

**IN THE MATTER OF
TIDALHEALTH
PENINSULA REGIONAL, INC**

*** BEFORE THE
* MARYLAND
* HEALTH CARE
* COMMISSION**

Docket No.: 24-22-CP058

**STAFF REPORT AND RECOMMENDATION
CERTIFICATE OF ONGOING PERFORMANCE
FOR PRIMARY & ELECTIVE PERCUTANEOUS CORONARY INTERVENTION
SERVICES**

March 20, 2025

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 these hospitals from the requirement for co-location of 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 development of 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 Cardiac Surgery and PCI Services chapter (Cardiac Services Chapter) of the State Health Plan for Facilities and Services (State Health Plan) 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 (non-primary) PCI services, for a time specified by the Commission 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 shall be conducted. The regulations authorize Commission staff to conduct a focused review based on reported patient safety concerns, aberrations in data, 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 the deficiencies cited or 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

TidalHealth Peninsula Regional, Inc.

TidalHealth Peninsula Regional, Inc. (Peninsula Regional), is a 275-bed acute care general hospital located in Salisbury, Maryland (Wicomico County). It is part of the TidalHealth System. Peninsula Regional has a cardiac surgery program on-site and currently provides both primary and elective PCI services.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. Peninsula Regional is in the Eastern/Lower Shore health planning region. This region includes Dorchester, Somerset, Wicomico, and Worcester Counties. Only two hospitals in this health planning region provide primary and elective PCI services. One of the two hospitals, Peninsula Regional, also provides cardiac surgery services.

C. Staff Recommendation

MHCC staff recommends that the Commission approve Peninsula Regional's application for a Certificate of Ongoing Performance to continue providing primary and elective PCI services with two conditions. A description of Peninsula Regional's documentation and MHCC staff's analysis of this information follows.

II. PRODEDURAL HISTORY

On June 2, 2022, MHCC notified Peninsula Regional of a focused review that was required by COMAR 10.24.17.07D(6)(c), due to the hospital's worse than average performance on its adjusted mortality rates (AMR) for the 12-month period ending on March 30, 2021. MHCC staff met with staff for Peninsula Regional to discuss the planned focused review on August 18, 2022.

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).

MHCC staff requested additional information from Peninsula Regional during the meeting which was provided on September 19, 2022. The focused review by the contractor hired by MHCC began in early 2023, with the contractor directly requesting records. MHCC provided the findings of the focused review to Peninsula Regional on April 26, 2024, and the hospital accepted these findings on May 14, 2024.

Peninsula Regional filed its application for a Certificate of Ongoing Performance for primary and elective PCI services on June 7, 2024, in accordance with the review schedule published by the Commission. MHCC staff reviewed the application and requested additional information on October 21, 2024, January 23, 2025, and February 24, 2025. Additional information was provided by Peninsula Regional on November 26, 2024, February 11, 2025, March 3, 2025, and March 6, 2025. Staff also spoke with staff from Peninsula Regional by phone on March 12, 2025 to obtain some additional information.

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.

Peninsula Regional participates in the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI and submits duplicate data to MHCC according to the schedule provided. The hospital also takes part in the "Get with the Guidelines" registry.

On March 18, 2024, Peninsula Regional received notification from MHCC of data deficiencies that required the resubmission of detailed line reports for Q2 2022, and Q1 and Q2 2023 to address the issue. MHCC staff met with hospital staff on March 27, 2024, and discussed the deficiencies. With its application, Peninsula Regional submitted documentation of correspondence with MHCC staff that includes details of the data deficiencies and steps taken to correct it. Additionally, the hospital reported hiring an additional 0.5 full-time equivalent (FTE) to help submit all data in a timely manner and emphasized to physicians the importance of data documentation.

Because key metrics, including AMRs, were unable to be calculated due to these data deficiencies, MHCC staff requested that Peninsula Regional provide the number of mortalities that took place within 30 days of a PCI, for ST-segment elevation myocardial infarction (STEMI) patients, non-STEMI patients, and STEMI patients with arrest or cardiogenic shock, for each of the three rolling 4-quarter periods, as shown in Table 1.

Table 1. Peninsula Regional's Reported STEMI and Non-STEMI Deaths Within 30 Days of PCI

| Category | Rolling 4-Quarters | | |
|---|--------------------|---------|---------|
| | Q2 2022 | Q1 2023 | Q2 2023 |
| STEMI Deaths | 1 | 2 | 5 |
| Non-STEMI Deaths | 2 | 3 | 3 |
| STEMI Deaths with Arrest or Shock* | 1 | 1 | 4 |

Source: Peninsula Regional's supplemental information for the hospital's application for a Certificate of Ongoing Performance (March 3, 2025).

* Numbers in this category are also included in the number of STEMI Deaths reported.

Staff Analysis and Conclusion

While Peninsula Regional submitted data to the ACC-NCDR CathPCI Registry and to MHCC in accordance with the established schedule, the hospital's data submissions lacked required information in Q2 2022, Q1 2023, and Q2 2023. As a result, for three reporting periods in the last five years the ACC could not calculate key metrics for the hospital, including AMRs, due to the missing information. The hospital worked with MHCC and corrected its data submissions to the ACC-NCDR, achieving the ideal level of completeness expected for its submissions from Q3 2023 onward. Peninsula Regional also hired and dedicated an additional 0.5 FTE to ensure timely data submission.

Additionally, MHCC staff reviewed the data Peninsula Regional submitted, regarding the number of patient deaths that occurred within 30 days of a PCI. For STEMI patients without cardiac arrest or shock, no deaths occurred in Q2 2022, and only one death occurred in both Q1 and Q2 2023. Because Peninsula Regional has corrected its data issues and the number of deaths of STEMI patients is consistent with other programs of similar size that are performing similar to the national benchmark for mortality used by MHCC, the hospital is likely providing good quality care, similar to other hospitals.

MHCC staff recommends that the Commission find the hospital in compliance with this 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.

Peninsula Regional has three CCLs on-site. The hospital reported experiencing a complete loss of computer access on December 29, 2023, from 10:04am to 1:06pm, which affected all CCLs. During this time, the hospital was on a bypass for CCL and trauma cases. This event is documented in the Maryland County Hospital Alerts Tracking System (CHATS) for hospitals that exists for tracking Emergency Department (ED) bypass and diversions. Peninsula Regional submitted documentation of this notification with its application. During this period, the hospital stated that

no cases were diverted or delayed, and clinical services remained unaffected. Additionally, the hospital reported that no downtime occurred for repairs or maintenance of the CCLs beyond routine maintenance from calendar year (CY) 2020 through CY 2024. Table 2 shows the dates, duration, location, and reason for CCL downtime experienced during the review period.

Table 2. Peninsula Regional’s CCL Downtime by Location, Date, and Duration, January 2020 – March 2024

| Room | Date | Start Time | Duration (Hours) | Description |
|-------|------------|------------|------------------|----------------------------------|
| CCL 4 | 3/3/2020 | 10:00 AM | 5.00 hrs | Preventive maintenance |
| CCL 3 | 5/7/2020 | 9:15 AM | 5.00 hrs | Preventive maintenance |
| CCL 4 | 9/24/2020 | 3:47 PM | 8.00 hrs | Preventive maintenance |
| CCL 3 | 11/11/2020 | 9:45 AM | 5.25 hrs | Preventive maintenance |
| CCL 1 | 1/13/2021 | 10:00 AM | 4.50 hrs | Preventive maintenance |
| CCL 4 | 3/11/2021 | 11:00 AM | 5.00 hrs | Preventive maintenance |
| CCL 3 | 5/3/2021 | 1:38 PM | 4.37 hrs | Preventive maintenance |
| CCL 1 | 8/5/2021 | 11:14 AM | 3.70 hrs | Preventive maintenance |
| CCL 4 | 9/17/2021 | 12:00 PM | 3.00 hrs | Preventive maintenance |
| CCL 3 | 11/2/2021 | 10:30 AM | 4.50 hrs | Preventive maintenance |
| CCL 1 | 2/16/2022 | 10:30 AM | 4.50 hrs | Preventive maintenance |
| CCL 4 | 3/11/2022 | 9:30 AM | 6.50 hrs | Preventive maintenance |
| CCL 3 | 5/12/2022 | 8:33 AM | 4.05 hrs | Preventive maintenance |
| CCL 1 | 8/4/2022 | 9:30 AM | 8.50 hrs | Preventive maintenance |
| CCL 4 | 9/29/2022 | 10:00 AM | 5.50 hrs | Preventive maintenance |
| CCL 3 | 11/15/2022 | 8:45 AM | 4.25 hrs | Preventive maintenance |
| CCL 1 | 2/7/2023 | 8:54 AM | 6.20 hrs | Preventive maintenance |
| CCL 4 | 3/26/2023 | 1:52 PM | 4.00 hrs | Preventive maintenance |
| CCL 3 | 5/24/2023 | 9:46 AM | 5.00 hrs | Preventive maintenance |
| CCL 1 | 8/18/2023 | 5:00 PM | 4.50 hrs | Preventive maintenance |
| CCL 4 | 9/8/2023 | 8:18 AM | 7.00 hrs | Preventive maintenance |
| CCL 3 | 11/8/2023 | 12:00 PM | 8.50 hrs | Preventive maintenance |
| ALL | 12/29/2023 | 10:04 AM | 3.02 hrs | Complete loss of computer access |
| CCL 1 | 2/14/2024 | 12:15 PM | 8.25 hrs | Preventive maintenance |
| CCL 4 | 3/26/2024 | 12:09 PM | 6.00 hrs | Preventive maintenance |
| CCL 3 | 5/24/2024 | 10:45 AM | 9.10 hrs | Preventive maintenance |
| CCL 1 | 8/7/2024 | 10:00 AM | 6.00 hrs | Preventive maintenance |
| CCL 4 | 9/30/2024 | 7:46 AM | 8.00 hrs | Preventive maintenance |
| CCL 3 | 11/25/2024 | 10:00 AM | 6.00 hrs | Preventive maintenance |

Source: Peninsula Regional’s application for a Certificate of Ongoing Performance 2024, p. 3, and supplemental information received on February 11, 2025.

Staff Analysis and Conclusion

MHCC staff reviewed the information on CCL room closures submitted by Peninsula Regional for CY 2020 through CY 2024 and determined that it is unlikely that all three rooms were unavailable simultaneously, except for one incident. On December 29, 2023, the hospital experienced a complete loss of power which affected all CCLs and PCI services for a three-hour period. Because there were no rooms with power available to act as a backup for PCI services, Peninsula Regional’s request to be put on bypass with CHATS was determined to be appropriate.

Otherwise, the hospital’s use of three CCLs ensured that a CCL was available for primary PCI services 24 hours per day, 7 days per week, during the review period.

MHCC staff determines that Peninsula Regional complies with this 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.

Peninsula Regional provided a signed statement from President and chief executive officer (CEO), Steven Leonard, Ph.D., MBA, FACHE, committing the hospital to provide primary PCI services as soon as possible, not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital also committed to track the door-to-balloon (DTB) times for transfer cases and evaluate areas for improvement.

Peninsula Regional provided the number and percentage of non-transfer primary PCI patients with a DTB time less than 90 minutes, for the period between January 2020 through March 2024, as shown in Table 3a. During this period, the hospital reported that between 80 and 100 percent of cases met this standard, indicating that the DTB standard was met for at least 75 percent of primary PCI patients in all quarters.

Table 3a. Peninsula Regional’s Reported Door-to-Balloon Times for Non-Transfer Primary PCI Cases by Quarter, January 2020 – March 2024

| Quarter Ending | Number of Non-Transfer Primary PCI Patients | Number of Non-Transfer Patients with DTB Time < 90 Minutes | |
|----------------|---|--|------------|
| | | Number | Percentage |
| CY 2020 Q1 | 18 | 18 | 100.0% |
| CY 2020 Q2 | 22 | 20 | 91.0% |
| CY 2020 Q3 | 33 | 31 | 94.0% |
| CY 2020 Q4 | 29 | 26 | 90.0% |
| CY 2021 Q1 | 19 | 19 | 100.0% |
| CY 2021 Q2 | 26 | 26 | 100.0% |
| CY 2021 Q3 | 22 | 22 | 100.0% |
| CY 2021 Q4 | 22 | 21 | 95.0% |
| CY 2022 Q1 | 20 | 19 | 95.0% |
| CY 2022 Q2 | 15 | 12 | 80.0% |
| CY 2022 Q3 | 20 | 16 | 80.0% |
| CY 2022 Q4 | 25 | 25 | 100.0% |
| CY 2023 Q1 | 15 | 15 | 100.0% |
| CY 2023 Q2 | 31 | 28 | 90.0% |
| CY 2023 Q3 | 26 | 24 | 92.0% |
| CY 2023 Q4 | 28 | 27 | 96.0% |
| CY 2024 Q1 | 22 | 20 | 90.9% |

Source: Peninsula Regional’s application for a Certificate of Ongoing Performance 2024, p.4-5.

Peninsula Regional also provided the number and percentage of transfer patients who met the DTB time of 120 minutes or less for each quarter, between January 2019 and March 2024, as shown in Table 3b. During this period, the hospital reported that between zero and 75 percent of

transfer cases met the DTB time of 120 minutes or less, which is consistent with the guidelines of the ACC and American Heart Association (AHA).

Table 3b. Peninsula Regional’s Reported Door-to-Balloon Times for Primary PCI Transfer Cases by Quarter, January 2019 – March 2024

| Quarter Ending | Number of Transfer Primary PCI Patients | Number of Transfer Patients with DTB Time < 120 Minutes | |
|----------------|---|---|------------|
| | | Number | Percentage |
| CY 2019 Q1 | 7 | 3 | 43.0% |
| CY 2019 Q2 | 3 | 1 | 33.0% |
| CY 2019 Q3 | 5 | 0 | 0.0% |
| CY 2019 Q4 | 4 | 2 | 50.0% |
| CY 2020 Q1 | 5 | 0 | 0.0% |
| CY 2020 Q2 | 2 | 0 | 0.0% |
| CY 2020 Q3 | 8 | 1 | 13.0% |
| CY 2020 Q4 | 8 | 5 | 63.0% |
| CY 2021 Q1 | 8 | 3 | 37.5% |
| CY 2021 Q2 | 6 | 3 | 50.0% |
| CY 2021 Q3 | 6 | 2 | 33.0% |
| CY 2021 Q4 | 7 | 4 | 57.0% |
| CY 2022 Q1 | 4 | 2 | 50.0% |
| CY 2022 Q2 | 5 | 1 | 20.0% |
| CY 2022 Q3 | 7 | 1 | 15.0% |
| CY 2022 Q4 | 10 | 3 | 30.0% |
| CY 2023 Q1 | 4 | 1 | 25.0% |
| CY 2023 Q2 | 5 | 2 | 40.0% |
| CY 2023 Q3 | 9 | 6 | 67.0% |
| CY 2023 Q4 | 4 | 3 | 75.0% |
| CY 2024 Q1 | 5 | 1 | 20.0% |

Source: Peninsula Regional’s application for a Certificate of Ongoing Performance 2024, p. 6-7.

For quarters where Peninsula Regional did not meet the goal of 120 minutes or less for 75 percent of transfer cases, the hospital reported that each case that did not meet a DTB time of 120 minutes or less, was thoroughly reviewed. The hospital also provided an explanation of the factors that contributed to delays and potential opportunities for improvement. Factors reported to contribute to extended DTB times for primary PCI transfer cases included geographic and travel challenges; the Eastern Shore’s rural nature and seasonal traffic significantly impacts the hospital’s ability to meet transfer time goals. Additionally, the hospital reports that the local EDs in the hospital’s service area are taking longer to identify and diagnose STEMI patients prior to transfer, and at times, there are limited emergency medical services (EMS) available for transport. For example, Somerset County only has one Advanced Life Support ambulance to utilize for transfer of STEMI patients.

Peninsula Regional reported remaining committed to working with EMS providers and EDs at sending facilities to improve DTB times to continuously improve transfer times. As part of the Maryland Institute for Emergency Medical Services and Systems’ (MIEMSS) Cardiac Interventional Center (CIC) designation, a dedicated single-access line was established to receive acute cardiac care patient alerts from surrounding hospitals. This line is staffed 24 hours a day, seven day per week, by either a Nursing Supervisor or Bed Coordinator. The hospital briefed the

Division of Cardiology on the directive to use this one-call number. The hospital also provided a copy of its transfer improvement process and its policy regarding what to do when multiple STEMI patients present at the hospital simultaneously.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases for the period from CY 2020 to CY 2023, as shown in Table 4a. Staff found that Peninsula Regional met the DTB standard for non-transfer cases for all quarters between CY 2020 and CY 2023. During this period, between 76.5 and 100 percent of non-transfer primary PCI cases met the DTB standard of 90 minutes or less.

Table 4a. Peninsula Regional’s Compliance with Non-Transfer Primary PCI DTB Benchmark by Quarter, CY 2020 – CY 2023

| Quarter | Total Primary PCI Volume | Cases with DTB <= 90 Minutes | Percent of Cases with DTB <= 90 Minutes |
|------------|--------------------------|------------------------------|---|
| CY 2020 Q1 | 17 | 13 | 76.5% |
| CY 2020 Q2 | 16 | 15 | 93.8% |
| CY 2020 Q3 | 29 | 25 | 86.2% |
| CY 2020 Q4 | 25 | 21 | 84.0% |
| CY 2021 Q1 | 23 | 18 | 78.3% |
| CY 2021 Q2 | 27 | 22 | 81.5% |
| CY 2021 Q3 | 22 | 20 | 90.9% |
| CY 2021 Q4 | 22 | 18 | 81.8% |
| CY 2022 Q1 | 22 | 20 | 90.9% |
| CY 2022 Q2 | 14 | 11 | 78.6% |
| CY 2022 Q3 | 12 | 10 | 83.3% |
| CY 2022 Q4 | 24 | 21 | 87.5% |
| CY 2023 Q1 | 5 | 5 | 100.0% |
| CY 2023 Q2 | 26 | 21 | 80.8% |
| CY 2023 Q3 | 17 | 15 | 88.2% |
| CY 2023 Q4 | 18 | 17 | 94.4% |

Source: MHCC staff analysis of ACC-NCDR CathPCI data for CY 2020 – CY 2023.

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. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers the hospital’s performance over rolling eight-quarter periods, as shown in Table 4b. Over rolling eight-quarter periods from CY 2020 to CY 2023, between 83 and 91.7 percent of non-transfer primary PCI cases met the DTB time standard.

Table 4b. Peninsula Regional’s Non-Transfer Primary PCI Case Volume and Percentage of Cases with DTB Less Than or Equal to 90 Minutes, by Time Period

| Time Period | Quarter | | | Rolling Eight-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 |
| CY 2018 Q1 | 27 | 23 | 85.2% | | | |
| CY 2018 Q2 | 28 | 23 | 82.1% | | | |
| CY 2018 Q3 | 25 | 23 | 92.0% | | | |
| CY 2018 Q4 | 31 | 31 | 100.0% | | | |
| CY 2019 Q1 | 24 | 22 | 91.7% | | | |
| CY 2019 Q2 | 19 | 17 | 89.5% | | | |
| CY 2019 Q3 | 28 | 25 | 89.3% | | | |
| CY 2019 Q4 | 20 | 19 | 95.0% | | | |
| CY 2020 Q1 | 17 | 13 | 76.5% | 192 | 173 | 90.1% |
| CY 2020 Q2 | 16 | 15 | 93.8% | 180 | 165 | 91.7% |
| CY 2020 Q3 | 29 | 25 | 86.2% | 184 | 167 | 90.8% |
| CY 2020 Q4 | 25 | 21 | 84.0% | 178 | 157 | 88.2% |
| CY 2021 Q1 | 23 | 18 | 78.3% | 177 | 153 | 86.4% |
| CY 2021 Q2 | 27 | 22 | 81.5% | 185 | 158 | 85.4% |
| CY 2021 Q3 | 22 | 20 | 90.9% | 179 | 153 | 85.5% |
| CY 2021 Q4 | 22 | 18 | 81.8% | 181 | 152 | 84.0% |
| CY 2022 Q1 | 22 | 20 | 90.9% | 186 | 159 | 85.5% |
| CY 2022 Q2 | 14 | 11 | 78.6% | 184 | 155 | 84.2% |
| CY 2022 Q3 | 12 | 10 | 83.3% | 167 | 140 | 83.8% |
| CY 2022 Q4 | 24 | 21 | 87.5% | 169 | 140 | 82.8% |
| CY 2023 Q1 | 5 | 5 | 100.0% | 148 | 127 | 85.8% |
| CY 2023 Q2 | 26 | 21 | 80.8% | 147 | 126 | 85.7% |
| CY 2023 Q3 | 17 | 15 | 88.2% | 142 | 121 | 85.2% |
| CY 2023 Q4 | 18 | 17 | 94.4% | 138 | 120 | 87.0% |

Source: MHCC staff’s analysis of ACC-NCDR CathPCI data for CY 2018 – CY 2023.

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

For the period from CY 2019 through CY 2023, MHCC staff also reviewed the information reported by Peninsula Regional regarding the number and percentage of PCI transfer cases with a DTB time of 120 minutes or less. As shown in Table 3b, only one of 21 quarters had 75 percent of transfer PCI cases with a DTB time of 120 minutes or less. The percentage of cases achieving this DTB time ranged from zero to 75 percent in each quarter. This data is consistent with MHCC staff’s analysis of the ACC-NCDR CathPCI data, which is shown in Table 4c. The percentage of transfer cases achieving a DTB time of 120 minutes or less in each quarter ranged from zero to 100 percent.

Table 4c. Peninsula Regional's Compliance with Primary PCI Transfer DTB Benchmark by Quarter, CY 2019 – CY 2023

| Quarter | Total Primary PCI Volume | Cases with DTB <= 120 Minutes | Percent of Cases with DTB <= 120 Minutes |
|------------|--------------------------|-------------------------------|--|
| CY 2019 Q1 | 4 | 2 | 50.0% |
| CY 2019 Q2 | 8 | 3 | 37.5% |
| CY 2019 Q3 | 4 | 0 | 0.0% |
| CY 2019 Q4 | 2 | 1 | 50.0% |
| CY 2020 Q1 | 5 | 1 | 20.0% |
| CY 2020 Q2 | 4 | 0 | 0.0% |
| CY 2020 Q3 | 8 | 1 | 12.5% |
| CY 2020 Q4 | 4 | 2 | 50.0% |
| CY 2021 Q1 | 5 | 0 | 0.0% |
| CY 2021 Q2 | 3 | 2 | 66.7% |
| CY 2021 Q3 | 3 | 0 | 0.0% |
| CY 2021 Q4 | 6 | 4 | 66.7% |
| CY 2022 Q1 | 4 | 1 | 25.0% |
| CY 2022 Q2 | 4 | 1 | 25.0% |
| CY 2022 Q3 | 2 | 2 | 100.0% |
| CY 2022 Q4 | 8 | 5 | 62.5% |
| CY 2023 Q1 | 2 | 1 | 50.0% |
| CY 2023 Q2 | 4 | 0 | 0.0% |
| CY 2023 Q3 | 9 | 5 | 55.6% |
| CY 2023 Q4 | 2 | 1 | 50.0% |

Source: MHCC staff's analysis of ACC-NCDR CathPCI data for CY 2019 – CY 2023.

Although hospitals strive to achieve DTB times of 120 minutes or less in primary PCI transfer cases, many factors impacting the DTB times are outside of the hospital's control. For this reason, there is not the requirement for a certain percentage of cases to achieve a benchmark of 120 minutes or less each quarter. Instead, a hospital is required to track the DTB times for transfer cases and evaluate areas for improvement. Peninsula Regional provided descriptions and documentation of its efforts to improve DTB times for transfer cases.

MHCC staff concludes that Peninsula Regional complies with this standard.

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.

Peninsula Regional provided the number of physicians, nurses, and technicians available to provide cardiac catheterization services to acute myocardial infarction (AMI) patients one week prior to the application being submitted, as shown in Table 5a. Peninsula Regional states that the staffing levels reported are consistent with the hospital's typical staffing levels for the CCL.

Table 5a. Total Number of CCL Physician, Nursing, and Technical Staff

| Staff Category | Number/FTEs | Cross Training (S/C/M*) |
|----------------|-------------|-------------------------|
| Physician | 9.00 | |
| Nurse | 8.18 | S/C/M |
| Technician | 7.93 | S/C/M |

Source: Peninsula Regional's application for a Certificate of Ongoing Performance 2024, p. 9.

*Scrub (S), Circulate (C), Monitor (M)

Staff Analysis and Conclusion

MHCC staff compared Peninsula Regional’s staffing levels to information reported by three other existing PCI programs with similar case volumes. A comparison of volume and staffing levels for Peninsula Regional, Sinai Hospital of Baltimore (Sinai), University of Maryland Medical Center (UMMC), and St. Agnes Hospital (St. Agnes) is shown in Table 5b. Compared to these three PCI programs, Peninsula Regional had a higher volume of PCI cases in 2023, but its staffing was not higher across all categories. Peninsula Regional reported nine interventionalists, which is two more than both Sinai and UMMC, and five more than St. Agnes. Consistent with this pattern, Peninsula Regional also has approximately one more technician FTE devoted to working with primary PCI patients than Sinai and UMMC, while the hospital has three more FTEs for technicians than St. Agnes. Peninsula Regional also has about the same number of nurse FTEs as St. Agnes, 1.8 more nurse FTEs than Sinai, and 4.8 fewer nurse FTEs than UMMC.

Table 5b. CCL Staffing for Peninsula Regional and Other Select PCI Programs

| Program and Year Reported | Total PCI Volume 2023 | Number of Interventionalists or FTEs | Nurse FTEs | Technicians FTEs |
|---------------------------|-----------------------|--------------------------------------|------------|------------------|
| Peninsula Regional | 509 | 9.00 | 8.18 | 7.93 |
| Sinai | 438 | 7.00 | 6.40 | 7.00 |
| UMMC | 485 | 7.00 | 13.0 | 7.50 |
| St. Agnes | 429 | 4.00 | 8.30 | 5.00 |

Source: Peninsula Regional’s application for a Certificate of Ongoing Performance 2024, p. 9; Sinai’s application for a Certificate of Ongoing Performance 2024, p. 8; UMMS’ application for a Certificate of Ongoing Performance 2024, p. 12-13; and St. Agnes’ application for a Certificate of Ongoing Performance 2024, p. 6.

Based on the comparative information available, MHCC staff concludes that the hospital has adequate physician, nursing and technical staff available to provide PCI services. Staff concludes that Peninsula Regional complies with this 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.

Peninsula Regional provided a written commitment, signed by President and CEO, Steven Leonard, Ph.D., MBA, FACHE, stating that the hospital will provide primary PCI services per the requirements established by MHCC in the Cardiac Services Chapter.

Staff Analysis and Conclusion

MHCC staff reviewed the letter of commitment provided and concludes that Peninsula Regional meets this 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.

Peninsula Regional reported that the hospital allocates a total of 1.37 FTEs dedicated to data management, reporting, and quality, which includes 0.5 FTE dedicated to data collection. The current positions that are accountable for these activities are the Director of the Cardiac

Catheterization and Electrophysiology Labs (0.3 FTE) and an Administrative Data Assistant (1.07 FTEs).

Staff Analysis and Conclusion

MHCC staff concludes that Peninsula Regional 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.

Peninsula Regional reported that Dr. Joseph Cinderella is the physician director of Interventional Cardiology Services. He has been under contract for many years and is responsible for defining and implementing credentialing criteria for the CCL and overall primary PCI program management including the responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges. Peninsula Regional provided a copy of his job description and goals for 2023 and 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the description of job duties for the physician director of Interventional Cardiology Services and concludes that Peninsula Regional 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.

Peninsula Regional submitted a list of competency and education requirements for the CCL, and the Critical Care and Cardiac Telemetry Units from FY 2020 to FY 2024. The hospital explained that all disciplines involved with PCI patients must complete three educational modules annually; these are tracked through NetLearning. Additionally, individual departments track specific unit-based competencies.

Staff Analysis and Conclusion

MHCC staff notes that the continuing medical education programming for staff includes appropriate topics. Staff concludes that Peninsula Regional is in compliance 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 PCL.

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to Peninsula Regional because the hospital provides cardiac surgery services on-site.

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.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Peninsula Regional, as the hospital provides both cardiac surgery services on-site and primary and elective PCI services.

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.

Peninsula Regional provided copies of attendance records for weekly interventional case review meetings for the period from CY 2019 through May 2024. Learning objectives are reported to include developing a consensus regarding patient treatment or referral to improve clinical outcomes, identifying appropriate diagnostic testing or other consultations required to determine appropriate treatment options and clinical course for the patient, determining and evaluating risk variables for each patient, identifying indications for surgical interventions, and comparing quality measures and outcomes to State expectations and registry benchmarks. These meetings are attended by interventionalists and other physicians who care for primary PCI patients; however, nurses and technicians do not attend these weekly meetings. Peninsula Regional stated that these meetings are for providers to reach a consensus on treatment plans, surgical eligibility, and/or unique clinical presentations. The hospital explained that rather than taking part in these meetings, its nurses and technicians who care for primary PCI patients take part in the monthly AMI meetings, which include interventional case review presentations at least quarterly.

Staff Analysis and Conclusion

The documentation submitted by Peninsula Regional includes dates and attendance records for weekly interventional case review meetings held between CY 2019 and May 2024. Documentation was provided for 51 meetings in CY 2019, 49 meetings in CY 2020, 50 meetings in CY 2021, 51 meetings in CY 2022, 51 meetings in CY 2023, and 13 meetings from January through May 2024. These meetings are attended by interventionalists and other physicians who care for PCI patients. Because nurses and technicians do not attend these meetings, MHCC staff also reviewed minutes and attendance lists for other monthly meetings for staff in the CCL. While CCL nurses and technicians attend these meetings routinely, staff determined that primary PCI

cases were reviewed in only four AMI meetings in CY 2021, three in CY 2022, two in CY 2023, and four meetings in CY 2024. MHCC's standard requires that interventional case review of primary PCI cases be completed at least six times each year. When asked to explain the discrepancy, Peninsula Regional stated that due to the volume of cases and the time required for preparation, interventional case reviews are held quarterly. The hospital also reported that the Joint Commission requires these reviews to take place at least quarterly, and it was an oversight by Peninsula Regional to not comply with MHCC's standard.

Because the hospital held too few meetings for PCI case reviews that included nurses, and technicians who care for primary PCI patients, MHCC staff recommends that the Commission find that Peninsula Regional complies with this standard, with the following condition:

Peninsula Regional shall hold meetings to review primary PCI cases at least every other month that include attendance by interventionalists and other physicians, nurses, and technicians, as required in COMAR 10.24.17.07D(5)(a). Peninsula Regional shall submit to Commission staff attendance lists for each of these meetings held between May and October by December 1 of each year and attendance lists for meetings held between November and April by June 1 of each year, beginning in April 2025, until at least March 2027, to document compliance with this condition. After this date, the Executive Director may release Peninsula Regional from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

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.

Peninsula Regional provided meeting minutes, including dates and attendees, for multiple care area group (or AMI) meetings that took place between CY 2019 and May 2024. These meetings include attendance by representatives from patient care services, nursing, the ED, cardiac rehab, and others who care for primary PCI patients, including CCL nurses and technicians. The hospital indicated that in 2019, the hospital underwent a migration to a new SharePoint system and the documentation for numerous meetings held in CY 2019 was not included in the data transfer. The hospital reported that in CY 2020 and CY 2021, four meetings were cancelled due to COVID-19 surges.

Staff Analysis and Conclusion

The documentation submitted by Peninsula Regional includes dates, meeting minutes, and attendance records for eight meetings in CY 2019, 10 meetings in CYs 2020 and 2021, 11 meetings in CY 2022, 12 meetings in CY 2023, and five meetings between January and May 2024. The hospital documented that sufficient meetings were held for the past four years, and these meetings included physician and nursing leadership, and other appropriate attendees. However, the hospital held too few meetings in CY 2019, based on the documentation available.

MHCC staff recommends that the Commission find Peninsula Regional in compliance with this 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.

Peninsula Regional submitted copies of the external review reports for elective PCI cases performed between January 2020 and June 2023. Peninsula Regional uses an MHCC approved review organization, the Cardiac Community Core Labs (CCCL), to complete these external reviews. These reviews include evaluation of angiographic images, medical test results, and the patient’s medical record and take place semi-annually. The hospital reported that each physician receives a summary and an individualized review of their selected cases. An overall summary is also presented to the Division of Cardiology or Cardiology Quality Assurance and the Corporate Compliance Committee.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted by the hospital. The volume of elective PCI cases for each review period, along with the number and percentage of cases reviewed, is shown in Table 6. Although only five percent of cases are required to be reviewed externally, between 14.5 and 16.9 percent of cases were reviewed each year. In addition, for the period between January 2020 and June 2023, MHCC staff verified that, if fewer than three cases had been performed by an interventionalist, then all cases were reviewed by the CCCL.

Table 6. Peninsula Regional’s External Reviews, January 2020 – June 2023

| Time Period | Reported PCI Volume | Number of Cases Reviewed | Percentage of Cases Reviewed | Review Frequency | Meets Standard |
|--------------------------|----------------------------|---------------------------------|-------------------------------------|-------------------------|-----------------------|
| CY 2020 | 377 | 60 | 15.9% | Semi-annually | Yes |
| CY 2021 | 427 | 62 | 14.5% | Semi-annually | Yes |
| CY 2022 | 356 | 60 | 16.9% | Semi-annually | Yes |
| January-June 2023 | 188 | 30 | 16.0% | Semi-annually | Yes |

Source: MHCC staff analysis of ACC-NCDR CathPCI data (CY 2020 - 2023), and CCCL external review reports (January 2020 – June 2023).

MHCC staff concludes that Peninsula Regional 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 at the hospital during the relevant period, as provided in Regulation .08; or*
- (iii) *A quarterly review 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 Subparagraphs .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 external review of PCI cases and the performance review of an interventionalist referenced in Paragraphs .07C(4)(c) and .07C(4)(d) 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.*

Peninsula Regional states that both internal and external reviews are conducted for each interventionalist, with the CCCL completing external reviews. The hospital provided the number of cases reviewed for each physician, both internally and externally, during the period from CY 2020 through June 2023. All external reviews include a review of angiographic images, medical test results, and patients' medical records.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided by Peninsula Regional and analyzed the ACC-NCDR CathPCI Registry 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 year and compared the results of the analysis to the number of PCI cases reviewed per physician, according to the hospital. MHCC staff observed that all physicians had ten percent, or ten cases reviewed, whichever is greater, for all reporting periods from CY 2020 through June 2023, with three exceptions.

Fewer than 10 PCI cases were reviewed for one physician in CY 2020 (six cases), CY 2021 (seven cases), and CY 2022 (nine cases), and in CY 2021 only three of another physician's PCI cases were reviewed. In response to MHCC staff's request for additional information, the hospital explained that the Division of Cardiology does not designate attendance at the weekly case conferences as mandatory, and the hospital requires that a physician be present if his or her case is discussed. As a result, for two physicians, too few cases were reviewed in one or more years. Additionally, too few PCI cases were reviewed for a third physician in CYs 2020, 2021, and 2022. In one of those years (CY 2020), the physician took extended sick leave and averaged only two on-call shifts for primary PCI per month, which led to fewer opportunities for cases to be reviewed.

Because the hospital's documentation shows that the greater of either 10 percent of cases or 10 cases were reviewed for all but three interventionalists each year, MHCC staff recommends that the Commission find Peninsula Regional to be in compliance with this standard, with the following condition:

Peninsula Regional shall evaluate the performance of each interventionalist through an internal or external review, by completing an annual review of at least 10 cases, or 10 percent of randomly selected PCI cases, whichever is greater, and all cases if the interventionalist performed fewer than 10 cases at the hospital, as required in COMAR 10.24.17.07C(4)(d). The hospital shall submit to Commission staff the number of PCI cases completed by each interventionalist, along with a list of cases reviewed for each interventionalist, for each CY by February 1 of each year, beginning with CY 2025 (due by February 2026), until at least February 2027, to document compliance with this condition. After this date, the Executive Director may release Peninsula Regional from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.

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.

Peninsula Regional submitted a written certification and an affidavit, signed by President and CEO Steven Leonard, Ph.D., MBA, FACHE, certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in COMAR 10.24.17.07C(4)(f) and .07D(5)(e), including those regarding internal and external peer review of cases. The affidavit certifies that the hospital will hold regularly scheduled meetings for internal case review, multiple area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

Staff Analysis and Conclusion

MHCC staff reviewed the written commitment and affidavit and concludes that Peninsula Regional 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.***

Peninsula Regional provided both a summary of recent quality assurance activities, as well as comprehensive documentation outlining the hospital's quality initiatives implemented as of December 2023 and the hospital's performance on new quality metrics. These new measures include the percentage of walk-in STEMI patients with a DTB time of 80 minutes or less, the percentage of STEMI patients who receive appropriate education at discharge, and the percentage of patients who receive a reassessment for pain in the CCL. The hospital also provided the results from internal and external peer review of cases, as well as actions taken in response to concerns raised.

One recommendation from the MIEMSS CIC onsite survey conducted on May 30, 2024, emphasized the need to improve door-to-electrocardiogram times for walk-in patients with cardiac symptoms and to trend symptomatology more effectively. In response, Peninsula Regional established a SharePoint site, which consolidates the hospital's measures of performance for AMI and PCI initiatives in matrices. These matrices are reviewed at the monthly AMI meetings. The hospital also reports expanding its focus on health care disparities.

Peninsula Regional also committed to holding monthly meetings specifically to review all PCI cases with mortality or complications beginning on June 17, 2024, in response to a conclusion of the focused review conducted by Advanta Government Services, LLC (AGS). These meetings include the Medical Director and Clinical Supervisor of the CCL and the Director of the Cardiac

Catheterization/Electrophysiology Labs, for the purpose of reviewing all cases of patients who underwent PCI and died during their hospitalization. In addition, the hospital indicated the findings will be reported to the Division of Cardiology quarterly, rather than annually.

The hospital reported that although it is awaiting data from new initiatives, staff has observed preliminary improvements in data reporting and documentation. Quantitative and qualitative data will be provided to MHCC, as it becomes available.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation provided by Peninsula Regional and spoke with staff for Peninsula Regional to confirm the circumstances faced by the hospital during CY 2020 and CY 2021 and how those challenges affected PCI case reviews. Based on the description of quality assurance activities implemented, staff concludes that the hospital is in compliance with this standard.

Patient Outcome Measures

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.***

10.24.17.07C(5)(a) An elective PCI program shall meet all performance standards established in statute or 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 mortality rate for non-STEMI PCI cases.

- (i) The primary benchmark is the national median risk-adjusted in-hospital 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 a reporting period, then the statewide median in-hospital risk-adjusted mortality rate for elective PCI cases will be used as a second benchmark.*

Peninsula Regional stated that MHCC notified the hospital of a focused review of eight cases spanning CY 2020 to CY 2021. The focused review was conducted by AGS.

Table 7. Peninsula Regional Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

| Reporting Period | STEMI | | | | NON-STEMI | | | |
|------------------|----------------------------------|-------------------------|----------------------------------|---------------------|----------------------------------|-------------------------|----------------------------------|---------------------|
| | Hospital Adjusted Mortality Rate | 95% Confidence Interval | National Adjusted Mortality Rate | Meets MHCC Standard | Hospital Adjusted Mortality Rate | 95% Confidence Interval | National Adjusted Mortality Rate | Meets MHCC Standard |
| 2023q3-2024q2 | 1.82 | [0.05, 9.85] | 0.78 | Yes | 1.16 | [0.38, 2.69] | 1.99 | Yes |
| 2023q2-2024q1 | 2.08 | [0.05, 11.15] | 0.79 | Yes | 0.34 | [0.01, 1.87] | 2.00 | Yes |
| 2023q1-2023q4 | 2.35 | [0.06, 12.39] | 1.88 | Yes | 0.00 | [0.00, 1.49] | 1.99 | Yes |
| 2022q4-2023q3 | 2.17 | [0.05, 11.54] | 1.91 | Yes | 1.37 | [0.28, 3.94] | 2.02 | Yes |
| 2022q3-2023q2 | NR | NR | 1.89 | N/A | NR | NR | 2.02 | N/A |
| 2022q2-2023q1 | NR | NR | 1.89 | N/A | NR | NR | 2.05 | N/A |
| 2022q1-2022q4 | 1.02 | [0.03, 5.52] | 2.00 | Yes | 2.18 | [1.00, 4.10] | 2.14 | Yes |
| 2021q4-2022q3 | 2.16 | [0.26, 7.57] | 2.11 | Yes | 1.97 | [0.85, 3.84] | 2.20 | Yes |
| 2021q3-2022q2 | NR | NR | 2.18 | N/A | NR | NR | 2.26 | N/A |
| 2021q2-2022q1 | 3.36 | [0.70, 9.56] | 2.82 | Yes | 1.24 | [0.40, 2.87] | 1.16 | Yes |
| 2021q1-2021q4 | 5.56 | [2.06, 11.76] | 2.74 | Yes | 1.14 | [0.37, 2.65] | 1.16 | Yes |
| 2020q4-2021q3 | 7.44 | [3.26, 14.24] | 2.18 | No | 1.61 | [0.65, 3.29] | 2.23 | Yes |
| 2020q3-2021q2 | 12.54 | [6.35, 21.85] | 7.51 | Yes | 1.65 | [0.67, 3.38] | 1.18 | Yes |
| 2020q2-2021q1 | 6.07 | [1.67, 15.07] | 6.89 | Yes | 0.82 | [0.17, 2.38] | 1.13 | Yes |
| 2020q1-2020q4 | 9.20 | [4.02, 17.63] | 6.92 | Yes | 1.65 | [0.67, 3.38] | 1.13 | Yes |
| 2019q4-2020q3 | 4.88 | [1.01, 13.78] | 6.37 | Yes | 1.10 | [0.30, 2.79] | 1.06 | Yes |
| 2019q3-2020q2 | 3.07 | [0.64, 8.77] | 6.06 | Yes | 1.22 | [0.45, 2.63] | 1.00 | Yes |
| 2019q2-2020q1 | 4.25 | [1.39, 9.69] | 5.99 | Yes | 0.94 | [0.31, 2.18] | 0.95 | Yes |

Source: MHCC staff's compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data Registry for PCI cases performed between April 2018 and June 2024.

Notes: A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the national benchmark 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 benchmark for STEMI or non-STEMI cases for each reporting period. Reporting on STEMI cases in the ACC-NCDR CathPCI reports changed beginning in the period ending 2021q3; for this period and later, the performance metric excludes cases with cardiogenic shock.

N/R indicates that the hospital sent incomplete data to the ACC-NCDR CathPCI Registry for the last quarter in the reporting period; therefore, the Hospital's AMR and CI were unable to be calculated for the corresponding reporting period.

N/A indicates that MHCC was unable to determine compliance with the standard in the corresponding reporting period.

Staff Analysis and Conclusion

MHCC staff reviewed the AMR data by rolling 12-month periods for both STEMI and non-STEMI patients and determined that the hospital's risk-adjusted mortality rate was not statistically significantly different than the national benchmark in any reporting period, except for the period from 2020q4-2021q3 for STEMI patients. The national benchmark fell within the 95 percent confidence interval for Peninsula Regional for all other 12-month reporting periods between April 2019 and June 2024, for both STEMI and non-STEMI patients.

The hospital's statistically worse than average performance on the mortality metric for STEMI cases triggered a focused review of deaths in STEMI patients for the 12-month period ending in September 2021. MHCC staff contracted with an external organization, AGS, to provide an independent review by a board-certified interventionalist. The focused review evaluated the quality of care provided to PCI patients and whether the hospital responded appropriately to issues identified. A total of eight cases were reviewed. The reviewer concluded that the actions of staff did not contribute to patient mortality in any of the cases. The focused review report was provided to Peninsula Regional on April 26, 2024. The hospital accepted the results of the report on May 14, 2024.

Based on the hospital's acceptable performance on the mortality metric for STEMI cases since the period ending in 2021 Q3, and the findings of the focused review conducted, MHCC staff recommends that the Commission find that Peninsula Regional is in compliance with this standard.

Physician Resources

10.24.17.07C(6)(a) and .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.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Peninsula Regional because the hospital provides on-site cardiac surgery services.

10.24.17.07C(6)(b) and .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 annually averaged 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 Peninsula Regional because the hospital has on-site cardiac surgery.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI procedures annually averaged over a 24-month period, 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.***

Staff Analysis and Conclusion

MHCC staff determined that this standard does not apply to Peninsula Regional because the hospital has on-site cardiac surgery services.

10.24.17.07C(6)(e) and .07D(7)(e) Each physician shall be board-certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or completed their training before 1998 and did not seek board certification before 2003.

10.24.17.07C(6)(f) and .07D(7)(f) Each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

Peninsula Regional submitted a signed and dated statement from Dr. Joseph Cinderella, Medical Director of the CCL, acknowledging that all physicians performing primary PCI services at the hospital are board-certified in interventional cardiology and obtained board certification within three years of completion of a fellowship in interventional cardiology.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that Peninsula Regional meets this standard.

10.24.17.07C(6)(g) and .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.

Peninsula Regional submitted signed and dated attestations from Drs. Cinderella, Hearne, Agarwal, Wieland, Singh, Abu-Haniyeh, Bounds, Treuth, Subrayappa, Heda, and Chodnicki stating that each has completed a minimum of 30 hours of continuing medical education credits in interventional cardiology in the last two years. No attestation was provided for Dr. Frey; however, the hospital submitted a list of continuing education credits completed by Dr. Frey in CYs 2023 and 2024. Only 22 continuing education credits were completed by this physician during the two-year period; however, Peninsula Regional reported that Dr. Frey closed his office practice and relinquished his privileges at the hospital effective December 31, 2024.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that Peninsula Regional complies with this standard.

10.24.17.07C(6)(h) and .07D(7)(h) Each physician who performs primary PCI agrees to participate in an on-call schedule.

Peninsula Regional submitted a signed and dated statement from Dr. Cinderella, Medical Director of the CCL, acknowledging that each physician who has performed primary PCI services during the performance review period has participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. Copies of the November and December 2024 on-call schedules were provided.

Staff Analysis and Conclusion

MHCC staff reviewed the documentation submitted and concludes that Peninsula Regional complies with this 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.

(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.

Peninsula Regional provided PCI volume information for CY 2020 through March 2024, as shown in Table 8. This information shows that Peninsula Regional performed between 509 and 596 total PCI cases annually for the period from CY 2020 through CY 2023.

**Table 8. Peninsula Regional's
Total PCI Volume, CY 2020 – CY 2023**

| Calendar Year | Total PCI |
|---------------|-----------|
| 2020 | 562 |
| 2021 | 596 |
| 2022 | 524 |
| 2023 | 509 |

Source: Supplemental information received from Peninsula Regional for the application for Certificate of Ongoing Performance 2024 (November 26, 2024).

Staff Analysis and Conclusion

MHCC staff reviewed the PCI volume information submitted by Peninsula Regional and determined that the hospital met the annual target volume of 200 PCI cases for the period from CY 2020 to CY 2023.

MHCC staff concludes that Peninsula Regional complies with this standard.

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 primary PCI volume for CY 2020 through CY 2023. This analysis shows primary PCI volume ranged from 144 to 183 cases each CY (Table 9) and confirms that Peninsula Regional exceeded the threshold of 36 cases annually, which is referenced in the standard. Because Peninsula Regional exceeded the 36-case threshold no focused review is required.

**Table 9. Peninsula Regional's
Primary PCI Volume, CY 2020 – CY 2023**

| Calendar Year | Primary PCI Volume |
|---------------|--------------------|
| 2020 | 183 |
| 2021 | 178 |
| 2022 | 144 |
| 2023 | 166 |

Source: MHCC staff's analysis of the ACC-NCDR CathPCI data, CY 2020 – CY 2023.

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

The hospital stated that the hospital's interventionalists only complete primary PCI cases at Peninsula Regional. For those physicians who did not meet the target volume of 11 primary PCI cases annually, the hospital provided reasons for this.

Staff Analysis and Conclusion

MHCC staff reviewed and analyzed ACC-NCDR CathPCI registry data for each interventionalist's primary PCI volume. This analysis shows that between January 2020 and December 2023, at least 11 primary PCI procedures were completed per year for each interventionalist, with a few exceptions.

Drs. Heda and Frey do not take STEMI cases, but the hospital reported that when one of their patients arrived during working hours, these physicians performed the primary PCIs in CYs 2020, 2021, and 2022; however, Peninsula Regional stated that the practice of an interventionalist taking a primary PCI patient when the interventionalist's patient arrives in the ER during regular working hours is no longer in place. In CY 2021, Dr. Singh only performed eight PCI cases, but he was only employed for six months of the year. Similarly, Dr. Sawant was only employed for eight months in CY 2021 and completed just one primary PCI case that year. In addition, Drs. Abu-Haniyeh and Subrayappa were not hired until July 2023, resulting in less than 11 primary PCI cases performed that year by both physicians.

Because Peninsula Regional explained the instances when physicians did not meet the target volume of 11 primary PCIs annually, MHCC staff recommends that the Commission find that Peninsula Regional is in compliance with this standard.

Patient Selection

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.

Peninsula Regional stated that the hospital commits to providing elective PCI services only for appropriate patients. The hospital indicated that there have not been any elective cases reviewed internally as being inappropriate from CY 2019 through March 2024. External review of cases by the CCCL identified three PCI cases that were determined to be "rarely appropriate" according to one of the following review criteria: angiographic, clinical, or ACC/AHA guidelines. Peninsula Regional reports that each physician received an individual copy of the report pertaining to the CCCL's findings for their individual PCI cases and Dr. Cinderella presented an overview of the review summary to the Division of Cardiology for each review period.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports from January 2019 through June 2023 and determined that all cases were "appropriate" or "maybe appropriate" in terms of angiographic, clinical, and ACC/AHA appropriate use criteria. Three cases were found to be "rarely appropriate" with respect to one of these categories; these cases were reviewed by multiple CCL reviewers. Staff notes that "rarely appropriate" does not mean inappropriate. All interventionalists were provided with a copy of their individual results of their elective PCI cases reviewed.

MHCC staff determines that Peninsula Regional complies with this standard.

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 the 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.**

Peninsula Regional stated that throughout the review period, there were several patients who received PCI following failed thrombolytic therapy, as shown in Table 10. The hospital reported that all of these patients were transferred from another facility in the region, as PCI services were available at Peninsula Regional.

Table 10: Number of Patients Who Received Thrombolytic Therapy, CY 2019 – CY 2023

| Year | Number of Patients |
|-------------|---------------------------|
| 2019 | 2 |
| 2020 | 2 |
| 2021 | 2 |
| 2022 | 5 |
| 2023 | 1 |

Source: Supplemental information received on November 26, 2024, for Peninsula Regional's application for a Certificate of Ongoing Performance 2024.

Staff Analysis and Conclusion

MHCC staff's analysis of the ACC-NCDR CathPCI data for CY 2019 through CY 2023 is consistent with the information reported by the applicant. Additionally, the hospital's ACC-NCDR CathPCI reports for the period from CY 2019 through CY 2023 indicate that no primary PCI patients with acute coronary syndrome received PCI that was considered rarely appropriate.

MHCC staff determines that Peninsula Regional complies with this standard.

RECOMMENDATION

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

1. Peninsula Regional shall hold meetings to review primary PCI cases at least every other month that include attendance by interventionalists and other physicians, nurses, and technicians, as required in COMAR 10.24.17.07D(5)(a). Peninsula Regional shall submit to Commission staff attendance lists for each of these meetings held between May and October by December 1 of each year and attendance lists for meetings held between November and April by June 1 of each year, beginning in April 2025, until at least March 2027, to document compliance with this condition. After this date, the Executive Director may release Peninsula Regional from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition
2. Peninsula Regional shall evaluate the performance of each interventionalist through an internal or external review, by completing an annual review of at least 10 cases, or 10 percent of randomly selected PCI cases, whichever is greater, and all cases if the interventionalist performed fewer than 10 cases at the hospital, as required in COMAR 10.24.17.07C(4)(d). The hospital shall submit to Commission staff the number of PCI cases completed by each interventionalist, along with a list of cases reviewed for each interventionalist, for each CY by February 1 of each year, beginning with CY 2025 (due by February 2026), until at least February 2027, to document compliance with this condition. After this date, the Executive Director may release Peninsula Regional from the reporting requirement if the Executive Director determines that the hospital has achieved substantial compliance with this condition.