IN THE MATTER OF	*	BEFORE THE MARYLAND
UNIVERSITY OF MARYLAND SHORE	*	HEALTH CARE COMMISSION
MEDICAL CENTER AT EASTON	*	
Docket No. 25-20-CP066	*	

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STAFF REPORT AND RECOMMENDATION

CERTIFICATE OF ONGOING PERFORMANCE FOR PRIMARY AND ELECTIVE PERCUTANEOUS CORONARY INTERVENTION SERVICES

March 19, 2026

I. INTRODUCTION

A. Background

Percutaneous coronary intervention (PCI), commonly known as coronary angioplasty, is a non-surgical procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing. Primary (or emergency) PCI programs provide emergency PCI intervention in the event of a heart attack shortly after it begins. Elective (or non-primary) PCI programs provide interventions that revascularize coronary arteries that are substantially blocked but have not yet resulted in an immediate cardiac event.

For many years, only Maryland hospitals with on-site cardiac surgery services could provide PCI. However, in the 1990s, Maryland began allowing some hospitals to perform primary PCI services without cardiac surgery on-site, first as part of research trials evaluating the safety of providing primary PCI at such hospitals and, later, as a regular clinical service, based on the research findings. The Maryland Health Care Commission (MHCC or Commission) issued waivers to hospitals to exempt them from the requirement for co-location of primary PCI services with cardiac surgery. In the following decade, similar research evaluated the safety of providing elective PCI services at hospitals without on-site cardiac surgery.

The nine Maryland hospitals that obtained waivers to provide elective PCI services participated in a multi-site clinical trial, C-PORT E, a study that was approved by the Commission upon the recommendation of its Research Proposal Review Committee. This non-inferiority study provided evidence that elective PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. In 2012, the Maryland legislature passed a law directing the Commission to establish a process and minimum standards for a hospital to obtain and maintain Certificates of Ongoing Performance for the provision of cardiac surgery and PCI. The legislation required the Commission to establish a Clinical Advisory Group (CAG) to advise the agency on regulations to implement the new law.

After extensive discussion with the CAG, comprised of national and regional experts, and considering the CAG's and other stakeholders' recommendations, COMAR 10.24.17, the State Health Plan (SHP) for Facilities and Services: Specialized Health Care Services - Cardiac Surgery and PCI Services chapter (Cardiac Services Chapter)was replaced, effective August 2014. The Cardiac Services Chapter was subsequently revised in November 2015 and again in January 2019.

The Cardiac Services Chapter contains standards for evaluating the performance of established cardiac surgery and PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services authorizes a hospital to continue to provide PCI services, either primary or both primary and elective PCI services, for a period of time that cannot exceed five years, unless an extension is granted by the Executive Director. At the end of the period, the hospital must demonstrate that it continues to meet the requirements in the Cardiac Services Chapter in order for the Commission to renew the hospital's authorization for a Certificate of Ongoing Performance.

In between renewals for a Certificate of Ongoing Performance, if a hospital is not in compliance with certain standards, a focused review must be conducted. Staff has the authority to conduct a focused review based on reported patient safety concerns, aberrations in data identified by Commission staff, or failure to meet quality standards established in State and federal regulations.[1] A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance must receive a detailed list of deficiencies from Commission staff and submit a plan of correction within 30 days of receipt of the list of deficiencies.[2] If a hospital does not submit a plan of correction that addresses deficiencies cited or does not successfully complete a plan of correction, the hospital shall upon notice of the Executive Director of the Commission, voluntarily relinquish its authority to perform cardiac surgery or emergency or elective PCI services, as applicable.[3]

B. Applicant

University of Maryland Shore Medical Center at Easton

The University of Maryland Shore Medical Center at Easton ("Shore") is a 132-bed acute care general hospital that is located in Easton (Talbot County). Shore is part of the University of Maryland Medical System and does not have a cardiac surgery program on-site.

Shore received a Certificate of Conformance and began providing primary PCI services in April 2016 and elective PCI services in March 2017. Shore filed a Certificate of Ongoing Performance application on August 26, 2020 and received its first Certificate of Ongoing Performance to provide primary and elective PCI services on November 18, 2021. This is the first renewal of Shore's Certificate of Ongoing Performance for its PCI program.

Health Planning Region

Four health planning regions for adult cardiac services are defined in the Cardiac Services Chapter. The regions are defined by geographic areas. Talbot County is in the Baltimore/Upper Shore region, which also includes Baltimore City and Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Howard, Kent, Queen Anne's, and Harford counties. Fourteen hospitals in this region provide PCI services. Five of these hospitals provide both cardiac surgery and PCI services while nine, including Shore, provide only PCI services.

Staff Recommendation

MHCC staff recommends that the Commission approve Shore's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services. Staff review and analysis of Shore's documentation of its compliance with SHP standards follows.

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[1] COMAR 10.24.17.07B(2)(a), .07C(2)(a), and .07D(2)(a).

[2] COMAR 10.24.17.07B(2)(c), .07C(2)(c), and .07D(2)(c).

[3] COMAR 10.24.17.07B(2)(e), .07C(2)(e), and .07D(2)(e).

II. PROCEDURAL HISTORY

On June 20, 2025, Shore applied to renew its Certificate of Ongoing Performance. Staff reviewed the application and requested additional information on July 20, 2025, and received a response on September 19, 2025. On November 18, 2025, MHCC notified the hospital that its prior Certificate of Ongoing Performance would be extended for six months, until May 18, 2026.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07C(3) and .07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACC-NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI program shall also cooperate with the data collection requirements deemed necessary by the Maryland Health Care Commission to assure a complete, accurate, and fair evaluation of Maryland's PCI programs.

Staff Analysis and Conclusion

Shore has generally submitted its data in a timely manner to both the NCDR CathPCI registry and to MHCC. There was a single instance, in June of 2024, wherein Shore missed the registry's deadline. However, within a few weeks the missing data was submitted and, both prior to and, since that event no registry deadlines were missed. Also, that event occurred shortly after a new individual was hired to manage the data submission process. Given these circumstances and that the untimely submission was a single occurrence, MHCC staff recommend that the Commission find that Shore has complied with the standard.

Institutional Resources

10.24.17.07D(4)(a) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction, 24 hours per day, seven days per week.

Shore provided the following table of instances where both of the rooms in its cardiac catheterization laboratory (CCL) were unavailable:

Table 1: Shore CCL Downtime January 2023 – June 2025

Date	Reason	Length
October 25, 2023	Electrical Issue that caused power switch to emergency supply without adequate confidence that equipment outages would be completely avoided.	3 hours, 20 minutes
November 18, 2023	Physician Emergency	3 hours
June 3, 2024	Lack of Interventional Cardiologist following a suspension of Physician privileges by the Maryland Board of Physicians	13 hours, 30 minutes
October 7, 2024	Lack of Interventional Cardiologist	4 hours, 30 minutes
March 30, 2025	Internal disaster – HVAC	5 days

Source: Shore application, response to Question 2

Shore also provided a copy of its STEMI diversion policy and explained that hospital policy directs that if one of its two labs is unavailable due to planned maintenance, the schedule is adjusted so that all cases can be completed in the remaining lab that remains available.

Staff Analysis and Conclusion

MHCC staff reviewed the hospital's reported CCL closures during the period from January 2023 through June 2025 and determined that on occasions when both CCL rooms were out of commission simultaneously, which only took place for reasons beyond the hospital's control, the hospital timely followed its STEMI diversion policy and notified the Maryland Institute for Emergency Medical Services Systems (MIEMSS) of the hospital's temporary inability to provide PCI services. Given the infrequency with which the downtimes occurred, the fact that they were beyond the hospital's control and the fact that the hospital followed, in those unique circumstances, its internal STEMI diversion policy to provide the best possible patient care, MHCC staff recommend that the Commission find that Shore meets the standard.

10.24.17.07D(4)(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

Shore provided a signed statement from Kenneth D. Kozel, MBA, FACHE, President and Chief Executive Officer (CEO), dated March 31, 2025, stating that Shore will provide 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 the appropriate patients and will track the door-to-balloon (DTB) times for transfer cases and evaluate areas for improvements.

Shore provided quarterly counts of non-transfer patients who received primary PCI and the number who had a DTB time of less than 90 minutes, as shown in Table 2 below. According to the information provided by Shore, the DTB standard was met in 10 of the 12 quarters between January 2022 and December 2024.

Table 2: Shore Reported Compliance with DTB Benchmark for Non-Transfer Primary PCI Cases by Quarter, January 2022 – December 2024

Quarter	Total Non-Transfer Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <=90 Minutes
2022 Q1	12	11	92%
2022 Q2	20	14	70%
2022 Q3	15	15	100%
2022 Q4	13	10	77%
2023 Q1	16	13	81%
2023 Q2	6	5	83%
2023 Q3	14	11	79%
2023 Q4	6	5	83%
2024 Q1	8	5	63%
2024 Q2	10	9	90%
2024 Q3	6	5	83%
2024 Q4	6	5	83%

Source: Shore application, response to Question 3

Shore provided quarterly information on its DTB times for transfer patients for the period of January 2022 through December 2024, as shown below in Table 3. The hospital met the 120 minute DTB goal in 75%, or more, of cases in only one of the twelve quarters between January 2022 and December of 2024.

Table 3: Shore Reported Compliance with DTB Benchmark for Transfer Primary PCI Cases by Quarter, January 2022 – December 2024

Quarter	Total Transfer Primary PCI Volume	Cases with DTB <= 120 Minutes	Percent of Cases with DTB <=120 Minutes
2022 Q1	3	2	67%
2022 Q2	7	4	57%
2022 Q3	2	1	50%
2022 Q4	1	1	100%
2023 Q1	7	2	29%
2023 Q2	7	5	71%
2023 Q3	5	1	20%
2023 Q4	6	2	33%
2024 Q1	2	0	0%
2024 Q2	5	3	60%
2024 Q3	1	0	0%
2024 Q4	0	0	--

Source: Shore application, response to Question 3

Shore provided a list of the strategies it has employed, since receiving its prior application, in collaboration with the sending facilities, in an effort to improve transfer times. Initiatives have included protocols to promptly identify patients with epigastric pain, chest pain, or diaphoresis and timely provision of an EKG, usage of an internal messaging system to directly message the on-call cardiology team for quick consult to verify STEMI status, and the institution of a standby ambulance at a partner facility who transfers STEMI patients to Shore.

Staff Analysis and Conclusion

MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for the delay, and MHCC includes all cases in reviewing compliance with this standard.

As displayed in Table 4 below, MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer PCI cases and observed that, based on that data source, Shore did not meet the DTB standard in 5 of the 15 quarters from January 2022 through September 2025.

Table 4: Shore Non-Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period

Quarter	Total Non-Transfer Primary PCI Volume	Cases with DTB <= 90 Minutes	Percent of Cases with DTB <=90 Minutes
2022 Q1	10	8	80.0%
2022 Q2	19	13	**68.4%**
2022 Q3	14	14	100.0%
2022 Q4	12	8	**66.7%**
2023 Q1	15	12	80.0%
2023 Q2	10	6	**60.0%**
2023 Q3	16	12	75.0%
2023 Q4	12	11	91.7%
2024 Q1	7	6	85.8%
2024 Q2	12	6	**50.0%**
2024 Q3	7	4	**57.1%**
2024 Q4	9	7	77.8%
2025 Q1	9	8	88.9%
2025 Q2	11	9	81.8%
2025 Q3	14	13	92.9%

Source: MHCC analysis of ACC-NCDR CathPCI data, January 1, 2022 – June 30, 2025.

MHCC staff asked the hospital to explain the reasons for delays in the quarters wherein the hospital did not achieve the 75% standard. In Q2 of 2022, Q4 of 2022 and Q2 of 2023, the great majority of delays were patient-centered delays and not due to factors that the hospital controlled. In Q2 of 2024, three cases were delayed for patient-centered reasons and one case was delayed for a patient-centered reason in Q3 of 2024. The hospital acknowledged that during 2024, on five occasions, there was a delay in the hospital's emergency department either in determining the patient to be a STEMI or in contacting the on-call interventional cardiologist. Prior to MHCC involvement, the hospital identified this issue, through its normal quality assurance processes, and implemented a corrective action plan. As mentioned elsewhere in this report the corrective actions taken included new protocols to promptly identify patients with epigastric pain, chest pain, or diaphoresis and timely provision of an EKG and related training materials, a new internal messaging system to directly message the on-call cardiology team for quicker consultation and verification of a patient's STEMI status, and an internal recognition program whereby ED staff who participate in a successful STEMI case receive a certificate and anatomical heart badge pin to display for meeting the internal institutional goals. Since the design and implementation of the corrective action plan, for 4 consecutive quarters, Shore has exceeded the 75% threshold.

With respect to transfer cases, staff analyzed the hospital's performance relative to a DTB benchmark of 120 minutes, as shown below in Table 5. The benchmark of 120 minutes is consistent with the American Heart Association and American College of Cardiology guidelines.

Table 5: Shore Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 120 Minutes, by Time Period

Time Period	Total Transfer PCI Volume	Cases with DTB<=120 Minutes	Percent of Cases with DTB <=120 Minutes
2022 Q1	2	2	100%
2022 Q2	2	0	0%
2022 Q3	1	0	0%
2022 Q4	0	n/a	n/a
2023 Q1	3	1	33.3%
2023 Q2	4	2	50%
2023 Q3	2	0	0%
2023 Q4	1	0	0%
2024 Q1	2	0	0%
2024 Q2	3	1	33.3%
2024 Q3	3	1	33.3%
2024 Q4	0	n/a	n/a
2025 Q1	4	1	25%
2025 Q2	3	1	33.3%

Source: MHCC analysis of ACC-NCDR CathPCI data, January 1, 2022 – June 30, 2025.

MHCC staff's analysis of the ACC-NCDR CathPCI data shows that in 11 of the 14 quarters between January 2022 and June 2025, 50% or less of the transfer PCI cases achieved a DTB of 120 minutes or less in each quarter. A hospital is expected to strive to achieve a DTB time in primary PCI transfer cases of 120 minutes or less. However, many factors outside of a hospital's control affect the DTB times in transfer cases. For this reason, there is not a requirement that a certain percentage of cases achieve the benchmark of 120 minutes in each quarter. Instead, a hospital is required to track the DTB times for transfer cases and evaluate areas for improvement, which Shore has done.

In addition to tracking DTB times for transfer cases, Shore provided information on the strategies it has attempted to utilize for improving DTB times for transferred PCI patients. The hospital revised its criteria for administering EKGs to patients in the emergency department (ED) and began utilizing a new internal messaging system to directly message the on-call cardiology team for quicker consultation and for verification of a patient's STEMI status. Also, a standby ambulance was restationed at one of the freestanding medical facilities that transfers STEMI patients to Shore for primary PCI, and that same facility began using air transport for faster transfers. Finally, Shore worked with MIEMSS to connect with other rural hospitals and attempt to recreate strategies that other facilities had found effective for reducing transfer times.

MHCC staff recommends that the Commission find that complies with the DTB standard for both transfer and non-transfer cases. The hospital met the standard for non-transfer cases in most quarters and self-identified and worked to resolve the issues in quarters when the standard was not met. The hospital attributed these instances largely to patient-related factors and identified a limited number of cases involving delays in emergency department recognition of STEMI or notification of the interventional cardiologist. Shore reported that it implemented corrective actions through its internal quality assurance processes to address these issues, and performance in the most recent quarters indicates improvement and sustained compliance with the benchmark. In the most recent quarters, since implementing new strategies, Shore has consistently exceeded

the required threshold. The hospital met the standard for transfer cases by tracking the DTB times and working to improve the DTB times in transfer cases.

10.24.17.07D(4)(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.

Shore provided the number of physicians, nurses, and technicians staffing its CCL. This information is shown in Table 6.

Table 6: Shore Reported CCL Physician, Nursing, and Technician Staff

Role	Number / FTEs	Cross Training (S/C/M)*
Physician	3	
Nurse	6	5 - C/M 1 – C/M/S
Technician	4	7 – M/S

Source: Shore June 2025 PCI Certificate of Ongoing Performance application
*(S) scrub, (C) circulate, (M) monitor.

Staff Analysis and Conclusion

MHCC staff compared the reported staffing levels at Shore to the staffing levels for programs at three other hospitals with similar PCI case volumes. Table 7 provides comparative information on the PCI volume and staffing levels for Shore, Johns Hopkins Howard County Medical Center (JHHCMC), Carroll Hospital Center (CHC), and University of Maryland Baltimore Washington Medical Center (UMBWMC). Shore employs the same number of interventionalists as UMBWMC even though UMBWMC's PCI volume is approximately 25 percent higher. While JHHCMC uses significantly more physicians, a comparison of the number of interventionalists at different hospitals is not particularly meaningful because some interventionalists may perform PCI at multiple hospitals, and there is not a strong correlation between the number of interventionalists needed and PCI volume. Shore uses a similar number of technicians as compared to JHHCMC and CHC, and fewer than UMBWMC, but as noted above, that facility's PCI volume is higher. With regard to nurses, Shore uses fewer nurses than the comparable programs but has experienced no quality of care issues that would indicate insufficient nursing staff, nor has experienced any CCL downtime attributable to a nursing shortage.

Table 7: CCL Staffing, Shore and Selected Other PCI Programs

PCI Program	Total PCI Case Volume (July 1, 2024 – June 30, 2025)	Interventionalists	Nurse FTEs	Technician FTEs
Shore	186	3	6	4
JHHCMC	168	9	11	5
CHC	175	4	9.8	4
UMBWMC	232	3	7.5	7

Sources: Shore's June 2025 PCI COP application and supplemental data submission of September 2025 and Shore's PCI volume from ACC-NCDR CathPCI registry report for period ending June 30, 2025; JHHCMC's January 2024 COP application for Primary and Elective PCI Services and JHHCMC's PCI volume from ACC-NCDR CathPCI registry report for period ending June 30, 2025; CHC's April 2024 PCI COP application and CHC's PCI volume from ACC-NCDR CathPCI registry report for period ending June 30, 2025; UMBWMC's January 2024 COP application for Primary and Elective PCI Services and UMBWMC's PCI volume from ACC-NCDR CathPCI registry report for period ending June 30, 2025.

Based on the above analysis of the number of staff reported at other hospitals with comparable PCI volumes to Shore, MHCC staff concludes that Shore complies with the standard.

10.24.17.07D(4)(d) The hospital president or chief executive officer, as appropriate, shall provide a written commitment stating the hospital administration will support the program.

Shore provided a letter, dated March 31, 2025, wherein the hospital's president and CEO, Kenneth D. Kozel, MBA, FACHE, stated that Shore will "provide the staffing and facility support necessary to provide primary PCI services in accordance with the requirements for primary PCI programs established by the Maryland Health Care Commission."

Staff Analysis and Conclusion

MHCC staff reviewed the letter and conclude that Shore complies with the standard.

10.24.17.07D(4)(e) The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

Shore stated that the hospital employees a third party vendor to assist with data management and reporting. The CCL unit manager holds the responsibility of coordination and institutional quality improvement efforts. No FTEs are solely dedicated to this work. At the time when its application was submitted, Shore employed a Cath Lab Manager and a staff nurse from the ED whose duties include data management.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and confirmed that the hospital has been submitting complete and timely information to the ACC-NCDR CathPCI registry and is consistently engaging in the required quality assurance activities. MHCC staff concludes that Shore complies with this standard.

10.24.17.07D(4)(f) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the cardiac 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.

Shore stated that Dr. Etherton accepted his position of lnterventional Cardiology Medical Director on October 10, 2016 and submitted a copy of that position's job description. In a supplemental submission of data in September 2025, the applicant provided additional details about which functions are handled independently by Dr. Etherton and which he performs with administrative support.

Staff Analysis and Conclusion

MHCC staff reviewed the job description provided. The responsibilities listed include continuous monitoring and improvement of the quality of care of interventional cardiology, evaluating the appropriateness of the interventional cardiology services delivered, providing input concerning the interventional cardiology capital budget, approving the call schedule and providing feedback to personnel regarding clinical performance, acquisition of diagnostic information and refinement of technique. Based on the job description provided, MHCC concludes that Shore complies with this standard.

10.24.17.07D(4)(g) The hospital shall have a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

Shore provided a chart of the continuing medical education sessions provided to its CCL staff between January 2022 and March 2025. The chart detailed the date of the educational session, the topic, and attendees broken down by the number of technicians, nurses and providers. Additionally, the hospital explained that many education sessions are provided by manufacturer representatives on the newest equipment and that sessions are scheduled in advance and placed on the most heavily staffed day as to educate as many people as possible in the shortest amount of time. Shore keeps a record of education sessions and who attended and has yearly competencies that are required by all staff. While the exact skills tested vary somewhat by year, certain basic PCI competencies are tested annually, including balloon pump insertion preparation, use of the Zoll Defibrillator, arrhythmia test, access site post care and sheath pulls.

Staff Analysis and Conclusion

MHCC staff reviewed the list of educational sessions provided to Shore's CCL staff and notes that the sessions include appropriate topics such as radiation safety, coronary anatomy, interventional equipment such as wires and stents, cardiac rhythm monitoring, Intra-Aortic Balloon Pump (IABP) and other topics pertaining to emergency care, and specifically cardiac emergency medicine. The hospital has a method for tracking the completion of the required educational activities. MHCC staff concludes that Shore complies with this standard.

10.24.17.07D(4)(h) A hospital that performs 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.

Shore's president and CEO, Kenneth D. Kozel, MBA, FACHE, signed a transfer agreement with Dana Farrakhan, Senior Vice President of University of Maryland Medical Center, effective October 13, 2015. Shore reported that the October 2015 agreement remains the current binding contract between Shore and UMMC.

Staff Analysis and Conclusion

MHCC staff reviewed the patient transfer agreement and concludes that Shore meets this standard.

10.24.17.07D(4)(i) The hospital shall maintain a formal written agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

Shore submitted a copy of its agreement with University of Maryland Medical System Corporation d/b/a Maryland Expresscare, executed in April 2023.

Staff Analysis and Conclusion

Under the above-referenced contract, the vendor guarantees arrival of the air or ground ambulance at the hospital within thirty (30) minutes of a request for transportation of patients undergoing such services when clinically necessary. MHCC staff concludes that Shore adheres to the standard.

Quality

10.24.17.07C(4)(a) and .07D(5)(a) The 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.

Shore provided a list of Cardiac Services Steering Committee (CSSC) and PCI internal case review meetings that took place between January 2022 and December 2024, as well as the names of the meeting attendees and their respective roles.

Staff Analysis and Conclusion

MHCC reviewed dates and attendance records for interventional case review meetings and noted that there were 11 meetings held in CY 2022; 10 meetings in CY 2023; and nine in CY 2024. The meetings included physicians, nurses, and technicians. MHCC staff concludes that Shore complies with the standard.

10.24.17.07C(4)(b) and .07D(5)(b) The 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.

Shore reported that its multiple care area group known as the CSSC includes members from the ED, nursing, Emergency Medical Services, and CCL leadership. The committee convenes monthly and all members are required to attend. Shore reported that CCL staff join the meetings each month for the case review portion. The CSSC is responsible for monitoring and evaluating the care and activities that relate to cardiac patients through the full continuum of care. Shore provided a list of meeting dates and attendees for the CSSC meetings held between January 2022 and December 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation for meetings between January 2022 through December 2024. There were 11 meetings held in CY 2022; 10 meetings in CY 2023; and nine in CY 2024. The meeting was scheduled to occur monthly and usually did, with cancellations occurring due to holidays, committee chair illness, or other urgent internal hospital issues requiring the presence and involvement of all active leadership. MHCC staff also reviewed the titles of attendees and determined that leaders of other care areas, as well as other relevant organizations (e.g., Queen Anne's County County Emergency Medical Services and Kent County Emergency Medical Services) attended the meetings. MHCC staff concludes that Shore complies with the standard.

10.24.17.07C(4)(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

Shore provided MHCC with external review reports for the period January 2021 through June 2023. The external reviews were completed by the Maryland Academic Consortium for

Percutaneous Coronary Intervention Appropriateness and Quality (MACPAQ), an MHCC-approved external review organization.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. As shown below in Table 8, the percentage of cases reviewed per year was greater than 5 percent, as required. MHCC staff reviewed the MACPAQ reports and determined that during the period January 2021 through June 2023, the semiannual reviews included at least three cases per physician.

Table 8: Shore External Review, CY 2021 – June 2023

Review Period	Elective PCI Case Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Meets Standard
CY 2021	195	20	10.3%	Yes
CY 2022	211	21	10.0%	Yes
2023 (Jan-Jun)	131	13	9.9%	Yes

Source: MHCC Analysis, Shore Application Q13, and MACPAQ Reports

MHCC staff concludes that Shore complies with this standard.

10.24.17.07C(4)(d) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

(i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or

(ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than three cases during the relevant period, as provided in Regulation .08; or

(iii) A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraph .07C(4)(d)(i).

10.24.17.07D(5)(c) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

(i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or

(ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08; or

(iii) For a hospital with both primary and elective PCI programs, a quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraphs .07C(4)(c) and .07D(5)(c).

10.24.17.07C(4)(e) and .07D(5)(d) The performance review of an interventionalist referenced in Paragraph .07D(5)(c) shall:

(i) Include a review of angiographic images, medical test results, and patients' medical records; and

(ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.

In addition to the external review reports from MACPAQ discussed above, Shore provided the number of cases reviewed per physician, per year.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by Shore and analyzed the ACC-NCDR CathPCI data to determine the number of elective PCI cases performed by each interventionalist. Staff calculated the number of cases required to be reviewed for each interventionalist, per calendar year, and compared the results of the analysis to the number of PCI cases reviewed internally and externally, per physician, according to the hospital. MHCC staff observed that all physicians had 10 percent, or 10 cases reviewed, whichever was greater, for all reporting periods from January 2021 through December 2023.

The external review conducted by MACPAQ meets the requirements of 10.24.17.07D(5)(d) because it includes a review of angiographic images, medical test results, and patients' medical records. In addition to external review of individual interventionalists, Shore's internal review process includes the review of PCI cases for individual interventionalists. Based on staff's review of the number of cases the hospital reported were reviewed internally and through MACPAQ for

each interventionalist, Shore exceeded the requirement that at least 10 percent of PCI cases be reviewed for each individual interventionalist.

MHCC staff concludes that Shore complies with this standard.

10.24.17.07C(4)(f) and .07D(5)(e) The chief executive officer of the hospital shall certify upon request by Commission staff that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in this chapter, including those regarding internal peer review of cases and external review of cases.

Shore submitted an affidavit from Kenneth D. Kozel, MBA, FACHE, President and CEO, dated June 17, 2025, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist reviews.

Staff Analysis and Conclusions

MHCC staff reviewed the statement provided and concludes that Shore complies with this standard.

10.24.17.07C(4)(g) and.07D(5)(f) A hospital's application for a Certificate of Ongoing Performance shall demonstrate that it has taken appropriate action in response to each concern identified through its quality assurance processes.

(i) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.

(ii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

Shore provided a list of its quality assurance meetings, the attendees and a number of quality of care enhancements made to its PCI program through its internal quality assurance process. Enhancements to PCI at Shore since its prior certificate have included:

1. Balloon Pump – Shore cath lab staff developed a comprehensive training for ICU nursing staff caring for Balloon Pump patients. Additionally, the balloon pump representative came in and did even more education on trouble shooting the machine and educating about real time assistance via an 800 number.

2. Vascular Compression Devices – When the team on Shore's telemetry unit was uncomfortable with a change in vascular compression device, caused by a lack of receivables due to the Key Bridge collapse, Shore did an educational session with the telemetry unit to provide information on the new device. Additionally, a cath lab nurse attended the Telemetry Unit Skills day and provided more hands on education.

3. Intravascular Ultrasound (IVUS) – When Shore discovered that the IVUS in its newly remodeled room was not operating up to standard, a full upgrade of the IVUS was purchased and the installation is scheduled for March 4, 2026.

4. Door to EKG – After noticing a dip in Door-to-EKG efficiency in the ED, a meeting was held with the ED leaders from all 4 sites under the UMD Shore Health umbrella and a place was created to help. To coincide with this, an internal recognition program was developed where the ED staff who participate in a STEMI getting front end times receive a certificate and anatomical heart badge pin to display for meeting certain institutional goals.

5. Orientation – To resolve some rural health recruitment challenges, Shore created an Educational Track to ensure that experienced RNs from other hospital units (ICU, ED, Telemetry) but new to the cath lab, would have the opportunity for a comprehensive orientation to the unit.

6. Expansion of Cardiac Pre and Post daily census – The applicant converted a CNA FTE to an RN FTE with the intention of having coverage in the pre and post unit to accommodate more afternoon cases. This readily relieved a backlog of cases and decreased Shore's 'Order-to-Schedule' date from 18 days to less than 8 days.

Staff Analysis and Conclusion

Based on review of the meetings and the examples quality assurance activities provided, MHCC staff concludes that Shore complies with this standard.

<u>Patient Outcome Measures</u>

10.24.17.07C(5)

(a) An elective PCI program shall meet all performance standards established in statute or in State regulations.

(b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

(c) A hospital shall be subject to a focused review if it has a risk-adjusted mortality rate for non-STEMI PCI cases that exceeds an established benchmark beyond the 95 percent confidence interval calculated for the hospital's all-cause in-hospital risk-adjusted rate for non-STEMI PCI cases.

(i)The primary benchmark is the national median in-hospital risk-adjusted mortality rate for non-STEMI PCI cases, calculated from the CathPCI Registry data; and

(ii) If the statewide median risk-adjusted mortality rate for elective PCI cases is

obtained by the Commission within twelve months of the end of the reporting period, then the statewide median in-hospital risk-adjusted mortality rate for elective PCI cases will be used as a second benchmark.

10.24.17.07D(6)

(a) A primary PCI program shall meet all performance standards established in statute or in State regulations.

(b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

(c) A hospital with a risk-adjusted mortality rate for STEMI PCI cases that exceeds the established benchmark beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause in-hospital risk-adjusted mortality rate for STEMI PCI cases.

(i)The primary benchmark is the national median risk-adjusted in-hospital mortality rate for STEMI PCI cases; and

(ii) If the statewide median risk-adjusted in-hospital mortality rate for primary PCI cases is obtained by the Commission within twelve months of the end of a reporting period, then the statewide median risk-adjusted in-hospital mortality rate for primary PCI cases will be used as a second benchmark.

Shore's adjusted mortality rates for STEMI and non-STEMI PCI patients, by rolling 12-month reporting period, for reporting periods ending between 2022 Q1 and 2025 Q2, are shown in Table 9.

Table 9: Shore Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Periods and Performance on MHCC Standards for PCI Programs								
Reporting Period	STEMI				NON-STEMI			
	Hospital AMR	95% CI	National AMR	Meets MHCC Standard	Hospital AMR	95% CI	National AMR	Meets MHCC Standard
2021q2-2022q1	3.68	[0.45,12.67]	2.19	Yes	2.35	[0.64, 5.92]	2.25	Yes
2021q3-2022q2	4.46	[0.54,15.35]	2.18	Yes	2.90	[0.79, 7.28]	2.26	Yes
2021q4-2022q3	7.52	[1.57, 20.78]	2.11	Yes	2.69	[0.74, 6.77]	2.20	Yes
2022q1-2022q4	6.46	[0.79, 22.11]	2.00	Yes	3.08	[1.01, 7.04]	2.14	Yes
2022q2-2023q1	3.22	[0.39, 11.12]	1.89	Yes	1.84	[0.22, 6.53]	2.05	Yes
2022q3-2023q2	5.11	[1.07, 14.14]	1.89	Yes	1.36	[0.28, 3.90]	2.02	Yes
2022q4-2023q3	2.88	[0.36, 9.94]	1.91	Yes	1.54	[0.50, 3.53]	2.02	Yes
2023q1-2023q4	2.63	[0.32, 9.10]	1.88	Yes	1.38	[0.45, 3.17]	1.99	Yes
2023q2-2024q1	**							
2023q3-2024q2	0.00	[0.00, 7.76]	0.78	Yes	2.66	[0.99, 5.64]	1.99	Yes
2023q4-2024q3	2.97	[0.08, 15.36]	0.75	Yes	3.44	[0.95, 8.60]	1.97	Yes
2024q1-2024q4	2.84	[0.07, 14.59]	0.74	Yes	3.38	[0.41, 11.96]	1.95	Yes
2024q2-2025q1	2.69	[0.07, 14.15]	0.73	Yes	3.30	[0.68, 9.47]	1.94	Yes
2024q3-2025q2	2.83	[0.07, 14.83]	0.80	Yes	1.18	[0.03, 6.45]	1.92	Yes

Source: MHCC Staff compilation of results from the hospital's quarterly reports form the American College of Cardiology for the National Cardiovascular CathPCI Data Registry for PCI cases performed between April 2021 through June 2025.

** As noted above, there was a sinlge instance, in June of 2024, wherein Shore missed the registry's deadline. However, within a few weeks the missing data was submitted and both prior to and since that event no registry deadlines were missed. Also, that event occurred shortly after a new individual was hired to manage the data submission process.

Note: A hospital's AMR meets the MHCC standard as long as the hospital's 95% confidence interval (CI) includes the National AMR or indicates statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the National AMR for STEMI or non-STEMI cases, as applicable.

Staff Analysis and Conclusion

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for both STEMI and non-STEMI cases. The hospital's risk-adjusted mortality rate for both STEMI non-STEMI cases was not statistically significantly different than the national benchmark in any reporting period between January 2022 and December of 2024. MHCC staff concludes that Shore complies with this standard.

Physician Resources

10.24.17.07D(7)(a) Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24-month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight-quarter basis and report the results to the Commission on a quarterly basis.

Shore submitted the total number of primary and elective PCI cases that were performed at Shore for four interventionalists (Drs. Sardi, Etherton, Pena-Sing, and Patel), by quarter, from 2022 through 2024. Each physician signed and dated an affidavit affirming under penalties of perjury that the information provided is true and correct to the best of their knowledge.

Staff Analysis and Conclusion

MHCC staff reviewed the reported PCI volume for the interventionalists at Shore and the ACC-NCDR CathPCI data submitted by the hospital. Staff determined that current interventionalists performed, on average, at least 50 PCI procedures on a rolling eight-quarter basis between January 2022 and December 2024. MHCC staff concludes that Shore complies with this standard.

10.24.17.07D(7)(b) For each physician who performs primary PCI at a hospital without on-site cardiac surgery and does not perform a minimum of 50 PCI procedures averaged annually over a 24-month period, for reasons other than a leave of absence, the hospital shall arrange for an external review of all the physician's cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to the Commission. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to Shore. While the hospital does not have on-site cardiac surgery, each physician performing primary PCI performed 50 PCI procedures annually when averaged over a 24-month period.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital without on-site cardiac surgery and who does not perform ae minimum of 50 PCI procedures averaged annually over a 24-month period, and who took a leave of absence of less than one year during the 24-month period measured, may resume the provision of primary PCI provided that:

(i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;

(ii) The physician continues to satisfy the hospital's credentialing requirements; and

(iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.

Shore submitted information on the volume of primary and elective PCI cases at Shore and other hospitals, by physician and quarter, for January 2022 through December 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the reported physician volumes for the interventionalists who performed primary PCI services at Shore from January 2022 through December 2024 and determined that each interventionalist performed at least 50 PCI procedures annually on average. In addition, MHCC staff analyzed the ACC-NCDR CathPCI data for January 2022 through December 2024 to confirm each interventionalist performed at least 50 PCI procedures annually on average. MHCC staff determined that Shore complies with this standard.

10.24.17.07D(7)(e) Each physician shall be board-certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or who completed training before 1998 and did not seek board certification before 2003 or physicians who completed a fellowship in interventional cardiology less than three years ago.

10.24.17.07D(7)(f) Each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

Shore submitted a signed letter, dated June 12, 2025, stating that the two providers then performing PCI at Shore, as well as the PCI providers who had left the facility, but who had performed PCI at Shore since receipt of the Certificate of Ongoing Performance, were Board Certified in Cardiovascular Medicine as well as lnterventional Cardiology through the American Board of Internal Medicine.

Staff Analysis and Conclusion

MHCC staff reviewed the letter provided and concludes that Shore complies with this standard.

10.24.17.07D(7)(g) An interventionalist shall complete a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology during every two years of practice.

With its application, Shore submitted affidavits signed by all of the inteventional cardiologists then performing PCI at the hospital, stating that they had completed more than 30 hours of interventional cardiology continuing medical education units within the prior two years.

Staff Analysis and Conclusion

MHCC staff reviewed the affidavits provided and concludes that Shore complies with this standard.

10.24.17.07D (7)(h) Each physician who performs primary PCI agrees to participate in an on-call schedule.

Initially, Shoresubmitted a letter, date June 12, 2025, from Dr. Jeffrey Etherton, Medical Director of the CCL at Shore, stating that Shore has 24 hour coverage, 7 days a week provided by Certified Interventional Cardiologists, himself and Gabriel Sardi, MD. Subsequently, via email on February 12, 2026, Shore stated that is newest interventionalist, Dr. Bishesh Shrestha, who completed his orientation in October 2025, also pariticipates in the on-call schedule and provided a copy of the schedule for the period from November 2025 through February 2026.

Staff Analysis and Conclusion

MHCC staff reviewed the above-referenced schedule and observed that all three of the hospital's current interventionalists are regularly included. Shore complies with the standard.

Volume

10.24.17.07C(7)(a) The target volume for an existing program with both primary and non-primary PCI services is 200 cases annually.

10.24.17.07C(7)(b) A PCI program that provides both primary and elective PCI that fails to reach the target volume of 200 cases annually may be subject to a focused review.

Shoreprovided a table identifying the number of PCI cases for CY 2022 through CY2024. This information is shown in Table 10.

Table 10: Shore PCI Case Volume as Reported by Shore

Year	Total PCI Cases
CY 2022	277
CY 2023	311
CY 2024	266

Source: Shore PCI COP application, response to Question 25

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the volume of PCI cases performed at Shore from CY 2022 through CY 2024. As shown in Table 11 below, the elective PCI case volume always exceeded the regulatory standard of 200 cases per year. MHCC staff concludes that Shore complies with this standard.

Table 11: Shore PCI Case Volume per NCDR CathPCI Patient Level Data

Year	Total PCI Cases
CY 2022	214
CY 2023	248
CY 2024	222

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2022 – CY 2024.

10.24.17.07D(8)(a) For primary PCI cases, if a program falls below 36 cases for rural PCI providers and 49 cases for non-rural providers, a focused review will be triggered.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the volume of primary PCI cases performed at Shore from CY 2022 through CY 2024. As shown in Table 12, between CY 2022 and CY 2024, the primary PCI volume ranged from 49 to 74 cases each year, annually. Because Shore met or exceeded the 49-case threshold, staff concludes that Shore complies with this standard and no focused review is required.

Table 12: Shore Primary PCI Volume

Year	Primary PCI Volume
CY 2022	64
CY 2023	74
CY 2024	49

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2022 – CY 2024.

10.24.17.07D(8)(b) The target volume for each physician who performs primary PCI is 11 or more primary PCI cases annually.

Staff Analysis and Conclusion

MHCC staff reviewed the patient level Cath-PCI data for the years CY 2022 through CY 2024 and observed that during that timeframe, each provider who performed PCI at Shore completed at least 11 primary PCI cases per year. Staff concludes that complies with this standard.

<u>Patient Selection</u>

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for appropriate patients, as described in Expert Guidelines for hospitals with and without cardiac surgery on-site.

10.24.17.07D(9) A hospital shall commit to only providing primary PCI services 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 concludes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

(c) Patients for whom primary PCI services were not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.

(d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) reasonably concludes that transfer to a tertiary institution may be harmful to the patient.

Shore stated that during the 3-year period from July 1, 2022 through May 31, 2025, only a single patient received thrombolytic therapy in lieu of PCI due to an extended downtime in the CCL during an internal disaster. The patient was subsequently transferred to UMMC where the culprit vessel was patent, and the patient had successful PCI before being discharged to home. Additionally, Shore stated that MACPAQ had not identified any cases of rarely appropriate elective PCI since the hospital received its last Certificate of Ongoing Performance for PCI.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for the period from CY 2022 through June of 2025 and found that zero PCI patients received thrombolytic therapy at Shore. Staff also notes that the ACC-NCDR CathPCI reports indicate that no PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate. Furthermore, MHCC staff reviewed the MACPAQ reports and agree that no cases were found to be rarely appropriate. Based on MHCC's analysis of the ACC-NCDR CathPCI data, the MACPAQ reports, and the ACC-NCDR CathPCI reports, MHCC staff concludes that Shore complies with the standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff recommends that the Commission find that Shore meets all the requirements for a Certificate of Ongoing Performance and issue a Certificate of Ongoing Performance that permits Shore to continue providing primary and elective percutaneous coronary intervention services for four years.