

**IN THE MATTER OF  
ESTABLISHMENT OF PRIMARY  
AND ELECTIVE PERCUTANEOUS  
CORONARY INTERVENTION  
SERVICES BY UNIVERSITY OF  
MARYLAND SHORE MEDICAL  
CENTER AT EASTON  
DOCKET NO. 23-20-CC042**

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**BEFORE THE  
MARYLAND HEALTH  
CARE COMMISSION**

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**STAFF REPORT AND RECOMMENDATION  
CERTIFICATE OF CONFORMANCE FOR PRIMARY AND ELECTIVE  
PERCUTANEOUS CORONARY INTERVENTION SERVICES**

**January 18, 2024**

## I. INTRODUCTION

In conjunction with the Certificate of Need (CON) application for the replacement and relocation of University of Maryland Shore Medical Center at Easton (UM SMC Easton, or hospital), Docket No. 23-20-2463, Shore Health System, Inc. (UM SHS, or applicant) submitted an application for a Certificate of Conformance to establish primary and elective percutaneous coronary intervention (PCI) services on behalf of UM SMC Easton.

### A. Background

In 2012, Maryland established a new regulatory model for PCI and cardiac surgery services. PCI is a procedure whereby a catheter is inserted in a blood vessel and guided to the site of a partially or fully blocked 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 or Commission), rather than indirectly regulated through “open heart surgery” regulations. Md. Code Ann., Health-Gen. § 19-120.1. Consideration of the establishment of a new PCI program now takes place through a process called a Certificate of Conformance review, with all providers of PCI services subject to revalidation and authorization through periodic on-going performance reviews.

Two categories of PCI programs are addressed in the Certificate of Conformance regulations: (1) Emergency or Primary PCI programs or (2) Elective PCI programs, COMAR 10.24.17. Emergency or Primary PCI Programs provide only emergent PCI intervention for a heart attack shortly after it begins. Elective PCI programs provide both emergency PCI services and elective PCI services. Elective PCI is non-emergent and involves intervention 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 eleven hospitals that provide cardiac surgery and both types of PCI services.<sup>1</sup> 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.<sup>2</sup> For this reason, the

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<sup>1</sup> Hospitals in Maryland that provide cardiac surgery programs and PCI services include Adventist HealthCare White Oak Medical Center, Luminis Health Anne Arundel Medical Center, University of Maryland Capital Regional Medical Center, Johns Hopkins Hospital, Medstar Union Memorial Hospital, TidalHealth Peninsula Regional Medical Center, Sinai Hospital, Suburban Hospital, University of Maryland Medical Center, University of Maryland St. Joe’s Hospital, and Western Maryland Regional Medical Center.

<sup>2</sup> Aversano T, Aversano LT, Passamani E, Knatterud GL, Terrin ML, Williams DO, Forman SA. “Thrombolytic Therapy vs Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery.” *Journal of the American Medical Association*. 287.15 (2002):1943-51.; Ting HH, Raveendran G, Lennon RJ, Long KH, Singh M, Wood DL, Gersh BJ, Rihal CS, Holmes DR Jr. “A Total of 1,007 Percutaneous Coronary Interventions Without On-site Cardiac Surgery: Acute and Long-term

Commission permitted non-SOS hospitals that could meet certain volume and quality standards to provide primary PCI services. Ultimately, 13 such programs were established,<sup>3</sup> more than doubling the number of Maryland sites at which primary PCI can be performed. 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, studies showed that the provision of elective PCI in non-SOS hospitals was not inferior to the provision of elective PCI in hospitals with cardiac SOS.<sup>4</sup> 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 first operated their elective PCI programs as research "waiver"<sup>5</sup> hospitals. Then they graduated to "registry waiver"<sup>6</sup> status and now, through the 2012 legislation and resulting MHCC action, are regular clinical providers of both primary and elective PCI, subject to on-going performance reviews by MHCC. Additional background on the evolution of PCI regulation in Maryland can be found in Section .02 of the Cardiac Services Chapter, which can be accessed through the following link: <https://dsd.maryland.gov/regulations/artwork/10241701.pdf>.

## **B. Applicant**

### **Shore Health System, Inc.**

UM SHS operates UM SMC Easton, University of Maryland Shore Medical Center at Cambridge (UM SMC Cambridge), and University of Maryland Shore Emergency Center at Queenstown (UM SEC Queenstown). UM SHS also operates several outpatient facilities in Easton, Denton, Cambridge, and Centreville. UM SMC Easton is a 98-bed acute general hospital located in Talbot County. UM SMC Easton is the only hospital located within this jurisdiction and is designated as a primary stroke center and a cardiac interventional center (CIC) by the Maryland Institute for Emergency Medical Services System (MIEMSS).<sup>7</sup> It does not have a cardiac surgery program on-site. The proposed replacement hospital plans to have 122 inpatient beds, 25 observation beds, and two cardiac catheterization laboratories (CCL) to utilize for primary and

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Outcomes." *Journal of the American College of Cardiology*. 47.8 (2006):1713-21.

<sup>3</sup> In addition to the 11 hospitals that provide cardiac surgery and PCI services, the following hospitals have a primary PCI program: Adventist HealthCare Shady Grove Medical Center, University of Maryland Baltimore Washington Medical Center, Carroll Hospital Center, Frederick Health Hospital, Medstar Southern Maryland Hospital Center, Ascension Saint Agnes Hospital, University of Maryland Shore Medical Center at Easton, University of Maryland Upper Chesapeake Medical Center.

<sup>4</sup> Aversano T., Lemmon CC., Liu L. "Outcomes of PCI at Hospitals With or Without On-site Cardiac Surgery." *New England Journal of Medicine*. 366.19 (2012):1792-802.

<sup>5</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>6</sup> Authorized to provide the service with mandatory American College of Cardiology National Cardiac Data Registry reporting requirements for performance monitoring.

<sup>7</sup> <https://www.umms.org/shore/about>

elective PCI.

UM SHS applied for a Certificate of Conformance for both primary and elective PCI, in conjunction with the Certificate of Need (CON) application for the replacement and relocation of UM SMC Easton, in accordance with COMAR 10.24.17.04C(2). UM SMC Easton first received a Certificate of Conformance to provide primary and elective PCI services at the existing hospital in April 2016.<sup>8</sup> The hospital began providing elective PCI services in March 2017.<sup>9</sup> On November 18, 2021, UM SMC Easton received a Certificate of Ongoing Performance from the Commission.<sup>10</sup>

### Service Area Population Characteristics

UM SMC Easton primarily serves residents in a five-county region including Caroline, Dorchester, Kent, Queen Anne’s, and Talbot Counties on Maryland’s Eastern Shore. With an estimated population of 171,461,<sup>11</sup> this five-county service area is mostly rural. The most recent population forecast of the Maryland Department of Planning projects that the service area’s population will increase about 15 percent between 2020 and 2035.<sup>12</sup> Projected population growth in this jurisdiction is somewhat higher than for Maryland overall (approximately 8.5 percent between 2020 and 2035). For the population age 65 and over in the five-county service area, it is projected to see growth by approximately 41 percent over the next decade. Statewide, this population is projected to grow slightly higher, at 43 percent.

**Table 1: Projected Population for Primary Service Area and Maryland Statewide, 2020-2035**

Jurisdiction	2020 (Census)		2030		2035	
	Total Pop.	Age 65+	Total Pop.	Age 65+	Total Pop.	Age 65+
Caroline	33,293	5,685	37,703	7,883	40,001	8,540
Dorchester	32,531	6,606	35,155	8,554	36,400	8,884
Kent	19,198	5,455	20,903	7,358	21,351	7,870
Queen Anne’s	49,874	10,335	56,320	14,770	59,526	16,178
Talbot	37,551	11,296	39,653	13,677	40,549	14,164
<b>Total</b>	<b>172,447</b>	<b>39,377</b>	<b>189,734</b>	<b>52,242</b>	<b>197,827</b>	<b>55,636</b>
Statewide	6,074,725	974,979	6,413,698	1,296,675	6,588,745	1,395,231

Source: Maryland Department of Planning, Maryland State Data Center, “Projections to 2045.” (August 30, 2023).

<sup>8</sup> UM SHS’s Certificate of Conformance Application 2023, Exhibit 1.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx)

<sup>9</sup> Maryland Health Care Commission, UM SMC Easton’s Staff Report and Recommendation Certificate of Ongoing Performance for Primary and Elective Percutaneous Coronary Intervention Services (2021).

[https://mhcc.maryland.gov/mhcc/Pages/hcfs/hcfs\\_con/hcfs\\_con\\_staff\\_resport.aspx](https://mhcc.maryland.gov/mhcc/Pages/hcfs/hcfs_con/hcfs_con_staff_resport.aspx)

<sup>10</sup> Ibid.

<sup>11</sup> Suburban Stats. Population Demographics in Maryland in 2019-2020. Retrieved August 30, 2023, at

<https://suburbanstats.org/population/maryland/list-of-counties-and-cities-in-maryland>

<sup>12</sup> Maryland Department of Planning. “Projections to 2045.” Total Population Projections (Excel file).

[https://planning.maryland.gov/MSDC/Pages/S3\\_Projection.aspx](https://planning.maryland.gov/MSDC/Pages/S3_Projection.aspx)

## **Recommendation**

Based on staff review of the requirements found in COMAR 10.24.17.04C and COMAR 10.24.17.06, staff recommends that the Commission approve UM SHS's application for a Certificate of Conformance for primary and elective PCI services at the replacement hospital. UM SHS has shown that the population it proposes UM SMC Easton will serve would have insufficient access to PCI services if not relocated with the replacement hospital and demonstrated compliance with the other standards required to establish both primary and elective PCI services. Staff presents its review and recommendation regarding compliance with the standards for obtaining a Certificate of Conformance.

## **II. PROCEDURAL HISTORY**

UM SHS filed a Certificate of Conformance application on January 6, 2023, on behalf of UM SMC Easton. Subsequently, in response to requests for additional information and clarification, UM SHS submitted additional filings on April 13, 2023, and May 19, 2023.

## **III. PROJECT CONSISTENCY WITH REVIEW CRITERIA**

### **A. Commission Program Policies, COMAR 10.24.17.04C**

#### **Relocation of Programs.**

#### ***(2) Elective and primary PCI Services.***

***If a hospital with primary PCI services or both primary and elective PCI services, and without cardiac surgery, seeks to relocate, the hospital shall obtain a new Certificate of Conformance for each PCI service in conjunction with its Certificate of Need for relocation.***

UM SMC Easton is required to obtain a Certificate of Conformance for both primary and elective PCI services, in conjunction with the Certificate of Need application for the hospital to relocate.

### **B. Certificate of Conformance Criteria, COMAR 10.24.17.06**

#### **COMAR 10.24.17.06A - Primary PCI Services**

***A hospital issued a Certificate of Conformance to establish a primary PCI service shall agree to voluntarily relinquish its authority to provide primary PCI service if it fails to meet the applicable standards for a Certificate of Conformance.***

An affidavit and acknowledgment of this agreement was attached to UM SHS's Certificate of Conformance application on behalf of UM SMC Easton and signed by Ken Kozel, MBA FACHE, President and Chief Executive Officer (CEO), University of Maryland Shore Regional Health (UM SRH).

## **(1) General Standards.**

***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.

### **COMAR 10.24.10.04A – General Standards**

#### **(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:***

- (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 website,***
- (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. The applicant must provide policies that include procedures for promptly responding to individual requests for current charges for specific procedures, and requirements for staff training. UM SHS provided the required policies within Exhibit 5 of its CON application.<sup>13</sup> The policy requires a representative list of services and charges be made available to the public in written form at the hospital(s) and on its website. The policy also states that “individuals or their payor representative may make a request for an estimate of charges for any scheduled or non-scheduled diagnostic test or service.” The policy specifies that the Patient Financial Services department is responsible for ensuring that appropriate training and orientation is provided to its staff related to charge estimates. UM SHS also provided the current list of representative services and charges.<sup>14</sup>

### **Staff Analysis and Recommendation**

Staff reviewed UM SHS’s policy and UM SMC Easton’s charge information for inpatient services including psychiatric, medical/surgical, pediatric, and obstetric cases, as well as laboratory, radiology, and outpatient services estimated charges.<sup>15</sup> Based on staff’s analysis of the information provided in the CON application, and staff’s ability to locate updated charge

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<sup>13</sup> UM SHS’s CON Application, Exhibit 5.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_con/hcfs\\_con\\_UM\\_shore\\_medical\\_center.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con_UM_shore_medical_center.aspx)

<sup>14</sup> UM SHS’s CON Application, Exhibit 6.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_con/hcfs\\_con\\_UM\\_shore\\_medical\\_center.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con_UM_shore_medical_center.aspx)

<sup>15</sup> Ibid.

information on the hospital's website, staff concludes that UM SHS demonstrated UM SMC Easton is in compliance with the charge information standard in COMAR 10.24.10.04A(1).

**(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.***

**a. *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,***

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

**c. *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 quarter 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 the service area population.***

UM SHS 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.<sup>16</sup> UM SHS states that these policies apply to all UMMS member organizations. The financial assistance policy asserts that UMMS is committed to providing financial assistance to persons who have health care needs and are uninsured, underinsured, ineligible for a government program, or otherwise unable to pay, for emergent and medically necessary care. The charity care policy states that a determination of probable eligibility must be made within two business days following a request for financial assistance. UM SHS provided a copy of the notice regarding the availability of charity care that is posted in the hospital's emergency department (ED), as well as the Admission and Business offices. UM SHS also provided the notice that is published in local newspapers annually.<sup>17</sup> Additionally, UM SHS reports that each patient is advised of the charity care policy at the time of admission or outpatient registration. Financial counselors are also available to assist individuals with preparation and filing of documents for charity care.

UM SHS stated that the most recent available community benefit report from the Health

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<sup>16</sup> UM SHS's Certificate of Need Application, Exhibit 30.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_con/hcfs\\_con UM shore medical center.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con UM shore medical center.aspx).

<sup>17</sup> Copies of the notice for charity care was provided in UM SHS's Certificate of Need Application, Exhibit 8 and Exhibit 9. [https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_con/hcfs\\_con UM shore medical center.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con UM shore medical center.aspx).

Services Cost Review Commission (HSCRC) in 2020, indicates that UM SMC Easton provided a total net community benefit of 1.34 percent of operating expenses, ranking the hospital in the 3<sup>rd</sup> quartile of all acute care general hospitals in Maryland.

### **Staff Analysis and Recommendation**

Staff reviewed the financial assistance policy provided by UM SHS, as well as the notices posted at the hospital and in local newspapers. Additionally, staff reviewed the most recent HSCRC hospital benefit report (2022) and confirmed the level of charity care provided by UM SMC Easton in FY 2022 compared to other Maryland hospitals.<sup>18</sup> In FY 2022, the percentage of charity care provided by Maryland hospitals ranged from 6.1% for Holy Cross Hospital to less than 0.01% for Mount Washington Pediatric Hospital. The median amount of charity care provided was 1.7%. The amount of charity care provided by UM SMC Easton (1.9%) falls within the second quartile.<sup>19</sup> Based on this analysis and staff's review of UM SHS's financial assistance and charity care policies, staff concludes that UM SMC Easton complies 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.***

UM SHS provided copies of all necessary licenses, certifications, and accreditations.<sup>20</sup> The hospital is licensed by the State of Maryland and is currently accredited by the Joint Commission. UM SHS asserted that the hospital has not had its accreditation denied, limited, suspended, withdrawn, or revoked in the past three years, nor has it been placed on Accreditation Watch by the Joint Commission. UM SHS also reports that UM SMC Easton is a Medicare provider in good standing that has not been sanctioned, barred, or excluded from participating in the Medicare program in the previous five years.

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<sup>18</sup> [https://hscrc.maryland.gov/Pages/init\\_cb.aspx](https://hscrc.maryland.gov/Pages/init_cb.aspx)

<sup>19</sup> Maryland Health Services Cost Review Commission. Maryland Hospital Community Benefit Report: FY 2022. (September 27, 2023.)

<https://hscrc.maryland.gov/Documents/CommBen/FY%202022%20Final%20State%20Reports/HCB%20FY22%20Statewide%20Report%20Final%209-27-23.pdf>

<sup>20</sup> UM SMC Easton's license and accreditation certificates were provided in UM SHS's Certificate of Need Application, as Exhibit 10 and Exhibit 11.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_con/hcfs\\_con UM shore medical center.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con UM shore medical center.aspx)



This standard also requires that a hospital document each action taken to improve its performance on each quality measure included in the current Maryland Hospital Performance Evaluation Guide, when the hospital performs in the bottom quartile relative to other Maryland hospitals, unless the hospital has achieved 90% compliance or better. The performance measures have changed, and this standard is outdated. Instead, when a hospital performs below average on a performance measure, staff requests that a hospital explain the actions that it has taken to improve on the performance measures. UM SHS reported that UM SMC Easton scored “better than average” or “average” on 57 of the 76 quality measures. The hospital received no score on 15 quality measures, due to having no data or insufficient data to be included in the report and scored “below average” on four quality metrics.<sup>21</sup> Those measures for which UM SMC Easton scored below average include delivery, environment, and overall satisfaction; none of which, are related to cardiac care. For each of these, UM SHS provided corrective action plans in Exhibit 12 of its CON application.<sup>22</sup> These four measures, and the hospital’s actions to improve these measures are shown in Table 2.

**Table 2: UM SMC Easton’s Quality Improvement Actions**

<b>Measure</b>	<b>Action</b>
How often was the area around the patient’s rooms kept quiet at night?	Minimizing overhead announcements, quiet hours, increasing awareness amongst staff, and replacing loud carts and wheels.
How do patients rate the hospital overall?	Redesigning shift change handoff, reinforcing back to basics behaviors, education focusing on communication, implementing “Get to Know Me Boards”, setting a consistent definition of patient experience.
Would patients recommend the hospital to friends and family?	Same as previous.
How often babies in the hospital are delivered vaginally when the mother previously delivered by cesarean section (no complications)	Implementing a 24/7 inpatient hospitalist program, an inpatient 24/7 anesthesia service, and an inpatient pediatric hospitalist program. The hiring of a full-time maternal-fetal medical physician in February 2023 will further allow UM SMC at Easton to offer these expanded services.

Source: Exhibit 12 of UM SHS’s application for Certificate of Need.

### **Staff Analysis and Recommendation**

Staff reviewed UM SMC Easton’s performance on all 76 quality measures reported in the Maryland Hospital Evaluation Guide. Based on staff’s analysis of the current Maryland Hospital Performance Evaluation Guide that shows acceptable performance on 57 of 61 applicable measures, and quality improvement information submitted by UM SHS on four measures on which the hospital performed below average, staff concludes that UM SMC Easton complies with this standard.

<sup>21</sup> UM SHS’s CON Application, page 36.

<sup>22</sup> UM SHS’s CON Application, Exhibit 12.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_con/hcfs\\_con UM shore medical center.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con UM shore medical center.aspx).

**COMAR 10.24.17.06A - Primary PCI Services**

**(2) Need.**

- (a) 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.*
- (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.*

Using aggregated zip code data for Maryland hospitals, one hospital in the District of Columbia, and three hospitals in Delaware, UM SHS identified UM SMC Easton’s primary PCI service area as the following counties: Caroline, Dorchester, Kent, Queen Anne’s, and Talbot. UM SHS reported that these five counties account for 94.7 percent of the hospital’s total PCI cases in CY 2021. Most cases came from Talbot County (31.6%) and Caroline County (25%), with the remainder from Queen Anne’s (18.4%), Dorchester County (17.1%), and Kent (2.6%). In addition, 5.3 percent of the hospital’s cases were from other Maryland counties or other states (4 cases total). As shown in Table 3, of the 106 primary PCI cases generated from the hospital’s service area in CY 2021, close to 70 percent were performed at UM SMC Easton.

**Table 3: Calculation of UM SMC Easton’s Market Share for Primary PCI, CY 2021**

<b>Location</b>	<b>Total</b>	<b>UM SMC Easton</b>	<b>Market Share</b>
<b>Caroline</b>	21	19	90.5%
<b>Dorchester</b>	19	13	68.4%
<b>Kent</b>	5	2	40.0%
<b>Queen Anne’s</b>	33	14	42.4%
<b>Talbot</b>	28	24	85.7%
<b>Subtotal</b>	106	72	67.9%
<b>Other MD</b>	--	3	--
<b>Other States</b>	--	1	--
<b>Total</b>	106	76	--

Source: UM SMC Easton’s Certificate of Conformance application 2023, p. 10.

In projecting the future volume of primary PCI cases from its service area, UM SHS’s assumptions are based on the age 45 and older cohort as the most likely affected population. UM SHS relied on the Maryland Department of Planning projections for 2020 and 2025 for this age cohort to calculate population estimates for 2021, using the compound average growth rate. This information and the number of PCI cases in the hospital’s service area in 2021 was used to calculate use rates by county. UM SHS then applied these use rates to future population projections to estimate the need for primary PCI services. The hospital’s current market share in each county was used to determine its share of the total number of primary PCI cases projected in 2025 and 2030 by county. UM SMC Easton is projected to have a total of 79 primary PCI cases in CY 2025 and 82 primary PCI cases by CY 2030 as seen in Table 4.

**Table 4: Primary PCI Cases Projected at UM SMC Easton 2025 and 2030**

County	UM SMC Easton Market Share 2021	Total Cases 2025	UM SMC Easton Cases 2025	Total Cases 2030	UM SMC Easton Cases 2030
Caroline	90.5%	22	20	23	21
Dorchester	68.4%	20	14	21	14
Kent	40.0%	5	2	6	2
Queen Anne's	42.4%	34	14	36	15
Talbot	85.7%	29	25	30	25
<b>Subtotal</b>	67.9%	110	75	115	78
Other	5.6%	--	4	--	4
<b>Total</b>	--	--	79	--	82

Source: UM SHS's Certificate of Conformance application 2023, p. 11.

UM SHS noted that the previous version of the Cardiac Services Chapter (10.24.17, Effective August 18, 2014) recognized a need for more timely access to primary PCI services in UM SMC at Easton's five county PCI service area. It quoted a 2010 study conducted by the Maryland Institute for Emergency Medical Services (MIEMSS) on drive times to acute care hospitals.<sup>23</sup> UM SHS also cited the current Cardiac Services Chapter that references a more recent MIEMSS drive time analysis that was completed in 2018.<sup>24</sup> Staff concluded from the drive time analysis provided by MIEMSS<sup>25</sup> that the largest geographic areas without access to primary PCI within a 30-minute drive time included four of the five counties<sup>26</sup> in the UM SMC Easton's service area.

UM SHS stated that if the relocation of the existing PCI program is not approved at UM SMC Easton replacement hospital, the service area population will revert to not having a PCI program within a 30-minute drive. Using drive time from the most populous city in each county to the location of the replacement hospital, UM SHS provided a comparison to the drive time to other PCI service providers in the service area. As shown in Table 5 below, while the travel time to UM SMC Easton varies from 11 to 42 minutes for residents of the most populous city in each county, the travel time to alternate locations ranges from 34 to 116 minutes.

<sup>23</sup> UM SHS's Certificate of Conformance Application 2023, p. 16.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>24</sup> COMAR 10.24.17, <https://dsd.maryland.gov/regulations/artwork/10241701.pdf>.

<sup>25</sup> Ibid.

<sup>26</sup> Caroline, Dorchester, Kent, and Queen Anne's Counties.

**Table 5: Drive Times (in Minutes) Between the Most Populous City in Each County in UM SMC Easton's Primary PCI Service Area and Other PCI Providers**

	AAMC	BWMC	Bayhealth	Christiana	JHH	Nanticoke	PRMC	UM SMC at Easton	UMMC
<b>Denton (Caroline)</b>	48	67	40	75	99	34	59	<b>24</b>	79
<b>Cambridge (Dorchester)</b>	68	85	70	98	116	40	38	<b>30</b>	99
<b>Chestertown (Kent)</b>	58	76	68	52	102	79	100	<b>42</b>	85
<b>Centerville (Queen Anne's)</b>	34	53	62	59	87	59	80	<b>21</b>	64
<b>Easton (Talbot)</b>	49	69	63	80	103	46	56	<b>11</b>	80

Source: UM SHS's application for Certificate of Conformance 2023, p. 18.

\* UM SHS indicated that driving time was calculated using Google Maps on Thursday, May 5, 2022, between 1PM and 2PM. UM SHS's application for Certificate of Conformance 2023, p. 17.

### Staff Analysis and Recommendation

Staff analyzed the American College of Cardiology Nation Cardiovascular Data Registry (ACC-NCDR CathPCI) data to validate the service area for UM SMC Easton's PCI cases. This analysis shows that the hospital accurately described its service area for PCI services. Staff defined the hospital's service area as the top 90 percent of zip code areas for primary PCI cases performed in calendar year 2021, provided that at least two cases were performed at the hospital for a specific zip code area. This approach was taken for ease of analysis; including only some of the zip code areas from the five counties identified as the service area for the hospital yields almost the same results.

Using staff's service area definition for UM SMC Easton, staff calculated the market share captured by UM SMC Easton for primary PCI services in CY 2021. Staff compared these results to the market share analysis completed by UM SHS. Staff's analysis shows that 77.2% of primary PCI cases in the service area were completed at UM SMC Easton, with 8.9% of these cases completed at Anne Arundel Medical Center (AAMC) and 6.3% of primary PCI cases completed at Baltimore Washington Medical Center (BWMC). This analysis suggests that the applicant's assumptions regarding market share are reasonable.

Staff verified the estimated travel times generated using Google Maps, from the most populous city identified in each of the counties in UM SMC Easton's service area for primary PCI services, on August 30, 2023, for each of four times (9:00am, 1:00pm, 5:00pm, and 9:00pm), as shown in Appendix 1. Staff included the average estimated travel time if multiple routes were suggested by Google Maps. If a range was provided by Google Maps, rather than a single value, staff included the average using the end points provided; if multiple ranges were suggested for multiple routes, staff included the average of the endpoints for all routes suggested.

Timely care is critical for STEMI patients, and the importance of timely care, as established

by research, is the basis for having a door-to-balloon (DTB) time standard.<sup>27</sup> Staff notes that while a DTB time standard of 90 minutes or less is the benchmark used to evaluate hospitals for Certificates of Ongoing Performance, the 2013 guidelines of the American College of Cardiology Foundation/American Heart Association for STEMI patients include a recommendation that the goal for first medical contact (FMC)-to-device time be 90 minutes.<sup>28</sup> For STEMI patients who are transported to a hospital by ambulance, the first medical contact would likely be with emergency medical system personnel, and the time to travel to a hospital would be part of the calculation of FMC-to-device time for those patients. The change in the guidelines for treatment of STEMI patients, which emphasizes FMC-to-device time and sets a higher ideal standard of care for STEMI patients, suggests that reducing travel time for STEMI patients is an important component to improving outcomes for some STEMI patients. This lends further support to the conclusion that the primary and elective PCI programs at UM SMC Easton are needed to preserve timely access to PCI services for the population in the hospital's primary service area.

A travel time of 30 minutes or less is considered reasonable access to primary PCI services at alternative locations.<sup>29</sup> As shown in Table 5, while travel time to UM SMC Easton ranges from 11 to 42 minutes, no other hospital serving residents of the counties included in UM SMC Easton's service area has an estimated travel time of 30 minutes or less for primary PCI services. Staff has concluded that if there is no PCI program at the replacement hospital, candidates for primary PCI would likely not receive timely care.

Staff also notes that while in some Maryland locations an interventionalist can perform PCI services at multiple hospitals, this option is not readily available for an interventionalist working at UM SMC Easton. UM SMC Easton is located too far from other hospitals for this to be feasible. For this reason, staff concludes that UM SHS's concerns regarding the ability to retain and recruit interventionalists if only primary PCI services are established are valid.

Based on the analysis of need, market share, and travel time projections, staff concludes that the proposed program is needed for its service area population and will generate an annual case volume of at least 36 cases by the end of the second year of operation. UM SHS complies with this standard.

### **(3) Access.**

- (a) An applicant shall present evidence, including emergency transport data and patient-level data that demonstrate that the proposed program's service area population:***
- i. Has insufficient access to emergency PCI services; and***

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<sup>27</sup> Daniel S. Menees, M.D., et al. "Door-to-Balloon Time and Mortality Among Patients Undergoing Primary PCI." *New England Journal of Medicine*. September 5, 2013. <https://www.nejm.org/doi/full/10.1056/NEJMoa1208200>

<sup>28</sup> 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: Executive Summary. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. O'Gara, et al. December 17, 2012. <https://www.ahajournals.org/doi/10.1161/CIR.0b013e3182742c84>

<sup>29</sup> COMAR 10.24.17, <https://dsd.maryland.gov/regulations/artwork/10241701.pdf>.

**ii. Is receiving suboptimal therapy for STEMI.**

UM SHS stated that if the PCI program is not re-established at the replacement hospital, there will be a clear unmet need for primary PCI services in the hospital's service area.<sup>30</sup> This was recognized in the past by both MIEMSS and the Commission in accordance with the Cardiac Services Chapter,<sup>31</sup> which was updated in January 2019 and includes the following language:

*The Maryland Institute for Emergency Medical Services System (MIEMSS) analyzed the drive time to acute care Maryland hospitals and some hospitals outside the State based on 2018 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 several of the Mid-Shore counties of the Eastern Shore (Caroline, Dorchester, Kent, and Queen Anne's). Cardiac Interventional Centers are hospitals that have authorization from the Commission to provide primary PCI and are designated by MIEMSS and approved by its EMS Board to receive STEMI patients being transported by ambulance who meet specific criteria determined by the Maryland Medical Protocols for EMS Providers.*

Without the approval of the replacement program, UM SHS stated that patients would have to be transferred to other regions for care that are farther away. For residents in the service area, the average estimated drive times to UM SMC Easton (11 to 42 minutes) are much shorter than to other hospitals (34 to 116 minutes). (Table 5)

**Staff Analysis and Recommendation**

The Cardiac Services Chapter acknowledges that access to primary PCI services is an issue for residents of the mid-Shore region, in Caroline, Dorchester, Kent, and Queen Anne's counties and this is noted by the applicant.<sup>32</sup> Staff's travel time analysis suggests that the applicant's travel time estimates to alternative providers are reasonable. (Appendix 1.) Staff's analysis generated driving times ranging from 33 to 126 minutes to alternate PCI providers as compared to UM SHS's range of 34 to 116 minutes. The review also shows that while driving time in minutes to alternate PCI providers is variable, in some instance they may be drastically longer than the travel times to UM SMC Easton (11 to 42 minutes).

Staff concludes that UM SHS has presented sufficient evidence, including data on estimated emergency transport times, that the proposed population to be served will have insufficient access to primary PCI services, if the proposed program is not re-established at the replacement hospital. Staff concludes that the applicant complies with this standard.

**(4) Institutional Resources.**

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<sup>30</sup> UM SHS's Certificate of Conformance Application 2023, p. 19.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>31</sup> COMAR 10.24.17, <https://dsd.maryland.gov/regulations/artwork/10241701.pdf>.

<sup>32</sup> Ibid.

*(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.*

UM SHS stated that UM SMC Easton currently maintains the necessary facilities and staffing to be able to perform primary PCI 24 hours per day, seven days per week. At the replacement hospital, UM SHS plans to perform diagnostic catheterization and cardiac rhythm device implantation in two cardiac catheterization laboratories (CCL) across from the electrophysiology lab and adjacent to the operating room suites. Routine and preventative maintenance will be regularly scheduled to ensure the operational condition of each CCL. In the unlikely event of service interruption in both CCLs, UM SHS stated that elective procedures will be rescheduled, and “walk-in” STEMI patients will be transferred to the nearest hospital approved as a Cardiac Interventional Center.<sup>33 34</sup>

UM SHS reported that there were three occurrences since UM SMC Easton’s last Certificate of Ongoing Performance was completed in November of 2021, during which the hospital was unable to provide PCI services. The dates, amount of time, and the reasons for the PCI service downtimes, are shown in Table 6. These downtimes were four hours or less. During these incidents, notification was provided to the appropriate parties. In addition, UM SHS reported that there were no walk-in STEMI patients who had to be transferred to another CIC.<sup>35</sup>

**Table 6: CCL Downtime Incidents at UM SMC Easton, CY 2021 – 2022**

<b>Date/Time Incident</b>	<b>Date/Time Resolved</b>	<b>Description</b>	<b>Considerations</b>
3/17/21 12:48p	3/17/21 4:39p	Water damage/Flooding	Code Yellow – equipment needed testing for safe use
12/23/21 4:13p	12/23/21 7:39p	Lack of staffing	COVID exposure w/ quarantine guidelines
7/15/22 5:30p	7/15/22 8:00p	Lack of staffing	COVID exposure w/ quarantine guidelines

Source: UM SHS’s application for Certificate of Conformance 2023, p. 22.

### **Staff Analysis and Recommendation**

All downtimes reported by UM SHS were approximately four hours or less. There were no reported walk-in PCI patients during these downtimes who had to be transferred or who received suboptimal care at the hospital. The downtimes were relatively brief and due to unexpected circumstances. Because the hospital had a reasonable and appropriate plan in place to divert PCI cases, and no patients were reported to have been negatively affected, staff recommends that the Commission find that UM SMC Easton complies with this standard.

<sup>33</sup> Designation as a Cardiac Interventional Center indicates that a hospital complies with State standards to receive patients transported by emergency medical services, who are experiencing the most common type of heart attack called an ST-elevation myocardial infarction, or STEMI.

<sup>34</sup> UM SHS’s Certificate of Conformance Application 2023, p. 22.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>35</sup> Email from Hilary Cassel, Director of UM SRH’s Heart and Vascular Center, to Katie Neral, MHCC Program Manager, on December 4, 2023.



***(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.***

UM SHS provided a statement,<sup>36</sup> signed by hospital President and CEO of UM SRH, Kenneth Kozel, MBA, FACHE, who commits that UM SMC Easton will provide primary PCI services as soon as possible and not to exceed 90 minutes from the time of patient arrival at the hospital, for at least 75 percent of appropriate patients, in accordance with this standard. For transfer cases, UM SHS agreed to track door-to-balloon (DTB) times and evaluate areas for improvement.

At the current location, UM SHS reports that the hospital is achieving acceptable case volume and DTB times for primary PCI cases. As shown in Table 7, UM SHS reports achieving the DTB standard in all quarters since UM SMC Easton’s last Certificate of Ongoing Performance in 2021.

**Table 7: Door-to-Balloon Times Reported at UM SMC Easton by Quarter, January 2021 through March 2022**

<b>Quarter</b>	<b>Total Non-Transfer Primary PCI Cases</b>	<b>Total Cases Within 90 Minutes</b>	<b>Percent 90 Minutes or Less</b>
2021 q1	8	8	100%
2021 q2	5	5	100%
2021 q3	11	11	100%
2021 q4	5	5	100%
2022 q1	9	9	100%

Source: UM SHS’s application for Certificate of Conformance 2023, p. 23.

### **Staff Analysis and Recommendation**

Staff conducted an analysis of the ACC-NCDR CathPCI data submitted to MHCC by the hospital. As shown in Table 8, UM SMC Easton achieved compliance with DTB times in all but three quarters when the standard is applicable. The DTB standard was suspended for CY 2020 and CY 2021 due to the State of Emergency declared by the Governor for the COVID-19 pandemic. UM SMC Easton’s results in CY 2021 and 2022q1 differ from staff’s analysis because some cases were excluded, consistent with the ACC-NCDR’s evaluation of DTB performance for hospitals in standardized reports. There were non-system reasons for delay coded in the hospital’s ACC-NCDR CathPCI data for two cases in CY 2022q1, two cases in CY 2022q4, and three cases in CY 2021q4. A non-system delay is when the hospital did not have control over the circumstances causing a delay, such as when a patient is unstable and requires another intervention before PCI may be performed. The ACC-NCDR excludes those patients from calculations of DTB times. Based on staff’s analysis, although UM SMC Easton did not meet the DTB standard in every quarter, they would have met the standard if cases with non-system reasons for delay were excluded. In addition, UM SMC Easton met the DTB standard, when measured over rolling eight-quarter periods

<sup>36</sup> UM SHS’s Certificate of Conformance Application 2023, Exhibit 3.  
[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).



between July 2019 and December 2022 (Table 8). Staff recommends that the Commission find UM SHS complies with this standard.

**Table 8: UM SMC Easton’s Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period**

Time Period	Quarter			Rolling 8-Quarters		
	Total Primary PCI Volume	Cases with DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes	Total Primary PCI Volume	Cases with DTB<=90 Minutes	Percent of Cases with DTB <=90 Minutes
2019q2	17	13	76.5%			
2019q3	17	16	94.1%			
2019q4	13	13	100%			
2020q1	1	1	100%			
2020q2	10	8	80%			
2020q3	8	5	62.5%			
2020q4	5	4	80%			
2021q1	9	9	100%	80	69	86.3%
2021q2	16	12	75%	79	68	86.1%
2021q3	15	12	80%	77	64	83.1%
2021q4	15	11	73.3%	79	62	78.5%
2022q1	10	8	80%	88	69	78.4%
2022q2	19	13	68.4%	97	74	76.3%
2022q3	14	14	100%	103	83	80.6%
2022q4	12	8	67.7%	110	87	79.1%

Source: MHCC staff analysis of ACC-NCDR CathPCI registry data, CY 2021-CY 2022.

Note: Calculations for each quarter are based on the procedure date.

***(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.***

The applicant reports that UM SMC Easton’s CCL, ED, telemetry unit, Intensive Care Unit (ICU) and Coronary Care Unit are available to patients with acute myocardial infarction 24 hours per day, seven days per week. UM SHS’s staffing plans will remain the same at the replacement hospital as at the existing facility. The current CCLs are staffed Monday through Friday, 7am to 5:30pm. Two teams of three staff each support the two CCLs simultaneously throughout the day. Staffing consists of a minimum of one interventional cardiologist and one registered nurse, and the third staff member is either a nurse or technician. After-hours and weekend coverage is provided by on-call teams. UM SHS reports one less technician FTE and .75 less nurse FTEs than it reported in its Certificate of Ongoing Performance application, as shown in Table 9 below. The applicant also reports three FTEs dedicated to the routine provision of cardiac catheterization services.

**Table 9: Total Number of CCL Physician, Nursing and Technical Staff**

Staff Type	Cross-Training			
	January 6, 2023	August 26, 2020	October 11, 2016	Cross Training
Physicians	3	3	2	N/A
Nurses	7.25 FTE	8 FTE	5 FTE	Circulate/Monitor
Technicians	3.0 FTE	4 FTE	2 FTE	Scrub/Circulate/Monitor
Coordinator	1	--	--	Scrub/Circulate/Monitor

Source: UM SHS's application for Certificate of Conformance 2023, p. 25, and UM SMC Easton's 2021 Certificate of Ongoing Performance application, p. 7.

### Staff Analysis and Recommendations

Staff compared the staffing levels described by the applicant for UM SMC Easton over time (Table 9). Staffing levels were also compared to information reported by three other existing PCI programs, specifically the University of Maryland Baltimore Washington Medical Center (BWMC), Howard County General Hospital (HCGH) and Adventist Shady Grove Medical Center (SGMC).

UM SMC Easton has fewer full-time equivalent (FTE) interventionalists than HCGH and SGMC, however, the hospital has the same number of FTE interventionalists as BWMC, which performed more PCI cases than UM SMC Easton in CY 2021. UM SHS reported more nurses (7.25 FTEs) at UM SMC Easton than BWMC (5 FTEs), HCGH (6 FTEs), and SGMC (6 FTEs) but fewer technicians (3 FTEs) at UM SMC Easton than all three of these hospitals (5.8 FTEs, 6 FTEs, and 5 FTEs, respectively.) Details are provided in Table 10.

**Table 10: CCL Staffing for UM SMC Easton and Other Select PCI Programs**

Program	2021 Total PCI Volume	Number of Interventionalists	Nurse FTEs	Technician FTEs
UM SMC Easton	270	3	7.25	3
BWMC	317	3	5	5
HCGH	233	8	6	4
SGMC	281	5	6	7.5

Source: UM SHS's application for Certificate of Conformance 2023, p. 25; HCGH's Certificate of Ongoing Performance Staff Report 2020, p9; SGMC's Certificate of Ongoing Performance Staff Report 2021, p8; BWMC's Certificate of Ongoing Performance Staff Report 2020, p7.

Based on this analysis, and the number of staff reported at other hospitals with comparable PCI volumes, staff concludes that there are adequate nursing and technical staff to provide services 24 hours per day, seven days per week. UM SHS complies with this standard.

***(d) The hospital president or chief executive officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.***

UM SHS provided a written statement,<sup>37</sup> signed by hospital President and CEO of UM SRH, Kenneth Kozel, MBA, FACHE, committing hospital administration to supporting the PCI

<sup>37</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 4.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

program at the replacement hospital.

### **Staff Analysis and Recommendation**

Staff reviewed the letter of commitment and concludes that UM SHS meets this standard.

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

UM SHS states that UM SMC Easton's Interventional Cardiology PCI Program at the replacement hospital will participate in the ACC-NCDR, Get with the Guidelines Registry,<sup>38</sup> and the Cardiac Cath/PCI Registry.<sup>39</sup> In addition, the hospital will submit data to the Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ) for external reviews.

Currently, UM SHS reports that UM SMC Easton's data entry is being completed by existing designated positions within the hospital's CCL and by using the services of a data management company, Q-Centrix. The CCL manager, Clinical Coordinator, and nurses who work in the CCL also assist with the data collection efforts. At the replacement hospital, these efforts will continue and the Regional Director for Cardiovascular Services, along with the Medical Director of Cardiac Services and the Director of Interventional Cardiology, will oversee the data collection process for quality.

### **Staff Analysis and Recommendation**

Based on the applicant's plan for data collection and reporting and its track record of compliance with data management and reporting for the ACC-NCDR CathPCI data registry, staff concludes that UM SHS complies with this standard.

***(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.***

UM SHS reports that UM SMC Easton has established staff training protocols for its ED, CCL, ICU, and Telemetry Unit for the care of PCI patients. Staff in the ED attend a new hire departmental orientation that includes acute coronary syndrome recognition and STEMI processes. ED triage and assessment and STEMI procedures are reviewed monthly at Cardiac Services

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<sup>38</sup> The Get with the Guidelines registry tool is a voluntary, hospital-based quality improvement initiative that functions to improve the care of heart failure patients.

<sup>39</sup> The ACC NCDR CathPCI registry assesses the characteristics, treatments, and outcomes of cardiac disease patients who receive diagnostic catheterization and/or PCI procedures.

Steering Committee meetings, as well as during annual competency reviews. Hospital staff receive feedback as necessary, based on these reviews. Staff in the CCL attend a new employee orientation followed by a departmental orientation. New staff orientation, departmental training, and annual competency reviews are also a requirement for staff in the ICU and the Telemetry Unit. Additionally, annual competency validations and periodic ongoing educational sessions are required by the hospital.

UM SHS provided relevant UM SMC Easton policies and procedures in Exhibit 5,<sup>40</sup> including those for STEMI patients, triage of emergency services, emergency medical alert, transfer and transport of primary angioplasty patients, ICU admissions, and for On-Call CCL staff. A list of annual skills competencies was also provided. Protocols for telemetry monitoring and cardiac rhythm monitoring were subsequently provided on May 19, 2023, along with the ICU and Telemetry Units skills checklists. Applicant reports its on-call interventionalists will not be covering more than one hospital; therefore, an on-call coverage back-up plan is not required for UM SMC Easton.

### **Staff Analysis and Recommendation**

Staff reviewed the policies and procedures provided by UM SHS for UM SMC Easton, as well as the checklists for skills competencies. Based on its established staff protocols and training requirements, MHCC staff concludes that the hospital complies with this standard.

*(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.*

UM SHS indicates that the current UM SMC Easton Medical Director of interventional cardiology services is Jeffrey Etherton, M.D.

### **Staff Analysis and Recommendation**

Staff concludes that UM SHS has identified a physician in accordance with the standard. UM SHS complies with this standard.

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

UM SHS reports that UM SMC Easton's staff participate in continuing education trainings and services throughout the year, as needed or required, in the form of independent assigned learning, staff meetings, clinical inquiry meetings, best practice meetings, and PCI performance meetings. A list of continuing education sessions offered to staff in CY 2021 and CY 2022 was

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<sup>40</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 5.  
[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

provided by UM SHS.<sup>41</sup> Additionally, the hospital requires that all staff complete annual mandatory compliance training.

Staff in the CCL are assessed in their effort to seek and support opportunities for professional growth and development. All training and staff education activities are filed with the staff's department and included in the staff's annual performance evaluation.

### **Staff Analysis and Recommendation**

Staff's review of the continuing medical education program for hospital staff includes appropriate topics and concludes that UM SHS complies with this standard.

- (i) A hospital performing primary PCI without on-site cardiac surgery shall have a formal, written agreement with a tertiary institution that provides for unconditional transfer of the hospital's patients for any required additional care, including emergent or elective cardiac surgery or PCI.*

President and CEO of UM SRH, Kenneth D. Kozel, signed and dated an agreement<sup>42</sup> that provides for the unconditional transfer of primary PCI patients from UM SMC Easton to UMMC. The transfer policy states that the Maryland Express Care Transfer Center is the sole contact throughout the process. The policy further states that air transport is the preferred source of transportation. If a helicopter is unavailable, the Transfer Center will contact UM SMC Easton's contractual vendor for appropriate ground transportation.

### **Staff Analysis and Recommendation**

Staff concludes that UM SMC Easton meets this standard based on its review of the transfer agreement provided.

- (j) A hospital that performs primary PCI without on-site cardiac surgery 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 the hospital.*

UM SHS provided a copy of UM SMC Easton's contract with Butler Medical Services, a provider of specialty care transport and advanced or basic life support ambulance services.<sup>43</sup> The contract states that Butler Medical will arrive at UM SMC Easton within 30 minutes of receiving a call that a STEMI patient requires transfer.

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<sup>41</sup> UM SHS's Certificate of Conformance Application 2023, p. 28.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>42</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 6.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>43</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 7.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

## Staff Analysis and Recommendation

Staff reviewed the transport agreement and concludes that UM SMC Easton meets this standard based on its review of the written agreement provided.

### (5) Quality.

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

In a letter of commitment signed by President and CEO of UM SRH, Kenneth D. Kozel,<sup>44</sup> he states that a formal, regularly scheduled meeting for the purpose of interventional case review will be established at the replacement hospital. Meetings will be mandatory for interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

In addition, UM SHS provided the dates and attendees at the Cardiac Services Steering Committee,<sup>45</sup> during which interventional case reviews are conducted in the second half of each meeting. Exhibit 9 of the hospital's application indicates that 22 meetings were held between August 2020 and September 2022. Meetings in December were cancelled due to the holidays. In correspondence with staff on March 3, 2023, UM SHS indicates that the case review portion of the meeting includes members of the PCI patient care team and, if relevant to the cases being presented and discussed, representatives of EMS.

## Staff Analysis and Recommendation

Based on a review of the dates and attendees at interventional case review meetings and the letter of commitment provided, staff concludes that applicant meets this standard.

*(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 any and all issues related to the primary PCI system, identify problem areas, and develop solutions.*

The President and CEO of UM SRH, Kenneth D. Kozel, signed a letter of commitment<sup>46</sup> that the hospital will 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, at the replacement hospital. The group will meet monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

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<sup>44</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 8.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>45</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 9.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>46</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 10.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

UM SHS indicates that meetings of the Cardiac Services Steering Committee fulfill this requirement. The first half of the meeting is dedicated to a multi-disciplinary care area group discussion of issues related to the primary PCI system, identification of problem areas, and development of solutions. A list of attendees and dates of meetings held between August 2020 and September 2022 were provided.<sup>47</sup> This meeting is attended by representatives of the hospital's ED, ICU, hospitalist group, telemetry team, CCL, interventional cardiologists, and EMS.

### **Staff Analysis and Recommendation**

Staff concludes that UM SHS meets this standard based on the letter of commitment provided and a review of dates for meetings and meeting attendees.

- (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 patient's medical records; and*
  - (ii) External reviews shall be conducted by and external reviewer who shall meet all standards established by the Commission to ensure consistent rigor among external reviewers.*

UM SHS provided a letter signed by President and CEO of UM SRH, Kenneth D. Kozel,<sup>48</sup> that states the hospital is committed to conducting external reviews, at least semi-annually, for at least five percent of randomly selected PCI cases performed in the applicable time period at the replacement hospital, as provided in the Commission's regulations, which will include at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

UM SMC Easton contracts with the MACPAQ to perform periodic external case reviews as required by MHCC. A copy of each executive summary report was provided, for cases completed in CY 2020 and CY 2021.<sup>49</sup> These reports include the review of angiographic images, medical test results, and a patient's medical record.

### **Staff Analysis and Recommendation**

Staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 11.

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<sup>47</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 9.  
[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>48</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 11.  
[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>49</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 12.  
[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).



**Table 11: UM SMC Easton External Reviews, January 2020 – June 2022**

Time Period	Reported PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Review Frequency	Meets Standard*
01/20-06/20	74	10	13.5%	Semi-annually	Yes
07/20-12/20	92	9	9.8%	Semi-annually	Yes
01/21-06/21	89	11	12.4%	Semi-annually	Yes
07/21-12/21	106	9	8.5%	Semi-annually	Yes

Source: Staff analysis of MACPAQ reports.

\* Each semi-annual review is required to include at least three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

Staff verified that at least three cases were reviewed, every six months, for each interventionalist as specified in COMAR 10.24.17. Staff concludes that UM SHS complies with this standard based on the review of these reports and the letter of commitment provided.

- (d) A hospital shall evaluate the performance of each interventionalist at least annually through a review of:*
- (i) At least 10 cases or 10 percent of the interventionalist’s cases, whichever is greater; or*
  - (ii) If fewer than 10 cases have been performed by the interventionalist, then all cases should be reviewed.*
  - (iii) A hospital may choose another review period for evaluating the performance of each interventionalist, if the review will be conducted in a manner that assures that the review of cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraph .06A(5)(d) and is approved by the Commission’s Executive Director.*

UM SHS provided a letter of commitment signed by the hospital President and CEO of UM SRH, Kenneth D. Kozel,<sup>50</sup> acknowledging that the replacement hospital will evaluate the performance of each interventionalist through an internal or external review, as described in COMAR 10.24.17.07C(4)(d).

Additionally, UM SHS acknowledges in its response to additional questions asked on March 3, 2023, that due to the increase in PCI volume, the number of cases being reviewed by MACPAQ in CY 2020 and 2021 was lower than required by the performance evaluation standard. However, UM SMC Easton and MACPAQ have mutually agreed to increase the volume of cases reviewed during each semi-annual period going forward to ensure that the greater of three cases or 10 percent of PCI cases performed by each physician will be reviewed, as the hospital’s reported intention is to satisfy this review requirement through external case reviews.

### **Staff Analysis and Recommendation**

Staff reviewed the four MACPAQ reports for CY 2020 and 2021 and determined that two of the four periods had an adequate number of cases reviewed to meet the 10 percent standard. In

<sup>50</sup> UM SHS’s Certificate of Conformance Application 2023, Exhibit 13.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).



the other two review periods (July through December 2020 and 2021), there were 9.8 percent and 8.5 percent of cases reviewed, respectively. Although, the hospital expected to meet the case review requirements for the evaluation of individual interventionalist through external review of cases only, this requirement can be satisfied with internal or external case reviews. Staff concludes that the hospital met this standard, when the internal review of cases is counted too. Based on a review of the letter of commitment provided, the semi-annual external reviews, and the internal case reviews that are completed monthly at the Cardiac Services Steering Committee, staff concludes that UM SHS is in compliance with this standard.

*(e) The hospital shall participate in the American College of Cardiology’s National Cardiovascular Data Registry (ACC-NCDR) known as the CathPCI Registry.*

UM SMC Easton participates in the ACC-NCDR CathPCI Registry.

### **Staff Analysis and Recommendation**

Staff has been receiving a copy of the data submitted by UM SMC Easton to the ACC-NCDR CathPCI registry and a copy of the hospital’s performance reports for this registry. Staff concludes that UM SHS complies with this standard.

### **(6) Physician Resources.**

*Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery shall:*

*(a) Meet the Expert Guidelines; and*

*(b) Achieve an average annual case volume of 50 or more PCI cases over a two-year period.*

UM SHS provided a letter of commitment<sup>51</sup> signed by the hospital President and CEO of UM SRH, Kenneth D. Kozel, acknowledging that if UM SMC Easton obtains Commission approval to establish a primary PCI program at the replacement hospital, each physician who performs primary PCI services shall achieve an average annual case volume of 50 PCI cases over a twenty-four-month period. The applicant committed to tracking the physicians’ volume on a rolling eight-quarter basis and reporting the results to the Commission on a quarterly basis.

As part of the application, UM SHS submitted documentation showing that each physician on the staff roster who will be performing primary PCI services at the existing facility currently meets the case volume requirement.<sup>52</sup> UM SHS also agreed to submit documentation to demonstrate compliance with this standard 90 days prior to first use at the replacement hospital.

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<sup>51</sup> UM SHS’s Certificate of Conformance Application 2023, Exhibit 14.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>52</sup> UM SHS’s Certificate of Conformance Application 2023, Exhibit 17, received subsequently on April 13, 2023.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

## Staff Analysis and Recommendations

Staff's analysis of the ACC NCDR CathPCI data indicates that all three interventionalists performing PCI procedures at UM SMC Easton between January 2019 and December 2021 completed more than the minimum requirement of 50 PCI procedures annually, averaged over consecutive 24-month periods. The applicant commits that each physician will meet these minimum case volumes at the replacement hospital. Based on this analysis, staff concludes that UM SHS complies with this standard.

(7) Patient Selection.

***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 Expert Guidelines;***
- (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); and***
- (d) Patients who experience a return of spontaneous circulation following cardiac arrest and present at a hospital without cardiac surgery for treatment, when the treating physician(s) reasonably conclude that transfer to a tertiary institution may be harmful for the patient.***

President and CEO of UM SRH, Kenneth D. Kozel, signed a letter<sup>53</sup> that affirms the hospital's commitment to only provide PCI services for suitable patients.

## Staff Analysis and Recommendation

Staff concludes that UM SHS is in compliance with this standard based on a review of the letter provided.

### COMAR 10.24.17.06B - 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.***

An affidavit and acknowledgment of this agreement was attached to UM SHS's Certificate of Conformance application on behalf of UM SMC Easton and signed by Ken Kozel, President and CEO of UM SRH.

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<sup>53</sup> UM SHS's Certificate of Conformance Application 2023, Exhibit 15.  
[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

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

**(1) Need.**

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

Similar to UM SHS’s analysis of UM SMC Easton’s service area for primary PCI cases, the aggregated zip code data indicates the same five-county service area accounted for 94.8 percent of elective PCI cases performed at UM SMC Easton, with residents generating 344 elective PCIs in CY 2021. Of these, 56 percent, or 194 cases were performed at UM SMC Easton. See Table 12 for the hospital’s calculated market share for elective PCI services.

**Table 12: UM SMC Easton’s Market Share for Elective PCI Cases, CY 2021**

Patient Origin	Total Cases	Cases at UM SMC Easton	Market Share
Caroline	79	44	55.7%
Dorchester	68	42	61.8%
Kent	34	11	32.4%
Queen Anne’s	65	19	29.2%
Talbot	98	68	69.4%
<b>Subtotal</b>	<b>344</b>	<b>184</b>	<b>53.5%</b>
Other MD	--	3	--
Other States	--	7	--
<b>Total</b>	<b>344</b>	<b>194</b>	<b>--</b>

Source: UM SHS’s Certificate of Conformance application 2023, p. 15.

After estimating population projections and use rates, UM SHS used the percent of market share captured to calculate the total number of elective PCI cases projected at UM SMC Easton in CY 2025 and CY 2030. As shown in Table 13, UM SHS projects a total of 210 elective PCI cases in 2030.

**Table 13: UM SMC Easton Projection of Future Elective PCI Cases CY 2025 and CY 2030**

Patient Origin	UM SMC Easton Market Share 2021	Total Cases 2025	UM SMC Easton Cases 2025	Total Cases 2030	UM SMC Easton Cases 2030
Caroline	55.7%	83	46	88	49
Dorchester	61.8%	71	44	75	46
Kent	32.4%	36	12	38	12
Queen Anne’s	29.2%	67	20	71	21
Talbot	69.4%	100	70	103	72
<b>Subtotal</b>	<b>44.4%</b>	<b>357</b>	<b>191</b>	<b>374</b>	<b>200</b>
Other	5.4%	--	10	--	11
<b>Total</b>	<b>--</b>	<b>--</b>	<b>201</b>	<b>--</b>	<b>210</b>

Source: UM SMC Easton’s Certificate of Conformance application 2023, p. 15.

UM SHS projects that UM SMC Easton will have 82 primary PCI cases in CY 2030 (see Table 4). UM SHS stated that this volume alone is not enough to retain two interventional

cardiologists, which is essential to maintaining the PCI program at UM SMC Easton. This low volume of cases would result in physician recruiting challenges. UM SHS also reported that the projected volume will allow the physicians to maintain the appropriate skill level required for PCI services. UM SHS regards the hospital's elective PCI program as a critical component for maintaining a financially viable program that continues to serve residents in the Mid-Shore region.

As previously noted, UM SHS references the Cardiac Services Chapter that recognizes a need for more timely access to primary PCI services in Caroline, Dorchester, Kent, Queen Anne's, and Talbot counties.<sup>54</sup> UM SHS also stated that if the relocation of the existing PCI program is not approved at UM SMC Easton replacement hospital, the service area population will revert to not having a PCI program within a 30-minute drive. See Table 5. While the travel time to UM SMC Easton varies from 11 to 42 minutes for residents of the most populous city in each county, the travel time to alternate locations ranges from 34 to 116 minutes.

### **Staff Analysis and Recommendation**

Staff analyzed the ACC-NCDR CathPCI data to validate the service area for UM SMC Easton's PCI cases. This analysis shows that the hospital accurately described its service area for PCI services. Staff defined the hospital's service area as the top 90 percent of zip codes for elective PCI cases performed in calendar year 2021, provided that at least two cases were performed at the hospital for a specific zip code area. This approach was taken for ease of analysis. The results of this analysis are similar to the results generated by including all zip code areas for the five counties identified by UM SMC Easton as its service area.

Using staff's definition of the service area for UM SMC Easton, staff calculated the hospital's market share for elective PCI services in CY 2021. Staff compared this market share analysis to the one provided by UM SHS. Staff's market share analysis shows that UM SMC Easton completed 60.6% of those cases, with University of Maryland Medical Center (UMMC) completing 14.4%, AAMC (9.2%), and Peninsula Regional Medical Center (PRMC) (6.3%). This analysis suggests that the applicant's assumptions regarding market share are reasonable.

Staff verified the estimated travel times generated using Google Maps, from the most populous city identified in each of the counties in UM SMC Easton's service area for elective PCI services, as shown in Appendix 1. A travel time of 30 minutes or less is considered reasonable access to PCI services at alternative locations, as indicated in the Cardiac Services Chapter.<sup>55</sup> As shown in Table 5, while travel time to UM SMC Easton ranges from 11 to 42 minutes, no other hospital serving residents of the counties included in UM SMC Easton's service area has an estimated travel time of 30 minutes or less for elective PCI services. Based on this information, staff concludes that if there is no PCI program at the replacement hospital, candidates for primary PCI are unlikely to receive timely care.

While in some Maryland locations an interventionalist can perform PCI services at multiple hospitals, it would not be a readily available option for an interventionalist working at UM SMC

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<sup>54</sup> UM SHS's Certificate of Conformance Application 2023, p. 16.

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx).

<sup>55</sup> COMAR 10.24.17, <https://dcd.maryland.gov/regulations/artwork/10241701.pdf>.

Easton because of the distance to other hospitals with PCI services. For this reason, staff concludes that the applicant’s concerns regarding the ability to retain and recruit interventionalists, if the hospital only has an emergency PCI program, are valid.

UM SHS has demonstrated that the elective PCI program is needed to preserve timely access to primary PCI services for the population being served and ensure financial viability of PCI services. Based on the analysis of need, market share, and travel time projections, staff concludes that UM SHS complies with this standard.

**(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.***

UM SHS referenced the ACC NCDR-CathPCI data provided by MHCC to demonstrate that UM SMC Easton’s primary PCI volume of 76 cases in CY 2021, surpassed the minimum program volume standard of 36 cases per year for a hospital in a rural area. See Table 14. Additionally, UM SHS noted that the hospital completed 194 elective PCIs in CY 2021. For CY 2021, UM SMC Easton performed a total of 271 primary and elective PCI procedures, which exceeds the minimum target case volume of 200 PCI cases annually. To project annual case volumes, UM SHS used the Maryland Department of Planning population projections for 2020 and 2025, then applied the compound average growth rate between 2020 and 2025, to estimate the 2021 population. UM SHS then calculated the 2021 PCI use rates for each county and applied these rates to the population projections in CY 2025 and CY 2030 to project PCI volume in both of those years. The replacement hospital is expected to open in July 2028, and UM SHS project that UM SMC Easton will perform approximately 82 primary and 210 elective PCI cases in 2030 (Tables 4 and 13).

**Table 14: Primary and Elective PCIs at UM SMC Easton, CY 2019 - 2021**

<b>Calendar Year</b>	<b>Primary PCIs</b>	<b>Elective PCIs</b>	<b>Total PCIs</b>
<b>2019</b>	72	152	224
<b>2020</b>	62	167	229
<b>2021</b>	76	194	270

Source: UM SHS’s application for Certificate of Conformance 2023, p. 7.

**Staff Analysis and Recommendation**

Staff’s analysis of the ACC-NCDR CathPCI data confirmed the PCI case volumes completed by UM SMC Easton during the period from 2019 through 2021. Staff’s analysis of this data also validates that the projections for PCI volume in 2030 (292 cases) align with recent PCI case volumes at UM SMC Easton. Staff accounted for projected population changes and reasonable assumptions regarding market share in reaching this conclusion. UM SHS’s calculations of annual PCI case volumes are consistent with UM SHS’s assumptions regarding market share. UM SHS assumed UM SMC Easton would capture approximately 55 percent of the PCI market share for the hospital’s service area. Staff analysis, using the top 90 percent of zip codes in the service area to define the hospital’s service area, showed that 77.2 percent of primary

PCI cases in the service area were completed at UM SMC Easton in CY 2021, as well as 60.6 percent of elective cases. The distance from other PCI providers likely contributes to its high market share for PCI services.

Staff concludes that UM SHS has demonstrated that the hospital's proposed replacement PCI program is likely to achieve a volume of at least 200 or more total PCI cases by the end of the second year of providing PCI services at the replacement hospital. The applicant has met the standard.

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

***The Commission may waive the volume requirement 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.***

UM SHS is not seeking a waiver of the volume requirement that permits a hospital to demonstrate that the addition of elective PCI services will permit the PCI program to achieve financial viability.

As shown in Table 15, UM SHS provided a financial schedule of the revenue and expenses that show income generated from primary and elective PCI services (Form B) at the current hospital and projections for future years. UM SHS also provided a statement of assumptions.<sup>56</sup> The projected inpatient/outpatient mix, and payor mix is based on patients seen in 2022. Revenue is projected based on the FY 2023 budget, and grows by 0.9% annually, with volume, through 2032. Expenses are based on the FY 2023 budget with inflation assumed for salaries, supplies and other purchased services. Costs of equipment and construction are included in the main project budget submitted with the CON application.<sup>57</sup> UM SHS approximated that the PCI program will have a income of \$1,843,030 in CY 2032, but operating expense of \$2,596,338. The PCI program is projected to generate a net loss each year.

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<sup>56</sup> Exhibit 16 of UM SHS's application for Certificate of Conformance 2023, subsequently received on April 13, 2023. [https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/hcfs\\_cardiaccare\\_um\\_shore\\_easton.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/hcfs_cardiaccare_um_shore_easton.aspx)

<sup>57</sup> Table E of UM SHS's application for Certificate of Need 2023. [https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_con/hcfs\\_con\\_UM\\_shore\\_medical\\_center.aspx](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/hcfs_con_UM_shore_medical_center.aspx)

**Table 15: Projected Revenue and Expenses for UM SMC Easton by Time Period**

Category	Actual	Budget	Projected Years			
	2022	2023	2029	2030	2031	2032
<b>Revenue</b>						
<b>Inpatient Services</b>	\$1,582,482	\$1,596,725	\$1,684,885	\$1,700,049	\$1,715,348	\$1,730,781
<b>Outpatient Services</b>	\$3,403,156	\$3,433,784	\$3,623,376	\$3,655,986	\$3,688,885	\$3,722,075
<b>Gross Revenue</b>	\$4,985,638	\$5,030,509	\$5,308,261	\$5,356,035	\$5,404,233	\$5,452,856
<b>Adjustments to Revenue</b>						
<b>Allowance for Bad Debt</b>	\$38,254	\$35,062	\$36,998	\$37,331	\$37,667	\$38,006
<b>Contractual Allowance</b>	\$970,533	\$889,548	\$938,663	\$947,111	\$955,634	\$964,232
<b>Charity Care</b>	\$11,323	\$10,378	\$10,951	\$11,050	\$11,149	\$11,250
<b>Net Patient Service Revenue</b>	\$3,965,527	\$4,095,520	\$4,321,649	\$4,360,543	\$4,399,783	\$4,439,368
<b>Net Operating Revenue</b>	\$3,965,527	\$4,095,520	\$4,321,649	\$4,360,543	\$4,399,783	\$4,439,368
<b>Expenses</b>						
<b>Salaries, Wages, and Fees</b>	\$877,355	\$648,682	\$718,926	\$731,352	\$743,993	\$756,852
<b>Supplies</b>	\$1,037,769	\$1,231,541	\$1,589,651	\$1,658,736	\$1,730,824	\$1,806,043
<b>Other Expenses</b>	\$21,475	\$26,876	\$31,093	\$31,857	\$32,641	\$33,444
<b>Total Operating Expenses</b>	\$1,936,598	\$1,907,099	\$2,339,670	\$2,421,945	\$2,507,457	\$2,596,338
<b>Income</b>						
<b>Income from Operation</b>	\$2,028,929	\$2,188,422	\$1,981,979	\$1,938,598	\$1,892,327	\$1,843,030
<b>Net Income (Loss)</b>	\$2,028,929	\$2,188,422	\$1,981,979	\$1,938,598	\$1,892,327	\$1,843,030

Source: UM SHS's application for Certificate of Conformance 2023, Form B.

### Staff Analysis and Recommendation

This standard is inapplicable to the review of the application because applicant is not requesting a waiver from the minimum volume standard on the basis of the hospital's ability to achieve financial viability through the addition of elective PCI. Staff also notes that the hospital's PCI program is not projected to achieve financial viability even with both primary and elective PCI services, as described by the applicant and shown in Table 15.

## IV. SUMMARY AND RECOMMENDATION

UM SMC Easton is a provider of both primary and elective PCI services at its current hospital location. The information considered in this review indicates that maintaining a PCI program at the replacement hospital is important for maintaining timely access to these services for the population in the hospital's service area. UM SMC Easton's existing primary and elective PCI program has continued to be in conformance with the standards established by MHCC for PCI programs at hospitals without on-site cardiac surgery. The hospital is likely to perform over 200 PCI cases, if UM SMC Easton establishes both primary and elective PCI services at the replacement hospital. Staff recommends that the Commission approve the request of UM SHS for a Certificate of Conformance to establish primary and elective PCI services at the replacement hospital.

**IN THE MATTER OF  
ESTABLISHMENT OF PRIMARY  
AND ELECTIVE PERCUTANEOUS  
CORONARY INTERVENTION  
SERVICES BY UNIVERSITY OF  
MARYLAND SHORE MEDICAL  
CENTER AT EASTON  
DOCKET NO. 23-20-CC042**

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**BEFORE THE  
MARYLAND HEALTH  
CARE COMMISSION**

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**ORDER**

Having reviewed and considered the information and analysis contained in the Staff Report and Recommendation, it is, this 18th day of January 2024:

**ORDERED**, that the findings of fact and conclusions of law included in the Staff Report and Recommendation are adopted by the Maryland Health Care Commission and incorporated into this order; and it is further

**ORDERED**, that 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, the application filed by Shore Health System, Inc. for a Certificate of Conformance to establish establish primary and elective PCI services at the replacement University of Maryland Shore Medical Center at Easton is hereby **APPROVED** with the following conditions:

1. UM SMC Easton shall apply for a Certificate of Ongoing Performance within three years of establishing primary and elective PCI services at the replacement hospital, in accordance with the review schedule(s) published in the *Maryland Register*.
2. UM SMC Easton continues to comply with the requirements for a Certificate of Ongoing Performance at the hospital’s current location.



## Appendix 1:

### Estimated Travel Time to Major PCI Providers for Patients in the Most Populous City of the Counties in the Service Area of UM SMC Easton

		AAMC	BWMC	Bayhealth	Christiana	JHH	Nanticoke	PRMC	UMMS
9am	<b>Denton (Caroline)</b>	47	63	41	104	90	34	68	78
1pm		48	65	41	82	86	36	68	94
5pm		47	67	40	76	83	35	59	77
9pm		47	61	39	77	87	34	58	89
9am	<b>Cambridge (Dorchester)</b>	66	80	71	115	104	45	28	95
1pm		67	83	73	115	126	45	46	97
5pm		65	82	68	109	99	44	44	94
9pm		64	75	67	109	92	45	41	90
9am	<b>Chestertown (Kent)</b>	55	71	72	63	102	100	104	98
1pm		55	72	93	60	106	78	105	99
5pm		54	73	69	58	91	75	98	101
9pm		56	68	70	58	88	76	99	91
9am	<b>Centerville (Queen Anne's)</b>	33	48	64	72	76	62	85	63
1pm		33	50	76	69	72	62	83	79
5pm		34	56	61	66	70	60	80	67
9pm		35	47	62	67	63	65	78	62
9am	<b>Easton (Talbot)</b>	48	64	63	98	88	51	67	80
1pm		48	65	63	90	88	48	65	79
5pm		48	67	61	85	82	48	58	77
9pm		48	60	63	87	87	46	64	89

Source: Staff estimates of travel time for PCI patients in the service area of UM SMC Easton, based on Google Maps estimates of travel time for August 30, 2023.