
DOCKET NO. CC-15-20-0001	*	

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STAFF REPORT & RECOMMENDATION

APPLICATION FOR CERTIFICATE OF CONFORMANCE TO ESTABLISH PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION SERVICES

Released March 11, 2016

I. INTRODUCTION

A. Background

The Maryland Health Care Commission (MHCC) began regulating cardiac surgery and percutaneous coronary intervention (PCI) services through a Certificate of Need process in 1990. For many years, only hospitals with cardiac surgery services on-site could provide PCI services. This approach was adopted because emergency cardiac surgery may be required for a complication of, or inability to satisfactorily complete, PCI. Percutaneous coronary intervention, commonly known as coronary angioplasty, is a non-surgical cardiac procedure in which a catheter is used to place a stent to open blood vessels in the heart that have been narrowed or blocked by a buildup of plaque. Early PCI intervention is a critical factor in preserving life and minimizing damage to heart muscle, thereby improving the recovery potential for the patient. Primary PCI (pPCI) programs provide emergency PCI intervention in the event of a heart attack shortly after it begins. Non-primary PCI programs provide elective interventions that re-vascularize coronary arteries that are substantially blocked but have not resulted in an immediate cardiac event requiring emergency treatment.

As cardiologists gained experience with primary PCI and better techniques evolved, the risks of the procedure declined and results improved. Consequently, in 1996, Maryland began allowing some hospitals to perform primary PCI at hospitals without cardiac surgery on-site, through a program in which the MHCC issued waivers to the co-location requirement. In order to obtain and maintain a waiver to perform pPCI without onsite cardiac surgery services, a hospital had to meet standards adopted by the MHCC.

In its 2004 Cardiac Surgery & PCI Services Chapter of the State Health Plan, the Commission expressed its interest in considering a waiver from the co-location requirement to conduct a well-designed research study that would test the theory that performing non-primary (elective) PCI in a non-surgery-on-site hospital was not inferior to performing the procedure in a hospital with cardiac surgery on site. This change was very controversial. A research proposal by Dr. Thomas Aversano of Johns Hopkins was ultimately approved by the MHCC's Research Proposal Review Committee composed of national and regional experts. Nine Maryland hospitals participated in the C-PORT E research study. In 2012, Dr. Aversano presented new research from a multi-site clinical trial (C-PORT E) that found that elective PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. As a result of these new research findings, in 2012, at the MHCC's request, the Maryland legislature passed a law directing the Commission to adopt new regulations for the oversight of PCI services at hospitals without on-site cardiac surgery. After extensive discussion with a clinical advisory group that developed formal recommendations, MHCC staff developed proposed regulations. The Commission then adopted new regulations for cardiac surgery and PCI services that became effective in August 2014, and which were subsequently updated in November 2015.

COMAR 10.24.17, the State Health Plan chapter for both PCI and cardiac surgery, contains standards for the establishment of a new primary or elective PCI programs and for evaluating performance of established PCI services in Maryland. An applicant's request to establish a new pPCI program, elective PCI program, or both a pPCI and elective PCI program is

considered through a Certificate of Conformance review. A Certificate of Conformance for both primary and elective PCI, if granted, authorizes a hospital to provide the specified services for a specified period of time. At the end of the time period, the hospital must meet requirements in COMAR 10.24.17 to renew its authorization to provide the PCI service by obtaining a Certificate of Ongoing Performance issued by the Maryland Health Care Commission if a hospital demonstrates that it has met quality and performance standards.

B. Applicant

University of Maryland Shore Medical Center at Easton (UMSMC-E)

The University of Maryland Shore Medical Center at Easton (UMSMC-E or the Hospital), is a 112-bed general acute care hospital located in Easton, Maryland (Talbot County). The Hospital is designated as a primary stroke center by the Maryland Institute for Emergency Medical Services System (MIEMSS), and it includes a 20-bed acute inpatient rehabilitation center.[1] UMSMC-E is a member of the University of Maryland Medical System, specifically the UM Shore Regional Health network which serves the Mid-Shore region. In addition to the UMSMC-E, the network includes two other hospitals, the University of Maryland Shore Medical Center at Chestertown (Kent County) and the University of Maryland Shore Medical Center at Dorchester (Dorchester County), as well as the University of Maryland Shore Emergency Center at Queenstown (Queen Anne's County) and the University of Maryland Shore Medical Pavilion at Queenstown, the University of Maryland Shore Nursing and Rehabilitation Center at Chestertown, and a variety of inpatient and outpatient services in locations throughout the five-county region.[2]

UMSMC-E submitted an application for a Certificate of Conformance to perform pPCI and elective PCI services, and projects a capital cost of $2,568,600 for this project. This includes $1,650,000 for fixed equipment, including equipment to be used in a second proposed cardiac catheterization laboratory. An additional $918,600 is to be used for building, architect/engineering fees, and permits (Application, Form A).

Service Area

UMSMC-E primarily serves a five county area, including Caroline, Dorchester, Kent, Queen Anne's, and Talbot counties on Maryland's Eastern Shore. UMSMC-E is located in Talbot County, and is approximately 90 minutes from both Baltimore and Washington D.C.[3] With an estimated population of 37,782,[4] Talbot County and this mid-region of the Eastern Shore is not densely populated. (Talbot County has 140.7 persons per square mile compared with the

[1] University of Maryland Shore Regional Health (2016), University of Maryland Shore Medical Center at Easton. Retrieved from.http://umshoreregional.org/about/facilities/easton.

[2] University of Maryland Shore Regional Health (2016), About us. Retrieved from http://umshoreregional.org/about#sthash.dM3jBukl.dpuf.

[3] Talbot County (2014). About Talbot County. Retrieved from www.talbotcountymd.gov.

[4] Suburban Stats. Population Demographics for Talbot County, Maryland in 2016 and 2015. Retrieved Feb. 23, 2016 https://suburbanstats.org/population/maryland/how-many-people-live-in-talbot-county.

statewide Maryland ratio of 594.8 persons per square mile.[5] Talbot County also has an older population than the state overall (26.6% aged 65+ compared with Maryland's 13.8%). The balance of UMSMC-E's service area is rural in nature (an average of 91.3 persons per square mile) and, like Talbot County older than most of the state, ranging from 15.4% aged 65+ in Caroline County to 24.4% in Kent County.[6]

C. Staff Recommendations

MHCC staff recommends that the Commission conditionally APPROVE UMSMC-E's request for a Certificate of Conformance to establish both primary and elective PCI services, but only issue a Certificate of Conformance if, on or before April 11, 2016, UMSMC-E provides documentation satisfactory to MHCC staff demonstrating that: (1) The Hospital has protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure; and (2) The Hospital has executed an agreement that provides for 30-minute response time regardless of the circumstances. The Hospital has shown that the population it proposes to serve has insufficient access to pPCI services. UMSMC-E also has demonstrated that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served, and it has, with the exception of the items for which additional documentation is required, demonstrated compliance with the other criteria and standards for Certificates of Conformance for pPCI and elective PCI services. Staff's analysis of the information presented by UMSMC-E follows.

II. PROCEDURAL HISTORY

UMSMC-E filed a Certificate of Conformance application in October 2015. Subsequently, on December 4, 2015, UMSMC-E submitted responses to MHCC staff's questions, requests for additional information, and requests for clarification concerning its application for a Certificate of Conformance to establish pPCI and elective PCI services.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

10.24.17.06A(1) An applicant seeking a Certificate of Conformance to establish primary PCI services shall address and meet the general standards in COMAR 10.24.10.04A in its application.

The applicable standards from the Acute Care Hospital Services Chapter are shown below in bold.

(1) Information Regarding Charges.

Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

[5] U.S. Census Bureau State & County Quick Facts http://quickfacts.census.gov/qfd/states/24/24041.html.
[6] Maryland State Data Center http://www.mdp.state.md.us/msdc/s3_projection.shtml.

(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

Maryland hospitals are required to make information regarding hospital charges available to the public. UMSMC-E submitted its charge information for the ten most common inpatient surgical procedures, medical imaging services, and laboratory services. (Application p. 4; Exh. 1). The Hospital states that its charge information is displayed prominently within the Hospital. The charge information is also displayed on the Hospital's website. Requests for estimated charges are handled by the Hospital's financial counselors or by schedulers in Community-Wide Scheduling. In order to ensure that inquiries regarding charges are handled appropriately, training for financial counselors and schedulers is conducted during their initial training and then conducted annually by the Hospital's Patient Financial Services Department. (Application, Exh. 1).

Staff Analysis

Based on the information provided in UMSMC-E's application, and MHCC staff's ability to locate updated charge information on the Hospital's web site, MHCC staff concludes that UMSMC-E is compliant with this standard.

(2) Charity Care Policy.

Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.

(a) The policy shall provide:

(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.

(ii) Minimum Required Notice of Charity Care Policy.

1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;

2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital;

3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.

(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

UMSMC-E submitted a copy of its written policy for patient financial assistance

including eligibility criteria and its policy for the provision of charity care for indigent patients. (Application, Exh. 2). The applicant states that these policies apply to all Shore Health System acute care hospitals. The financial assistance policy states that Shore Regional Health is committed to providing financial assistance or charity care to all persons with health care needs who are uninsured or underinsured and unable to pay for medically necessary care. The charity care policy states that a determination of probable eligibility will be made within two business days following a patient's request for charity care services. The applicant stated that its policies are publicized on a yearly basis in the local newspapers and are also prominently displayed in key patient access areas of the Hospital and on the hospital website. UMSMC-E indicated that the policy was prepared in a culturally sensitive manner and is available in English and Spanish. UMSMC-E stated that the Hospital was not in the bottom quartile with respect to the percentage of charity care relative to total operating expenses, based on the most recent Health Services Cost Review Commission's Community Benefit Report (Application, p. 6). According to UMSMC-E, in FY 2014, the Hospital provided $5,828,000 in charity care, which was 3.62% of its total operating expenses. (Application, p.5).

Staff Analysis

MHCC staff confirmed the level of charity care provided by UMSMC-E in FY 2014 compared to other Maryland hospitals through analyzing the information provided in HSCRC's Community Benefit Report. In FY 2014, the percentage of charity care provided by Maryland hospitals ranged from 10.11% for Bon Secours to 1.11% for Anne Arundel Medical Center, and the median amount of charity care provided was 3.60%. The amount of charity care provided by UMSMC-E (3.62%) falls in the second quartile. Consequently, MHCC staff concludes that UMSMC-E is appropriately meeting its charity care obligations. In addition, based on the information provided by UMSMC-E on its financial assistance and charity care policies and MHCC staff's ability to locate these policies on UMSMC-E's web site, MHCC staff concludes that UMSMC-E is compliant with the charity care policy standard.

(3) Quality of Care.

An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

(i) Licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;

(ii) Accredited by the Joint Commission; and

(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.

(b) A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.

UMSMC-E is a Medicare provider in good standing and has not been sanctioned, barred or excluded from participating in the Medicare program in the previous five years. UMSMC-E is currently accredited by the Joint Commission and has not had its accreditation denied, limited, suspended, withdrawn, or revoked in the previous three years, nor has the Hospital been put on

Accreditation Watch by the Joint Commission. (Application, p. 3). UMSMC-E noted, however, that the hospital has several quality indicators that fall in the bottom quartile of all hospitals in Maryland, in the Maryland Hospital Performance Guide. These quality indicators include categories of deaths or returns to the hospital, heart attack and chest pain, heart failure, nursing care, and patient safety (Application, Exh. 3). The cardiac quality indicators in which UMSMC-E performed in the bottom quartile are shown in Table 1.

Table 1: Cardiac Quality Indicators for UMSMC-E Where UMSMC-E's Performance Is in the Bottom Quartile

Category	Sub-Category	Indicator	Higher or Lower is Better	Bottom Quartile Level	UMSMC-E
Deaths or returns to the hospital	Heart attack and chest pain	How often patients die in the hospital after heart attack	Lower	8.5	8.9
	Heart failure	How often patients die in the hospital after heart failure	Lower	3.4	4.0
Heart attack and chest pain	Recommended care-inpatient	Heart attack patients prescribed aspirin before leaving the hospital	Higher	99.0	96.0
	Results of care	How often patients die in the hospital after heart attack	Lower	8.5	8.9
Heart Failure	Recommended care	Heart failure patients given medicine to make the heart work better	Higher	96.8	96.0
	Results of care	How often patients die in the hospital after heart failure	Lower	3.4	4.0
Heart surgeries and procedures	Recommended care	Procedure used to find blocked blood vessels in the heart on both sides instead of one side of the heart. Doing this procedure on both sides often leads to more complications	Lower	2.1	9.4

Sources: UMSMC-E correspondence with MHCC staff October, 2015 and Application Exh.3.
Note: MHCC staff rounded values to the nearest 1/10th percent.

In response to the Hospital's initial Certificate of Conformance application, MHCC staff asked UMSMC-E to provide specific information regarding actions being taken to improve performance on those quality measures where it was in the bottom quartile. In the follow-up response dated December 4, 2015, UMSMC-E assured MHCC staff that it is taking specific actions to improve performance for indicators that fall in the bottom quartile, including adoption of a formal Mortality Review Committee and a Performance Management Committee. Both Committees review individual mortality cases. The Hospital has also formed a Core Measures Group that alerts managers to measures on their units.

Staff Analysis

MHCC staff reviewed UMSMC-E's performance on all 73 measures reported in the Maryland Hospital Evaluation Guide. Compared to other Maryland hospitals, UMSMC-E scored better than average in the risk-adjusted rate of readmissions within 30 days of discharge. The Hospital's performance on patient safety, nursing care, and in-hospital deaths from one of six

problems (heart attack, heart failure, stroke, internal bleeding, hip fracture, or pneumonia) was close to the Statewide average. There were, several cardiac-related quality indicators in which UMSMC-E performed in the bottom quartile, as shown in Table 1. However, the Hospital's performance on these quality measures did not fall below the 90% level of compliance. For example, the score for quality measure *aspirin prescription for heart attack patients* was 96% which was equivalent to two missed opportunities for aspirin prior to discharge in a 12-month period. (UMSMC-E Letter to MHCC Staff, December 4, 2015, Exh. 17).

The Hospital reported that it is taking specific actions to improve its performance for the 19 quality measures where the Hospital's performance falls in the bottom quartile. MHCC staff concludes that UMSMC-E complies with the quality of care standard.

Need

10.24.17.06A(2) A hospital shall demonstrate that the proposed program is needed for its service area population through an analysis of current utilization patterns of the population for primary PCI services

UMSMC-E defined its service area for pPCI services based on drive times from various communities within five Maryland counties (Caroline County, Dorchester County, Kent County, Queen Anne's County, and Talbot County) near UMSMC-E. (Application, p. 8). UMSMC-E stated that it obtained estimated travel times from the Maryland Institute for Emergency Medical Services Systems (MIEMSS) to various hospitals in the area, as well as information on the primary hospital for emergency cases (not just PCI), and the backup hospitals used based on traffic, alerts, and other factors. (Application, p. 8). UMSMC-E subsequently updated this information, after obtaining additional information on pPCI services for Delaware hospitals from MHCC staff.

UMSMC-E identified zip code areas in five Maryland counties near UMSMC-E as its service area. The number of pPCI cases originating from each zip code area within these five counties is shown in Table 2, along with the total pPCI cases for each zip code area in 2014 (71 cases). UMSMC-E estimated travel times to the nearest MIEMSS-designated Cardiac Interventional Centers for the population in its service area and reported the pPCI volume from its proposed service area for each location. As shown in Table 2 below, there were 20 cases performed at Anne Arundel Medical Center (AAMC), one case at Howard County General Hospital, 33 cases at Peninsula Regional Medical Center (PRMC), three cases at the University of Maryland Medical Center, 13 cases at Nanticoke Memorial Hospital in Seaford, Delaware, and one case at Christiana Hospital in Newark, Delaware. UMSMC-E estimates that the average drive time for service area patients requiring pPCI services would be reduced by 40.7 percent, if it were to establish a pPCI program, as shown in Table 2. (UMSMC-E Letter to MHCC staff, December 4, 2015).

UMSMC-E cited a statement on page 11 of the Cardiac Surgery and PCI Services Chapter, COMAR 10.24.17, as evidence that a pPCI program is needed in the mid-Eastern Shore region. (Application, p.9). This statement reads:

> The Maryland Institute for Emergency Medical Services Systems (MIEMSS) analyzed the drive time to acute care Maryland hospitals and some hospitals outside the State based on 2010 information. The map assembled by MIEMSS shows that the two largest geographic regions beyond a 30-minute drive time to a MIEMSS designated cardiac interventional hospital are: the three southernmost counties of Southern Maryland (Calvert, Charles, and St. Mary's); and the mid-Shore counties of the Eastern Shore (Caroline, Dorchester, Kent, Queen Anne's and Talbot).

UMSMC-E reported 28 walk-in STEMI patients in 2014 and noted that the University of Maryland Shore Medical Center at Dorchester had ten such patients and that the freestanding emergency center at Queenstown had one. UMSMC-E stated that a pPCI program at the Hospital would reduce transit times and that, without it, patients would be at greater risk of not obtaining a critical intervention in an optimal timeframe. UMSMC-E expressed concern that the optimal timeframe in the future may be a measure of first medical contact to balloon time, rather than door-to-balloon time. (Application, pp. 13-14).

Table 2: Number of Primary PCI Cases by Zip Code Area of Residence and Hospital (CY 2014) and Comparison of Drive Times to Hospitals

Location		Number of Cases							Driving Time (Minutes)					(Cases)x(Minutes)	
Zip Code Area	County	AAMC	Howard	PRMC	UMMC	Christina	Nanticoke	Grand Total	AAMC	PRMC	Christiana	Nanticoke	MSMC-E UMSMC-E	*Total Minutes to PCI Hospital	*Total Minutes to UMSMC-E
21629	Caroline						1	1				34	26	34	26
21632	Caroline						5	5				17	30	85	150
21639	Caroline	1						1	56				38	56	38
21640	Caroline			1				1	54	77			47	77	47
21655	Caroline	1			1		4	6	58			28	19	170	19
21660	Caroline	1						1	47				29	47	29
21613	Dorchester	1		12				13	65	36			20	497	260
21631	Dorchester			2				2		36			27	72	54
21643	Dorchester			1	1		2	4		37		22	32	70	96
21835	Dorchester	1						1	72	28			27	72	27
21869	Dorchester			2				2		24			36	48	72
21620	Kent				1	1		2			61		51	61	51
21619	Queen Anne's	5						5	22				35	110	175
21623	Queen Anne's	1						1	43				40	43	40
21638	Queen Anne's	1						1	22				29	22	29
21658	Queen Anne's	2	1					3	34				26	68	52
21601	Talbot	5		8				13	48				0	240	0
21624	Talbot						1	1				73	26	73	26
21625	Talbot	1		1				2	46	53			15	99	30
21663	Talbot			1				1		67			18	67	18
21671	Talbot			2				2		85			34	170	68
21673	Talbot			3				3		41			20	123	60
TOTAL		20	1	33	3	1	13	71						2,304	1,367
Average drive time														43.5	25.8
Total travel time savings (in minutes)															937
Savings %															40.7%

Sources: Number of Cases is from MHCC staff's analysis of NCDR CathPCI Registry CY 2014; UMSMC-E Letter to MHCC Staff, December 4, 2015.
*Note: The last two columns are the product of multiplying the number of cases projected by the estimated driving time.

Staff Analysis

The impact of door-to-balloon time on mortality rates led to the wide adoption of a door-to-balloon time standard of 90 minutes or less, and continues to be the standard, as reflected in the current (2013) guidelines of The American College of Cardiology/American Heart Association for the Management of STEMI patients. In COMAR 10.24.17.07D(4)(b), the Commission adopted this standard for evaluating the quality of primary PCI services. Maryland's primary PCI programs are expected to have a door-to-balloon time of 90 minutes or less for at least 75 percent of patients who receive pPCI, excluding transfer patients. Using the

NCDR CathPCI Registry, a large national registry used by participants for quality improvement, MHCC staff investigated whether patients who received pPCI from zip code areas in the service areas identified by UMSMC-E met this standard in CY 2014. MHCC staff calculated that only 61.8% of all patients in UMSMC-E's proposed service area had a door-to-balloon time of 90 minutes or less, without excluding transfer patients.

MHCC staff requested information from MIEMSS on the likely impact of a pPCI program at UMSMC-E on the EMS system, drive-times, and quality of care. MIEMSS reported that, for the period November 1, 2014 to October 31, 2015, there were a total of 34 patients within a drive time of 30 minutes to UMSMC-E identified as STEMI and 12 were transported to UMSMC-E, even though the patients likely would then be transferred to a hospital with pPCI services by commercial air services at potentially significant financial cost to the patients and significant delays in critical time to reperfusion. MIEMSS noted that all the other STEMI patients were driven to Anne Arundel Medical Center, Peninsula Regional Medical Center, Nanticoke Memorial Hospital, or University of Maryland Medical Center, all located at significantly further distance than UMSMC-E from the place at which the patient was transported MIEMMS also noted that, during the same one-year time period, an additional seven patients were flown from locations in Talbot County, within a 30-minute drive time to UMSMC-E, by Maryland State Police medevac helicopters to a hospital with pPCI services. (Email from MIEMSS to MHCC staff, December 15, 2015).

In addition to evaluating the door-to-balloon times for residents in UMSMC-E's proposed service area and information provided by MIEMSS, MHCC staff evaluated data presented by UMSMC-E regarding drive times. MHCC staff notes that, for approximately 20 patients, or 37% of the projected pPCI case volume for UMSMC-E, travel time would be reduced by 20 minutes or more and would likely be less than 30 minutes, if pPCI services were established at UMSMC-E. For another 18 patients, or 33% of the projected pPCI case volume for UMSMC-E, travel time would be reduced to between 10 and 18 minutes and would likely be less than 30 minutes. MHCC staff concludes that these reductions in travel time are significant. As noted in the SHP Chapter for cardiac surgery and PCI services, ideally, Maryland's residents should be within a 30-minute drive time of a hospital with pPCI services. Based on the travel times to pPCI services for residents in UMSMC-E's identified service area and the high percentage of these residents who did not achieve a door-to-balloon time of 90 minutes or less in CY 2014, MHCC staff concludes that UMSMC-E has demonstrated that the proposed program is needed for its service area population.

Access

10.24.17.06A(3)(a) An applicant shall present evidence, including emergency transport data and patient-level data that demonstrate that the proposed program's service area population has insufficient access to emergency PCI services and is receiving suboptimal therapy for STEMI.

UMSMC-E stated that both the Cardiac Surgery and PCI Services Chapter and MIEMSS recognize that there is an unmet need for pPCI services in the mid-Shore region because most of the population does not have access to pPCI services within a drive time of 30 minutes.

(Application, p. 22). In addition, UMSMC-E noted that patients in the mid-Shore Region are currently being transferred to PCI-capable hospitals for care with an average drive time of 43.5 minutes. The Hospital notes that the average drive time would be reduced for these patients to 25.8 minutes if a pPCI program were established at UMSMC-E. (UMSMC-E Letter to MHCC staff, December 4, 2015, p. 3).

UMSMC-E stated that during the summer months "beach traffic and accidents can double the driving time from UMSMC-E to AAMC. (Application, p. 23). UMSMC-E explained that long transport times lead to unacceptable pick-up-to-balloon times for STEMI patients and lead to tie-ups of emergency transport vehicles and staff, reducing the ready availability of resources for other emergency calls. (Application, p. 24). UMSMC-E also cited a Talbot County transportation planning study as evidence of access barriers due to traffic. This study concluded that traffic congestion during summer weekends "limits the ability for emergency vehicles to maneuver across the County in a timely fashion" (Application, p. 24). UMSMC-E noted that traffic along US 50, both eastbound and westbound during summer weekends was also identified as a concern in the Final Report on the 2007 *Analysis of Transit Only Concepts to Address Traffic Capacity Across the Chesapeake Bay* by the Maryland Transportation Authority. (Application, p. 24). Lastly, UMSMC-E noted that several letters of community support were submitted that identified lack of access to pPCI services as a concern. (Application, Exh. 6).

Staff Analysis

As noted by UMSMC-E, the State Health Plan chapter, COMAR 10.24.17, acknowledges that access to pPCI services is an issue for residents of the mid-Shore region (Application, p. 22). In addition, UMSMC presented evidence that excessive drive times are compounded by significant traffic issues during summer weekends. (Application, p. 23). MHCC staff also found, as discussed in its analysis of the need for pPCI services at UMSMC-E, that the door-to-balloon time standard often is not met for residents of the proposed service area. MHCC staff concludes that UMSMC-E has presented sufficient evidence, including data on estimated emergency transport times, that demonstrates the proposed population to be served has insufficient access to pPCI services.

10.24.17.06B(1) 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.

UMSMC-E cited its responses to the need and access standards without restating those responses. (Application, p. 26). In addition, the Hospital stated that the number of pPCI cases projected would not be enough to recruit two interventional cardiologists to establish a primary PCI program, unless the case volume also included elective PCI services, but that a combined pPCI and elective program with total case volume of 207 PCI cases is adequate for staffing a PCI program. (Application, p. 21). In addition, UMSMC-E stated that the estimated capital costs for starting a PCI program and adding a second cardiac catheterization laboratory ($2,568,600) would be too expensive if UCSMC-E were to provide only pPCI services. (Application, p.21).

UMSMC-E explained that the Health Services Cost Review Commission's reimbursement guidelines will apply, which means that there will be no increase in allowable

revenue for UMSMC-E in the first year that the Hospital provides PCI services. However, the University of Maryland Shore Regional Health (Shore) plans to submit a request for an increase in its total patient revenue cap to fund the new program, and Shore assumed that the HSCRC will approve an amount equal to the first year loss. Based on the assumption that HSCRC will approve additional revenue, UMSMC-E expects its PCI program to have a small net loss of $127,250 in 2020, which represents only 0.07% of UMSMC-E's revenue. (Application, p. 21).

Staff Analysis

MHCC staff concludes that maintaining a pPCI program with an annual volume limited to approximately 50 primary PCI cases would make it challenging for the Hospital to recruit interventionalists because each interventionalist must maintain an average annual case volume of 50 cases over each two-year period, as required by COMAR 10.24.17.06(A)(6)(b), and there are no other nearby Maryland hospitals with PCI programs. Although, three hospitals in Maryland currently provide only pPCI services (Holy Cross Hospital Silver Spring, Howard County General, and MedStar Franklin Square), these hospitals are less remote, so interventionalists may more readily perform PCI services at other hospitals too. MHCC staff also concludes that the cost of establishing a pPCI program without elective services would likely be prohibitive, given the significant capital costs reported by UMSMC-E ($2,568,600) and the net loss projected, even if the case volume exceeds 200 cases. MHCC staff notes that the financial projections of UMSMC-E, which show a small net loss, are generally consistent with those of Carroll Hospital Center, with respect to the overall revenue and expenses per case, as well as the supply cost per case. Carroll Hospital Center applied for a Certificate of Conformance to add elective PCI services in 2014, and its application included current, historical, and projected financial information.

Volume

10.24.17.06A(2)b At a minimum, an applicant shall demonstrate that its proposed program will achieve, by the end of the second year of operation, an annual case volume of at least 36 cases if the hospital is located in a rural area or an annual volume of at least 49 cases if the hospital is located in a non-rural area.

UMSMC-E projected the expected market share and PCI case volume for its proposed service area by evaluating the number of pPCI cases by zip code area and the drive times to the nearest hospital with pPCI services. UMSMC-E assumed that for some zip code areas it would be the primary hospital and would receive 100 percent of the cases. If the difference in drive time between UMSMC-E and another hospital was estimated to be five minutes or less, UMSMC-E assumed each would receive approximately 50 percent of the cases. UMSMC-E also assumed that if a secondary hospital would likely receive patients, even though UMSMC-E would be the primary hospital, then UMSMC-E's market share would be 75 percent. Using these assumptions, UMSMC-E estimated that it would have treated approximately 54 cases had it provided pPCI services in CY 2014. UMSMC-E projected its pPCI cases through 2020, based on its market share assumptions and population projections for two age cohorts 45-64 years and 65 years or older. UMSMC-E projected a volume of 55 cases in 2016, with a slight increase in volume each year through 2020, when approximately 58 cases are projected. The market share

assumptions of UMSMC-E are shown in Table 3. (Application, p. 12; UMSMC-E Letter to MHCC staff, December 4, 2015, p. 6).

Table 3: UMSMC-E pPCI Case Volume by Location CY 2014, Travel Times, Market Share Assumptions, and Projected pPCI Volume for UMSMC-E

Location Description			2014 Total pPCI Cases	Travel Time (minutes)					UMSMC-E Projections	
Zip Code Area	Name	County		AAMC	PRMC	Christiana (DE)	Nanticoke (DE)	UMSMC-E	Market Share	Number of pPCI Cases
21629	Denton	Caroline	1				34	26	100.0%	1
21632	Federalsburg	Caroline	5				17	30	0.0%	0
21639	Greensboro	Caroline	1	56				38	100.0%	1
21640	Henderson	Caroline	1	54	77			47	100.0%	1
21655	Preston	Caroline	6	58			28	19	100.0%	6
21660	Ridgely	Caroline	1	47				29	100.0%	1
CAROLINE TOTAL			**15**						**66.7%**	**10**
21613	Cambridge	Dorchester	13	65	36			20	100.0%	13
21631	East New Market	Dorchester	2		36			27	75.0%	1.5
21643	Hurlock	Dorchester	4		37		22	32	25.0%	1
21835	Linkwood	Dorchester	1	72	28			27	50.0%	0.5
21869	Vienna	Dorchester	2		24			36	25.0%	0.5
DORCHESTER TOTAL			**22**						**75.0%**	**16.5**
21620	Chestertown	Kent	2	54	99		61	51	50.0%	1
KENT TOTAL			**2**						**50.0%**	**1**
21619	Chester	Queen Anne's	5	22				35	25.0%	1.25
21623	Church Hill	Queen Anne's	1	43				40	50.0%	0.5
21638	Grasonville	Queen Anne's	1	22				29	25.0%	0.25
21658	Queenstown	Queen Anne's	3	34				26	75.0%	2.25
QUEEN ANNE'S TOTAL			**10**						**42.5%**	**4.25**
21601	Easton	Talbot	13	48	53			0	100.0%	13
21624	Claiborne	Talbot	1				73	26	100.0%	1
21625	Cordova	Talbot	2	46	65			15	100.0%	2
21663	Saint Michaels	Talbot	1		67			18	100.0%	1
21671	Tilghman	Talbot	2		85			34	100.0%	2
21673	Trappe	Talbot	3		41			20	100.0%	3
TALBOT TOTAL			**22**						100.0%	22
GRAND TOTAL			**71**						**75.7%**	**53.75**

Source: UMSMC-E Letter to MHCC staff, December 4, 2015, pp. 3-4.

Staff Analysis

MHCC staff examined the market share assumptions made by UMSMC-E and noted that

in most cases when UMSMC-E allocates 100% of the market share for a zip code area to itself, the nearest PCI center is much further away, based on the estimated drive-time reported. However, MHCC staff noted that in some cases, UMSMC-E allocated itself 100% of the market share, even though another hospital was seven or eight minutes away, such as zip code areas 21629 and 21640. This appears to be inconsistent with UMSMC-E estimating that it would capture 25% of the market share for zip code areas with a current travel time to pPCI that is only 7 to 13 minutes shorter than the travel time to UMSMC-E, such as 21643, 21869, 21619, and 21638. Consequently, MHCC staff concludes that UMSMC-E may have slightly overestimated the projected volume of its pPCI cases.

Overall, UMSMC-E's projection that it would have captured 75.7% of the market share for pPCI cases in its service area, had it operated in CY 2014 also appears high, relative to the two Maryland hospitals most comparable to UMSMC-E. Similar to UMSMC-E, both the University of Maryland Upper Chesapeake Medical Center (UCMC) and Meritus Medical Center (Meritus) are located far from alternative PCI providers, but each still captured far less than the 75.7% of market share for pPCI cases in its service area. UCMC captured 62% of the pPCI cases originating from zip code areas in its service area for pPCI services in CY 2014, and Meritus Medical Center captured 63% of the market share for zip code areas in its service area for pPCI services in CY 2014. However, the experience of these hospitals also suggests that Maryland hospitals with pPCI services located far from other providers may capture a very high percentage of pPCI market share for patients residing in the same county as the hospital or in a nearby county. In CY 2014, UCMC captured approximately 86 percent of the pPCI cases originating in Harford County zip code areas, and Meritus, located in Washington County, captured 93% of the pPCI services provided to Washington County residents. MHCC staff concludes that UMSMC-E would likely achieve an annual volume of at least 49 pPCI cases, as required.

10.24.17.06B(2) 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.

UMSMC-E calculated that, in 2014, a total of 247 elective PCI cases originated in the Hospital's identified five-county service area. UMSMC-E assumed that its market share for elective PCI services would align with Shore's market share of hospital discharges with a cardiology-related diagnosis. The market share reported by UMSMC-E for each of the five counties is shown in Table 4 below.

Table 4: UM SRH Cardiology Inpatient Admissions and Market Share by County, FY 2015

	Number of Cases by Location					Shore Total	
County	UMSMC-E	UMSMC-C	UMSMC-D	All Other Hospitals	Total	Number of Cases	Percent Market Share
Caroline	266	7	5	163	441	278	63.0%
Dorchester	83	0	329	225	637	412	64.7%
Kent	21	214	0	92	327	235	71.9%
Queen Anne's	102	47	4	377	530	153	28.9%
Talbot	515	0	18	230	763	533	69.9%
Total	987	268	356	1,087	2,698	1,611	59.7%

Source: UMSMC-E Application, p. 18.
Note: UMSMC-C refers to UMSMC in Chestertown and UMSMC-D refers to UMSMC in Dorchester.

UMSMC-E used projected population information for each of the five counties in its proposed service area for two age cohorts (45-64 and 65+) together with its assumptions about market share and historic population use rates for elective PCI services in each county to project the elective PCI case volume for UMSMC-E for the period 2017 through 2020. The market share assumptions range from 28.9% in Queen Anne's County to 71.9% in Kent County, consistent with the market share calculations shown in Table 4. UMSMC-E projects a total of approximately 152 cases in 2017, 154 cases in 2018, 156 cases in 2019, and 158 cases in 2020. (Application, pp. 18-20).

UMSMC-E projects over 200 total PCI cases each year, from 2017-2020. The Hospital's projections are shown in Table 5 below.

Table 5: Number of PCI Cases Projected by UMSMC-E, FY 2017-2020

Category	2017	2018	2019	2020
Primary PCI (pPCI)	55.7	56.4	57.1	57.8
Elective PCI (npPCI)	152.1	154	156	158
Both pPCI & npPCI	207.8	210.4	213.1	215.8

Source: UMSMC-E Letter to MHCC staff, December 4, 2015, p. 8.

In response to a request from MHCC staff, UMSMC-E provided an estimate of the number of patients identified as candidates for elective PCI in diagnostic cardiac catheterization procedures performed at the hospital in the last three fiscal years. This estimate, approximately 35 patients annually, was obtained through reviewing patient records with an abnormal finding from a diagnostic cardiac catheterization and factoring out patients who would likely receive medical management or cardiac surgery rather than PCI services. UMSMC-E commented that the volume of diagnostic catheterizations performed at the Hospital is constrained by the fact that PCI services are not available at the Hospital because local cardiologists who suspect a patient may require PCI refer patients to a hospital with elective PCI services, where diagnosis and treatment can sometimes occur in a single cardiac catheterization visit. (UMSMC-E Letter to MHCC staff, December 4, 2015).

Staff Analysis

MHCC staff examined the market share overlap between pPCI and elective PCI services for Maryland hospitals with both services. MHCC staff determined that University of Maryland Upper Chesapeake Medical Center and Meritus Medical Center were likely the most comparable hospitals to UMSMC-E, due to the distance between these hospitals and the nearest alternative hospital site with pPCI services. MHCC staff noted that for UCMC, which began providing elective PCI services only in 2015, there is extensive overlap between its service area for pPCI services and elective PCI services. For the first six months of 2015, 85% of the elective PCI cases were associated with patient zip code areas for the pPCI service area of UCMC. For Meritus, based on CY 2014 data, the overlap between its service area for pPCI services and elective PCI services was also approximately 85%. Therefore, it is appropriate to assume that the service area for elective PCI services at UMSMC-E will overlap substantially with its pPCI service area.

The market share projections of UMSMC-E for elective PCI cases are very high compared to the experience of other Maryland hospitals, including Meritus, the most comparable location with a full year of data during which it provided both pPCI services and elective PCI services, if the market share for elective PCI services is evaluated based on the market share captured by each hospital for pPCI services. However, due to access barriers to other providers based on travel times and traffic, it may be reasonable to assume UMSMC-E will be able to capture a greater share of the elective cases from its proposed service area. Meritus captured 71.7% of the market share for elective PCI services for zip code areas located in Washington County, where it is located. In addition, MHCC staff agrees that UMSMC-E's use of the market share capture for cardiology services as the basis for its projections is reasonable and accounts for difference in market share capture for each county. Therefore, MHCC staff concludes that UMSMC-E would likely achieve an annual volume of at least 200 total PCI cases as required.

10.24.17.06B(3) The Commission may waive the volume requirement of 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.

UMSMC-E stated that they are not requesting that the minimum volume requirement of 200 cases be waived because its projected total volume of PCI cases (primary and elective) exceeds this minimum.

Staff Analysis

This standard is not applicable because the Hospital is not requesting that the Commission waive the volume requirement for the proposed PCI services.

Institutional Resources

10.24.17.06A(4)(a) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction, 24 hours per day, seven days per week.

UMSMC-E has plans to add a second cardiac catheterization laboratory adjacent to its existing laboratory used for diagnostic cardiac catheterizations. UMSMC-E also stated that regular maintenance of equipment will be scheduled to ensure that one of the two labs will always remain in service. UMSMC-E reported that it has a protocol in place for unforeseen failure of equipment. It stated that elective PCI procedures will be rescheduled and STEMI patients would be transferred to the nearest hospital with PCI services designated as a Cardiac Interventional Center (CIC) by MIEMSS. The Hospital would also notify EMS services of its temporary inability to perform pPCI for STEMI patients, and EMS could then reroute ambulances to an alternative CIC. (Application, p. 27).

Staff Analysis

MHCC staff concludes that, based upon its plan to add a second cardiac catheterization laboratory and its protocol for handling STEMI patients during unforeseen equipment failures, the Hospital is compliant with this standard.

10.24.17.06A(4)(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

UMSMC-E provided a signed statement from the President and CEO of Shore, Kenneth D. Kozel, committing to the provision of pPCI services consistent with the current benchmark for door-to-balloon times. Mr. Kozel stated that UMSMC-E will support the program by providing the leadership and resources necessary to provide pPCI services in accord with the requirements established by MHCC. (Application, Exh. 7).

Staff Analysis

MHCC staff concludes that UMSMC-E meets this standard based on the letter of commitment provided. UMSMC-E stated that the Hospital will participate in the American College of Cardiology's National Cardiovascular Registry (ACC-NCDR). (Application, p. 30). UMSMC-E, like other Maryland hospitals with primary or elective PCI services, will also be required to submit duplicate information to MHCC. MHCC staff will have the ability to track the door-to-balloon times reported in the ACC-NCDR by UMSMC-E. Staff concludes that the Hospital is in compliance with this standard.

10.24.17.06 A (4)(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to patients with acute myocardial infarction 24 hours per day, seven days per week.

UMSMC-E submitted information on the proposed staffing pattern, the days and hours of operation, and the proposed call rotation. The proposed call rotation includes the response time and time to arrival at the hospital. UMSMC-E noted that the staff-to-patient ratio determines the staffing level for any given shift at the hospital. With regard to staffing for the cardiac catheterization laboratory (CCL), UMSMC-E provided the information shown in Table 6. (C), or monitor (M).

Table 6: **Total Number of Cardiac Catheterization Lab Physician, Nursing, and Technical Staff FTEs**

	Number/FTEs	Cross-Training (S/C/M)*
Physician	2.0 FTE	Interventional Cardiologist
Nurse	5.0 (FTE)	S/C/M
Technician	2.0 (FTE)	S/C/M

Source: UMSMCE Application, p. 29.

*S/C/M indicates whether the nursing and technical staff are cross-trained to scrub (S), circulate (C), or monitor (M).

UMSMC-E clarified the number of interventionalists who would provide PCI services, noting that there will be two interventional cardiologists who cover most of the operating and on-call hours. However, other interventionalists from UMMC will cover 6-8 weekends per year. UMSMC-E noted that UMMC cardiologists have agreed to this arrangement. (UMSMC-E Letter to MHCC staff, December 4, 2015).

Staff Analysis

MHCC staff compared the staff levels described by UMSMC-E to information reported by three existing primary PCI programs, MedStar Franklin Square, Holy Cross Silver Spring, and Carroll Hospital Center, during their last waiver renewals. These hospitals each reported either five or six interventionalists on staff for the hospital's PCI program. Unlike the other hospitals, UMSMC-E reported physician FTE's (2 FTEs) rather than the actual number of physicians available to provide pPCI services to patients. UMSMC-E's clarification that additional interventionalists will also provide coverage for weekend shifts suggests that physician coverage will be adequate.

UMSMC-E reported the same nursing staff levels (5 FTEs) as MedStar Franklin Square and Carroll Hospital Center. However, the Hospital reported a lower staffing level of technicians (2 FTEs) than Holy Cross Hospital (4 FTEs, 4 PRNs), MedStar Franklin Square (6 FTEs), and Carroll Hospital Center (6 FTEs). However, UMSMC-E projects fewer pPCI patients than Holy Cross Hospital, Carroll Hospital Center, and MedStar Franklin Square reported experiencing, which may account for the difference in staffing levels. In addition, UMSMC-E may be using a nurse to handle some tasks, rather than a technician. MHCC staff concludes that there will likely be adequate nursing and technical staff to provide services.

10.24.17.06A(4)(d) The hospital president or Chief Executive Officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.

UMSMC-E provided a letter of commitment regarding the establishment of a pPCI

program at the hospital from the hospital President and CEO, Kenneth D. Kozel. In his letter, Mr. Kozel stated that the Hospital and Shore are fully committed to the program to provide critical care cardiovascular services to the community. The letter also expressed the Hospital's commitment to provide primary PCI services in accord with the requirements for primary PCI programs established by the Maryland Health Care Commission. (Application, Exh. 8).

Staff Analysis

MHCC staff concludes that UMSMC-E meets this standard based on the letter of commitment provided.

10.24.17.06A(4)(e) The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

UMSMC-E provided a description of the staff that will be dedicated to the program for data collection, management, reporting, and quality improvement efforts. UMSMC-E stated that data entry will be assigned to two existing data administration positions in the Department of Cardiovascular & Pulmonary Services. UMSMC-E noted that these positions are cross-trained to perform similar registry data entry tasks in other specialty areas of the department. UMSMC-E also stated that its Regional Director for Cardiovascular Services will oversee the quality data collection process along with the Medical Director for Cardiac Services and the Director for Interventional Cardiology. Other staff that will be responsible for data collection, management, reporting and coordination of quality improvement include the Clinical Specialist for the CCL and registered nurses who work in the CCL. Based on this information, MHCC staff concludes that UMSMC-E is compliant with this standard. (Application, p. 30).

10.24.17.06A(4)(f) A hospital shall complete a PCI development plan that includes appropriate training for the emergency room, catheterization laboratory, coronary care unit and, if applicable, post-procedure unit. The plan shall include protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure. In addition, there shall be an on-call coverage back-up plan for primary PCI cases, when an on-call interventionalist covers more than one hospital on a given shift, as well as when two simultaneous STEMI patients present at the hospital.

UMSMC-E indicated that the interventionalists will not be covering more than one hospital and that simultaneous on-call coverage will not be permitted.

Staff Analysis

UMSMC-E did not submit information on protocols for routine and infrequent emergency situations, such as recurrent ischemia or infarction, or failed angioplasty requiring emergency CABG. UMSMC-E did describe how it would handle a system failure due to equipment or rooms that are unavailable for pPCI because two STEMI patients are already undergoing procedures. In the application provided to UMSMC-E, MHCC staff did not directly quote this standard or request all of the information specified. MHCC staff cannot conclude that

UMSMC-E meets this standard. MHCC staff recommends that, before the Commission issues the requested Certificate of Conformance to UMSMC-E, it requires the Hospital to provide documentation that is had protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure.

10.24.17.06A(4)(g) The hospital shall 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.

UMSMC-E stated that 90 days prior to first use approval, it will provide the name of the physician director of interventional cardiology services who will be responsible for defining and implementing credentialing criteria for the catheterization laboratory and for the overall primary PCI program management. The Hospital is in discussions with two interventional cardiologists, one of whom is expected to be the director. UMSMC-E regards the names of these cardiologists as sensitive competitive information until a contract is signed. (Application, p. 31).

10.24.17.06A(4)(h) The hospital shall design and implement a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

UMSMC-E submitted a chart to the MHCC of the continuing medical education program and skills competencies that it will implement for staff of the cardiac catheterization laboratory, the telemetry unit, the intensive care unit/coronary care unit (ICU/CCU), and emergency department. UMSMC-E uses a chart to track each employee's training and the evaluation of each employee's skills. UMSMC-E also provided a list of continuing education topics and mandatory training for each unit. (Application, Exh. 9).

Staff Analysis

MHCC staff notes that the continuing medical education program for staff includes appropriate topics and is consistent with the types of activities previously reported by hospitals seeking renewal of their Waivers for pPCI services. MHCC staff concludes that UMSMC-E complies with this standard.

10.24.17.06 A (4) (h) (i) The hospital shall have 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.

Shore's President and CEO, Kenneth D. Kozel signed and dated an agreement that provides for the unconditional transfer of pPCI patients from UMSMC-E to UMMC. (Application, Exh. 10). The transfer policy states that the Maryland ExpressCare Transfer Center at UMMC is the source of contact for the transfer process. The policy further states that

air transport is the preferred source of transportation. If a helicopter is not available to respond to UMSMC-E's request, the Maryland ExpressCare Transfer Center will contact the contractual ground transportation which is ALS equipped and will arrive within 30 minutes of a request for patient transfer.

Staff Analysis

MHCC staff concludes that UMSMC-E meets this standard based on the copy of the transfer agreement provided.

10.24.17.06A(4)(h)(ii) The hospital shall maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by a hospital performing primary PCI without on-site cardiac surgery.

UMSMC-E submitted a copy of a memorandum of understanding between UMMS and the Shore Health System and a copy of an Ambulance Transportation Services Agreement between UMMS Corporation and Best Care Ambulance. (Application, Exh. 11). UMSMC-E explained that Maryland ExpressCare is a division of the University of Maryland Medical System that provides around-the-clock patient transportation services for Shore. Maryland ExpressCare provides emergency air transport 24 hours a day except if prohibited by bad weather. When UMSMC-E requests emergency air transport, Maryland ExpressCare responds with a helicopter at UMSMC-E within 30 minutes. (UMSMC-E Letter to MHCC staff, December 4, 2015). Maryland ExpressCare also has a dedicated ground ambulance located at UMSMC-E between 8am and 8pm. Best Care Ambulance Inc. is a back-up ground transportation service through a private contractor. UMSMC-E concluded its discussion of emergency transportation with a summary chart of transportation services, availability, and possible restrictions, as shown in Table 7 below. Lastly, UMSMC-E stated that it is in the process of negotiating a new agreement to provide 30-minute response time regardless of the circumstances.

Table 7: Emergency Transportation Services, Availability, and Restrictions

Service	Availability	Possible Restrictions
Maryland ExpressCare Air Transport	Response time within 30 minutes on 24/7 basis.	Weather and other conditions occasionally prevent air transport.
Maryland ExpressCare Ground Transport- Dedicated Ambulance	Response time within 30 minutes between 8am and 8pm, seven days per week.	Not available between 8pm and 8am, and possibly not available due to another transport call.
Best Care Ambulance- Dedicated Ambulance	Response time within 30 minutes on 24/7 basis.	Possibly not available du to another transport call.
Best Care Ambulance- Non-Dedicated Ambulance	Response time within 30 minutes between 8am and 8pm seven days per week, and within 45 minutes between 8pm and 8am seven days per week.	No restrictions.

Source: UMSMC-E Letter to MHCC Staff, December 4, 2015, p.12.

Staff Analysis

MHCC staff concludes that UMSMC-E does not comply with this standard. For this reason, staff recommends that, before the Commission issues the requested Certificate of Conformance to UMSMC-E, it requires the Hospital to provide documentation satisfactory to MHCC staff that it has executed an agreement that provides for 30-minute response time regardless of the circumstances.

Quality

10.24.17.06A(5)(a) A hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

In the letter of commitment signed by Shore's President and CEO, Kenneth D. Kozel, he stated that a formal, regularly scheduled interventional case review schedule (meetings at least every other month) will be developed that requires the attendance by interventionalists and other physicians, nurses, and technicians who care for pPCI patients at UMSMC-E. (Application, Exh. 12).

Staff Analysis

MHCC staff concludes that UMSMC-E meets this standard based on the letter of commitment provided.

10.24.17.06A(5)(b) A hospital shall 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 COMAR 10.24.17 28 any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

Shore's President and CEO, Kenneth D. Kozel, signed a letter of commitment stating that UMSMC-E will create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory staff) 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 program, identify problem areas, and develop solutions. (Application, Exh. 13).

Staff Analysis

MHCC staff concludes that UMSMC-E meets this standard based on the letter of commitment provided.

10.24.17.06 A (5)(c) At least annually, as determined by the Commission, the hospital shall conduct an internal or external review of individual interventionalists. These reviews shall: (i) Include a review of angiographic images, medical test results, and patients' medical records; and (ii) External reviews shall be conducted by an external reviewer who shall meet all

standards established by the Commission to ensure consistent rigor among external reviewers.

In a letter of commitment signed by Shore's President and CEO, Kenneth D. Kozel, UMSMC-E acknowledges that at least semi-annually, as determined by the Commission, the Hospital will conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period and an internal review of at least ten percent of randomly selected PCI cases performed in the applicable time period. (Application, Exh. 14).

Staff Analysis

MHCC staff concludes that UMSMC-E meets this standard based on the letter of commitment provided.

Physician Resources

10.24.17.06 A (6) Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery shall: (a) Meet the ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures; and (b) Achieve an average annual case volume of 50 or more PCI cases over a two-year period.

Shore's President and CEO, Kenneth D. Kozel, UMSMC-E, acknowledged the Hospital's commitment that each physician who performs primary PCI services at UMSMC-E will achieve an average annual PCI case volume of 50 or more over a two-year period. (Application, Exh. 15). In addition, Mr. Kozel stated that the Hospital will provide documentation to MHCC demonstrating compliance with this standard 90 days prior to first use. (Application, Exh. 15). UMSMC-E also submitted documentation for the two interventionalists who will primarily provide pPCI services that shows each physician currently meets the case volume requirement (Application, Form C). The case volume information was provided to the Commission under seal to protect the identity of the physicians who will staff the program. (Application, p. 33).

Staff Analysis

MHCC staff concludes that UMSMC-E meets this standard based on the letter of commitment and documentation provided.

Patient Selection

10.24.17.06 A (7) The hospital shall commit to providing primary PCI services only for suitable patients. Suitable patients are:

(a) Patients described as appropriate for primary 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) Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) reasonably conclude may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in a worse outcome.

(c) Patients for whom primary PCI services were not initially available and who received thrombolytic therapy that subsequently failed. Such cases should constitute no more than 10 percent of cases. (d) Patients who experiences a return of spontaneous circulation following cardiac arrest and presents at a hospital without on-site cardiac surgery for treatment, when the COMAR 10.24.17 30 treating physician(s) reasonably conclude that transfer to a tertiary institution may be harmful for the patient.

In a letter of commitment signed by Shore's President and CEO, Kenneth D. Kozel, the Hospital states that it will meet the above standard for patient selection (Application, Exh. 16).

Staff Analysis

In addition to a letter of commitment signed by the Shore's President and CEO, the commitment letter must be signed by the medical director of cardiac interventional services to satisfy this standard. UMSMC-E has not determined who will be the medical director, and it is not required to provide such information until at least 90 days prior to first use approval, as directed by MHCC staff in the application for a Certificate of Conformance. MHCC staff concludes that the Hospital meets this standard, but recommends that a condition to this effect be placed on any Certificate of Conformance issued by the Commission.

Financial Viability

10.24.17.06A An applicant shall document that its proposed primary PCI program will achieve financial viability.

UMSMC-E determined that the introduction of pPCI and elective PCI services will require a capital expenditure of $2,568,600. This capital expenditure includes $1,690,000 for fixed equipment, $780,000 for building, $94,000 for architect/engineering fees, and $4,600 for permits. (Application, Form A). This capital expenditure is required for building a second catheterization laboratory and purchasing equipment. (Application, Form A). UMSMC-E provided a schematic of the planned 2,600 square foot area as well as a drawing of the existing area. (UMSMC-E Letter to MHCC Staff, December 4, 2015, Exh. 19).

MHCC staff also requested that the Hospital address its plans to relocate and replace the Hospital, as stated in a Certificate of Need application that was filed over two years ago. The application review has been inactive, since 2014, at the applicant's request. Specifically, MHCC staff asked if UMSMC-E would be able to salvage its investment in the cardiac catheterization laboratory if the hospital relocates within the next few years. (Letter to UMSMC-E, November 6, 2015). UMSMC-E stated that it anticipates a replacement hospital will not open until at least 2020. (UMSMC-E Letter to MHCC Staff, December 4, 2015, p. 13). UMSMC-E acknowledged that the investment in building a CCL would be lost upon relocation, but stated that the Hospital

plans to relocate equipment that is purchased for the cardiac catheterization laboratory. (UMSMC-E Letter to MHCC Staff, December 4, 2015, p. 13). UMSMC-E explained that given the immediate need for a PCI program to decrease morbidity and mortality, the Hospital decided to seek approval for a pPCI program now. The projected revenue and expenses for the proposed program between 2017 and 2020 are shown in Table 8.

Table 8: Projected Revenue and Expenses for UMSMC-E by Time Period

Category	Time Period			
	2017	2018	2019	2020
Revenue				
Gross Revenue	$1,163,406	$3,471,049	$3,500,377	$3,533,474
Adjustments to Revenue				
Bad Debt	$69,804	$71,396	$73,155	$75,141
Contractual Allowance	$423,681	$433,371	$444,041	$456,130
Net Operating Revenue	$669,921	$2,966,281	$2,983,180	$3,002,202
Expenses				
Salaries, Wages, Benefits	$1,543,086	$1,543,086	$1,543,086	$1,543,086
Project Depreciation	$148,477	$296,954	$296,954	$296,954
Supplies	$1,259,477	$1,260,475	$1,273,191	$1,289,412
Total Operating Expenses	$2,951,040	$3,100,515	$3,113,231	$3,129,452
Income				
Net Income (Loss)	($2,281,119)	($134,234)	($130,051)	($127,250)

Source: UMSMC-E Application, Form B.

Staff Analysis

MHCC staff compared the projected revenue and expenses per pPCI case to those projected by Carroll Hospital Center (CHC) when it applied for a Certificate of Conformance to establish an elective PCI program in 2014, after having operated a pPCI program for several years. CHC projected a capital investment of only $170,000 compared to $2,568,600 projected by UMSMC-E. However, CHC did not propose building a new cardiac catheterization laboratory, only purchasing moveable equipment. UMSMC-E projects higher per case revenue and expenses, as shown in Table 9. UMSMC-E, unlike CHC, did not project income from the provision of PCI services. The overall net loss projected by UMSMC-E in 2020, the fourth year of operation, ($127,250), is modest relative to the overall revenue base for the Hospital, accounting for only 0.07% of UMSMC-E's revenue (Application, p. 21). MHCC staff concludes that provision of these services by UMSMC-E is sustainable, despite the losses it will generate. MHCC staff concludes that UMSMC-E meets this standard.

Table 9: Financial Projections ($000s)
for pPCI and npPCI Programs at CHC and UMSMC-E

	CHC FY 2015-2018				UMSMC-E, FY 2017-2020			
Category	**2015**	**2016**	**2017**	**2018**	**2017***	**2018**	**2019**	**2020**
Number of Cases	132	206	227	247	246	249	252	255
Revenue/Case (in thousands)	$ 14.91	$ 11.94	$ 11.45	$ 11.06	$ 4.73	$ 13.94	$ 13.89	$ 13.84
Expense/Case (in thousands)	$ 14.27	$ 11.53	$ 11.07	$ 10.72	$ 12.00	$ 12.45	$ 12.35	$ 12.26
Supplies/Case (in thousands)	$ 4.30	$ 4.19	$ 4.16	$ 4.15	$ 5.12	$ 5.06	$ 5.05	$ 5.05
Net Income/Case (in thousands)	$ 0.64	$ 0.41	$ 0.38	$ 0.34	$(9.28)	$(0.54)	$(0.52)	$(0.50)

Sources: CHC Certificate of Conformance Application (2014)
*Note: UMSMC-E expects no additional inpatient revenue in its first year of operation, 2017, based on HSCRC payment policies.

III. RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff concludes that UMSMC-E has demonstrated that a PCI program is needed in the service area. The area population does not currently have sufficient access to emergency PCI services. UMSMC-E has also demonstrated that adding an elective PCI program in addition to a pPCI program, will increase case volume and enable the hospital's overall PCI services to become more financially viable than without elective PCI services. UMSMC-E has also committed to providing information on the director of the proposed program and documentation of compliance with the case volume standard for each interventionalist with privileges at UMSMC-E at least 90 days prior to first use approval.

Therefore, MHCC staff recommends that the Commission conditionally **APPROVE** UMSMC-E's request for a Certificate of Conformance to simultaneously establish a pPCI program and an elective PCI program, but only issue a Certificate of Conformance if, on or before April 11, 2016, UMSMC-E provides documentation satisfactory to Commission staff that:

1. The Hospital has protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure; and

2. The Hospital has executed an agreement that provides for 30-minute response time regardless of the circumstances.

In addition, MHCC staff recommends that, dependent on UMSMC-E providing the above documentation by April 11, 2016, a Certificate of Conformance issue with the following conditions:

1. At least 90 days prior to first use approval, UMSMC-E shall provide the names of its medical director and interventionalists on staff and documentation that each interventionalist on staff has achieved an average annual case volume of 50 or more PCI cases over a two-year period;

2. UMSMC-E shall agree to comply with the requirements for a Certificate of Ongoing Performance;

3. UMSMC-E shall apply for a Certificate of Ongoing Performance on or before June 30, 2020.

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IN THE MATTER OF	*	**BEFORE THE**
	*	
UNIVERSITY OF MARYLAND	*	**MARYLAND HEALTH**
SHORE MEDICAL CENTER	*	
AT EASTON	*	**CARE COMMISSION**
	*	
Docket No.: CC-15-20-0001	*	
	*	

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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 17th day of March, 2016, **ORDERED**:

That the application filed by University of Maryland Shore Medical Center at Easton (UMSMC-E) for a Certificate of Conformance that authorizes it to provide primary and elective PCI services is hereby **APPROVED**, if, on or before April 11, 2016, UMSMC-E provides documentation satisfactory to Commission staff that:

1. UMSMC-E has protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure; and

2. UMSMC-E has executed an agreement that, when clinically necessary, provides for a response by air or ground ambulance transport within 30 minutes.

If UMSMC-E provides the above documentation on or before April 11, 2016, a Certificate of Conformance shall issue with the following conditions:

1. At least 90 days prior to first use approval, UMSMC-E shall provide: the names of its medical director and interventionalists on staff; and documentation that each interventionalist on staff has achieved an average annual case volume of 50 or more PCI cases over the preceding two-year period;

2. UMSMC-E shall agree to comply with the requirements for a Certificate of Ongoing Performance;

3. UMSMC-E shall apply for a Certificate of Ongoing Performance on or before June 30, 2020.

MARYLAND HEALTH CARE COMMISSION