

**IN THE MATTER OF**

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**BEFORE THE**

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**PENINSULA REGIONAL**

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**MARYLAND HEALTH**

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**MEDICAL CENTER**

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**CARE COMMISSION**

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**Docket No.: 17-22-CP004**

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**STAFF REPORT & RECOMMENDATION  
CERTIFICATE OF ONGOING PERFORMANCE  
FOR CARDIAC SURGERY SERVICES**

**March 21, 2019**

## **I. INTRODUCTION**

### **A. Background**

In 2012, the Maryland legislature passed a law directing the Maryland Health Care Commission (“MHCC” or “Commission”) to adopt new regulations for the oversight of both cardiac surgery and percutaneous coronary intervention (“PCI”) services. The law directed MHCC to establish a process and minimum standards for obtaining and maintaining a Certificate of Ongoing Performance that incorporates, to the extent appropriate, recommendations on standards for cardiac surgery services and PCI services from a legislatively-mandated Clinical Advisory Group (“CAG”). The law also directed MHCC to incorporate several specific requirements in its regulations.

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 Surgery Chapter”) of the State Health Plan for Facilities and Services (“State Health Plan”) was replaced effective August 2014. The Cardiac Surgery Chapter was subsequently replaced in November 2015 and again in January 2019. The primary changes to the Cardiac Surgery Chapter that affect cardiac surgery programs have been an evolving definition of cardiac surgery that may affect a hospital’s compliance with volume standards for a Certificate of Ongoing Performance for cardiac surgery and a change to the benchmark used to evaluate hospitals’ risk-adjusted mortality rates. MHCC staff was unable to obtain benchmark information for risk-adjusted mortality rates consistent with the regulations adopted in November 2015 that reflected the recommendations of the CAG. As a result, the standard addressed by applicants was determined to be inapplicable; however, information on how hospitals performed relative to the newly adopted mortality standard is included in staff reports.

The Cardiac Surgery Chapter contains standards for evaluating the performance of established cardiac surgery services in Maryland and determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for cardiac surgery authorizes a hospital to continue to provide these services for a period of time specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must again demonstrate that it continues to meet the requirements in COMAR 10.24.17.07B for a Certificate of Ongoing Performance in order for the Commission to renew the hospital’s authorization to provide cardiac surgery services.

### **B. Applicant**

Peninsula Regional Medical Center (“PRMC”) is a 288-bed general acute care hospital located in Salisbury (Wicomico County) and is part of Peninsula Regional Health System. PRMC’s cardiac surgery program was established in 1982. It is the only cardiac surgery program operating on the Eastern Shore of Maryland.

#### **Health Planning Region**

There are four health planning regions defined in COMAR 10.24.17 for adult cardiac surgery services. These regions include the Eastern/Lower Shore, Western, Baltimore/Upper

Shore, and Metropolitan Washington regions. Counties in the Eastern/Lower Shore region include Dorchester, Somerset, Wicomico, and Worcester Counties. The regions were configured based on historic patterns of cardiac surgery utilization by the population in them. PRMC is the largest general hospital in the Eastern/Lower Shore region and offers the broadest range of specialized services. Other hospitals located in this region include Atlantic General Hospital in Berlin (Worcester County), Edward. W. McCready Memorial Hospital in Crisfield (Somerset County), and the University of Maryland Shore Medical Center at Dorchester in Cambridge (Dorchester County).

### **C. Staff Recommendation**

MHCC staff recommends that the Commission approve PRMC's application for a Certificate of Ongoing Performance to continue providing cardiac surgery services. A description of PRMC's documentation and MHCC staff's analysis of this information follows.

## **II. PROCEDURAL HISTORY**

PRMC filed a Certificate of Ongoing Performance application on October 27, 2017. On March 9, 2018, PRMC submitted responses to questions, requests for additional information, and clarifications concerning its application for a Certificate of Ongoing Performance for cardiac surgery services.

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

### **Data Collection**

*COMAR 10.24.17.07B(3). Each cardiac surgery program shall participate in uniform data collection and reporting. This requirement is met through participation in STS-ACSD, with submission of duplicate information to the Maryland Health Care Commission. Each cardiac 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 cardiac surgery programs.*

PRMC stated that it participates in the Society of Thoracic Surgeons' ("STS") adult cardiac surgery data registry ("STS-ACSD") and included a signed copy of its data sharing agreement in the application. PRMC also noted that it submits STS-ACSD data to MHCC staff as required.

### **Staff Analysis and Conclusion**

PRMC has complied with the submission of STS-ACSD data to MHCC in accordance with the established schedule. In 2015, MHCC staff conducted an audit of the STS-ACSD data for each Maryland hospital to validate that all hospitals submitted accurate and complete information to the STS-ACSD. Advanta Government Solutions, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of PRMC's STS-ACSD data for the period July 1, 2014 through December 31, 2014. MHCC staff concludes that PRMC complies with this standard.

## Quality

*COMAR 10.24.17.07B(4)(a) and (b). The chief executive officer of the hospital shall certify annually to the Commission 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. The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance process.*

PRMC stated that the primary group within the hospital that coordinates all quality assurance related activities is the Cardiac Surgery Performance Improvement Committee (“CSPIC”). Attendees at CSPIC meetings include the cardiac surgeons, nurses, and an infection control specialist. CSPIC met seven times between February 2015 and September 2017. PRMC provided a copy of the minutes for each meeting and a list of attendees.

PRMC explained that major quality indices reviewed at CSPIC meetings are those from STS quality reports, infection reports, and other information that pertains to specific quality initiatives. The STS report measures include the frequency of intraoperative red blood cell usage, clinical assessment of the use of an internal mammary artery, review of post-operative complications such as prolonged intubation, renal insufficiency, stroke, return for reoperation, patient medication, and mortality. PRMC provided specific results for each of these measures by month and the total for each year for calendar year (“CY”) 2015 through CY 2017, both overall and for specific categories of cardiac surgery cases.

In addition to the CSPIC meetings, PRMC noted that its cardiac surgeons meet twice a year to present a summary of the cardiac surgery procedures performed and discuss complications, quality indicators, and mortality rates. PRMC provided copies of the slides presented at these meetings in CY 2015, CY 2016, and CY 2017. At these meetings, the cardiac surgeons discuss recommendations to improve the quality of patient care. PRMC provided detailed information on two quality improvement projects, including the rationale for the projects, the outcomes measured, and the results.

PRMC provided detailed information on how the performance of individual cardiac surgeons is evaluated. PRMC also noted that there were no cardiac surgery cases referred for external review that were performed between January 2015 and September 2017.

Peggy Naleppa, President of PRMC in October 2017, submitted a letter stating that PRMC is committed to identifying areas for improvement in the quality and outcomes of its cardiac surgery program. She also stated that annually or upon request, PRMC will provide a report of the program’s quality assurance activities.

## **Staff Analysis and Conclusion**

PRMC provided information documenting its quality assurance activities and actions taken in response to any quality concerns identified. MHCC staff concludes that PRMC complies with this standard.







## **Performance Standards**

*COMAR 10.24.17.07B(5)(a) A cardiac surgery program shall meet all performance standards established in statute or in State regulations. The hospital shall maintain an STS-ACSD composite score for CABG of two stars or higher. If the composite score for CABG from the STS-ACSD is one star for two consecutive cycles, the program will be subject to a focused review. If the composite score for CABG from the STS-ACSD is one star for four consecutive rating cycles, the hospital's cardiac surgery program shall be evaluated for closure based on a review of the hospital's compliance with State regulations and recently completed or active plan of correction.*

## **Staff Analysis and Conclusion**

PRMC has consistently maintained an STS composite score for coronary artery bypass graft ("CABG") surgeries of two stars or higher, as required. Table 1 shows the star ratings for each of six overlapping 12-month periods, the volume of isolated CABG cases included in the ratings for each period, and the estimated overall percentage of PRMC's volume of cardiac surgery included in the STS ratings. As shown in Table 1, approximately 63 to 73 percent of PRMC's cardiac surgery volume is included in the composite STS star ratings for isolated CABG cases for the period January 2015 through June 2018. Hospitals with cardiac surgery programs typically perform multiple types of cardiac surgery and may perform CABG in combination with other types of cardiac procedures, but the STS ratings shown in Table 1 are based on only isolated CABG procedures. For an individual patient who requires a different type of cardiac surgery, the information included in Table 1 may not be relevant. However, the Cardiac Surgery Chapter uses isolated CABG as a reference point based not only on the recommendations of the Clinical Advisory Group but also on the continued advice of its current Cardiac Services Advisory Committee, which includes cardiac surgeons and interventional cardiologists. Isolated CABG is one of the most common cardiac surgery procedures performed, which allows for a consistent and fair basis for comparing programs and evaluating the overall performance of hospitals, with respect to one type of cardiac surgery.

**Table 1: Peninsula Regional Medical Center’s Cardiac Surgery Volume, CABG Volume, and Composite STS Ratings for CABG, by Reporting Period**

Reporting Period	Jan. 2015- Dec. 2015	July 2015- June 2016	Jan. 2016- Dec 2016	July 2016- June 2017	Jan. 2017- Dec. 2017	July 2017- June 2018
Composite Star Rating <sup>1</sup>						
Total Isolated CABG Cases Included <sup>2</sup>	253	262	250	241	241	237
Total Cardiac Surgery Case Volume <sup>3</sup>	399	380	345	330	333	323
Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating	63%	69%	72%	73%	72%	73%

Sources: PRMC submitted copies of its 2015 star ratings and CABG volume to MHCC for each time period shortly after receiving the information from STS; the total cardiac surgery volume is based on MHCC staff analysis of HSCRC discharge abstract data for January 2015- June 2018.

<sup>1</sup> The maximum number of stars awarded is three stars. Two stars indicates that a program is neither significantly better nor worse than the national average for cardiac surgery programs participating in the STS-ACSD.

<sup>2</sup> Isolated CABG cases are cases in which only CABG is performed. The number of eligible procedures ranges within the components of the star rating; the number in the table reflects the number of eligible procedures for the mortality component.

<sup>3</sup> Cardiac surgery case volume is based on counting discharges with any procedure code that is included in the definition of open heart surgery in COMAR 10.24.17, effective in November 2015, and using the procedure date to categorize cases by reporting period.

The STS composite star rating for isolated CABG surgeries has four components. The first component is the absence of operative mortality, which is measured by the percentage of patients who do not die during the hospitalization for CABG surgery or within 30 days of the surgery, if discharged.<sup>1</sup> The second component is the absence of major morbidity, which is defined to include any one of the following: reoperation; stroke; kidney failure; infection of the chest wound from surgery; or prolonged breathing support by a machine.<sup>2</sup> For the first two components STS adjusts the results in each case based on the severity of illness for each patient. The third component is use of at least one internal mammary artery for the bypass graft, which has been known for more than a decade to function longer than a saphenous vein graft.<sup>3</sup> The fourth component is receipt of all four specific perioperative medications that are believed to improve patient outcomes.<sup>4</sup> The

<sup>1</sup> Society of Thoracic Surgeons. (2017). STS Public Reporting Online. Retrieved from <https://publicreporting.sts.org/cabg-composite-score>

<sup>2</sup> Society of Thoracic Surgeons. (2017). STS Public Reporting Online. Retrieved from <https://publicreporting.sts.org/cabg-composite-score>

<sup>3</sup>Cameron, A., Davis, K.B., Green, G., Schaff, H.V. (1996). Coronary bypass surgery with internal-thoracic-artery grafts--effects on survival over a 15-year period. *New England Journal of Medicine*, 334(4):216-9; Goldman, S., Zadina, K., Moritz, T., Ovitt, T., Sethi G, Copeland, JG, . . . VA Cooperative StudyGroup #207/297/364 (2004). Long-term patency of saphenous vein and left internal mammary artery grafts after coronary artery bypass surgery: results from a Department of Veterans Affairs Cooperative Study. *Journal of the American College of Cardiology*, 44(11):2149-56. <https://doi.org/10.1016/j.jacc.2004.08.064>; Loop, F.D. (1996). Internal-thoracic-artery grafts. Biologically better coronary arteries. *New England Journal of Medicine*, 334(4):263-5.

<sup>4</sup> Society of Thoracic Surgeons. (2017). STS Public Reporting Online. Retrieved from <https://publicreporting.sts.org/cabg-composite-score>

first component, the absence of operative mortality carries the most weight in the overall composite star rating for isolated CABG cases, approximately 80%.<sup>5</sup> Nationally, the vast majority of programs receive a two-star rating, indicating the program did not perform worse or better than the average for all participants in the STS-ACSD, at a statistically significant level.<sup>6</sup>

*COMAR 10.24.17.07B (5)(b) The hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care. A hospital with an all-cause 30-day risk-adjusted mortality rate for a specific type of cardiac surgery, such as CABG cases, that exceeds the statewide average 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 the hospital's all-cause 30-day risk-adjusted mortality rate for a specific type of cardiac surgery case.*

### **Staff Analysis and Conclusion**

This standard is not applicable because hospitals and MHCC staff were not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality. However, MHCC staff has provided information below on how PRMC performed on the revised standard adopted in regulations that became effective January 14, 2019.

The difference between PRMC's all-cause risk adjusted operative mortality rate for isolated CABG cases and the national average is not statistically significant in any of the 12-month reporting periods between January 2015 and June 2018. A hospital's performance on this measure is acceptable as long as the hospital's risk adjusted operative mortality rate is similar or better than the national average for participants in the STS-ACSD. As shown in Table 2, for each of the six reporting periods, PRMC's 95% confidence interval ("CI") for its all-cause risk adjusted operative mortality rate for isolated CABG includes the national average, indicating that PRMC performed similar to the national average for all participants in the STS-ACSD. The results are shown graphically in Figure 1. In Figure 1, an 'X' indicates the national average, and a triangle indicates PRMC's performance. As shown in Figure 1, the national average falls within the CI for PRMC's performance in each reporting period. MHCC staff concludes that PRMC would have met the current performance standard, if it had been applicable between January 2015 and June 2018.

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<sup>5</sup> Society of Thoracic Surgeons. (June 2018). Report Overview- Risk Adjustment Supplement STS Report- Period Ending 12/31/2017.

<sup>6</sup> Society of Thoracic Surgeons. (June 2018). Report Overview- Risk Adjustment Supplement STS Report- Period Ending 12/31/2017.

**Table 2: All-Cause Risk Adjusted Operative Mortality Rates for Isolated CABG: PRMC Comparison to the National Average, by Reporting Period**

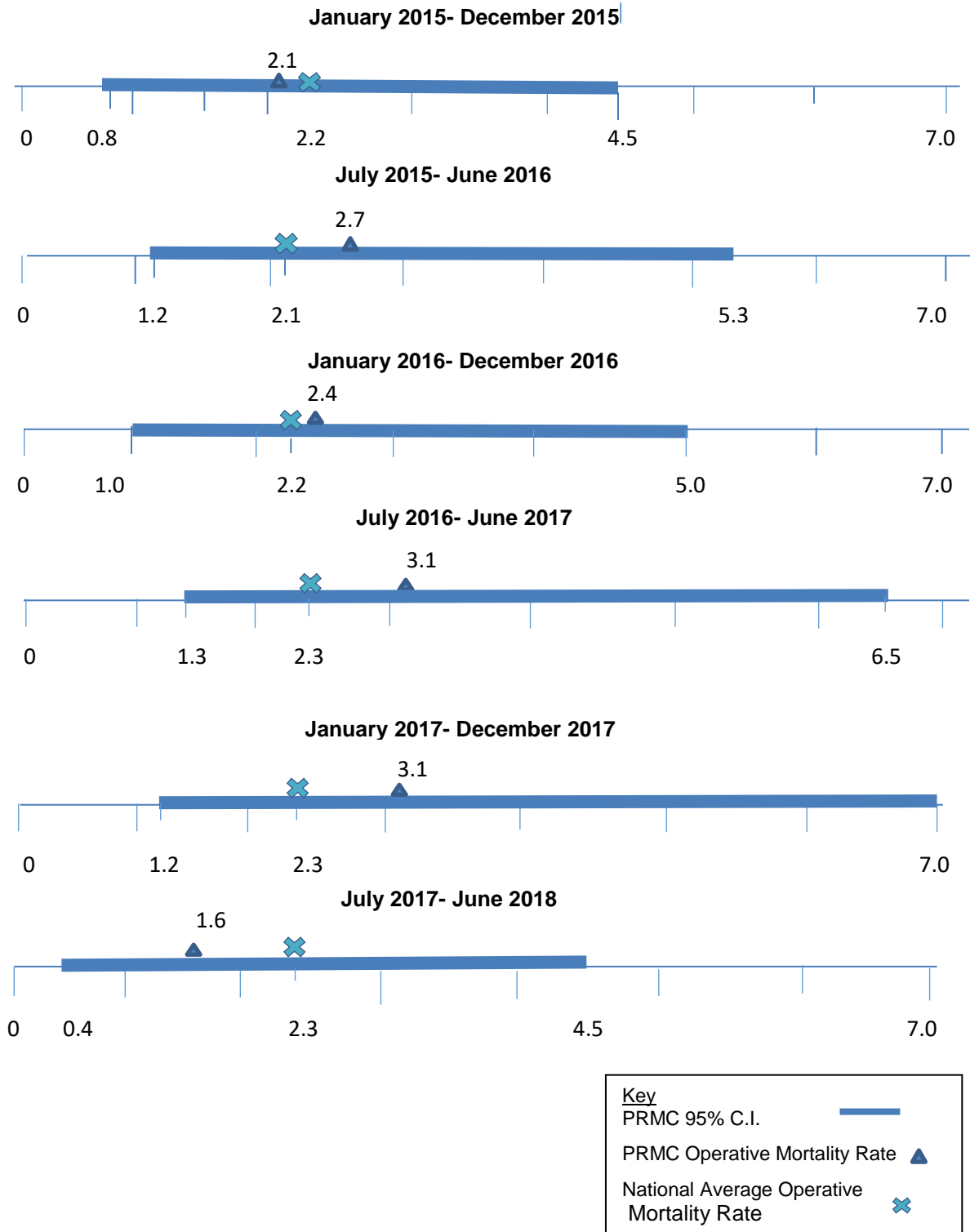
Reporting Period	Risk-Adjusted Isolated CABG Operative Mortality			95% Confidence Interval		
	Jan. 2015 - Dec 2015	Jul 2015 - Jun 2016	Jan. 2016 - Dec 2016	Jan. 2015 - Dec 2015	July 2015 - Jun 2016	Jan 2016 - Dec 2016
PRMC	2.1	2.7	2.4	(0.8 , 4.5)	(1.2 , 5.3)	(1.0 , 5.0)
National Average	2.2	2.1	2.2	--	--	--
Reporting Period	July 2016- June 2017	Jan. 2017- Dec. 2018	July 2017- June 2018	July 2016- June 2017	Jan. 2017- Dec. 2018	July 2017- June 2018
PRMC	3.1	3.1	1.6	(1.3,6.5)	(1.2, 7.0)	(0.4, 4.5)
National Average	2.3	2.3	2.3	--	--	--

Source: STS analysis of data collected in the STS-ACSD.

Notes: It is not valid to compare Maryland hospitals to each other and rank them based on the risk-adjusted operative mortality rates for individual hospitals. The risk-adjusted operative mortality rates and confidence intervals only provide information on whether a hospital has performed worse or better relative to the national average operative mortality rate at a statistically significant level. Operative mortality rates include in-hospital patient deaths following isolated CABG surgery and deaths for any reason within 30 days of isolated CABG surgery.



**Figure 1: All-Cause Risk-Adjusted Operative Mortality Rates for Isolated CABG: PRMC Compared to the National Average, by Reporting Period**



Across all Maryland hospitals, the all-cause risk adjusted operative mortality rates for isolated CABG fall within a relatively narrow range: for the 12-month period January 2015 to December 2015, the rates for Maryland cardiac surgery programs ranged from zero to 2.4%; for the 12-month period ending June 30, 2016, the rate range was zero to 2.7%; for CY 2016, the rate range was zero to 3.4%; for the 12-month period ending June 30, 2017, the rate range was zero to 5.8%; for CY 2017, the rate range was 0.4% to 5.2%; and, for the 12-month period ending June 30, 2018, the rate range was 0.4% to 3.8%. Given the relatively low rates for risk adjusted operative mortality across most programs and the volume of cases typically performed at individual hospitals, this performance measure cannot be used to discriminate meaningfully among programs, except to identify outliers relative to the national average.

### **Volume Requirements**

***COMAR 10.24.17.07B (6)(a) A cardiac surgery program shall maintain an annual volume of 200 or more cases.***

PRMC reported a volume of 434 adult cardiac surgery cases in fiscal year (“FY”) 2015, 408 cases in FY 2016, and 361 cases in FY 2017.

### **Staff Analysis and Conclusion**

MHCC staff analyzed the HSCRC data for PRMC in FY 2015, and the information reported to the STS-ACSD by PRMC. Based on MHCC staff’s analysis of the HSCRC data, PRMC performed a total of 420 adult cardiac surgery cases in FY 2015, 380 cases in FY 2016, 330 cases in FY 2017, and 323 cases in FY 2018. MHCC staff’s analysis of the STS data for PRMC indicates a total of 423 adult cardiac surgery cases in FY 2015, 396 cases in FY 2016, and 340 cases in FY 2017. MHCC staff concludes that these case counts may differ due to minor differences in the definitions of adult cardiac surgery used by STS, MHCC, and PRMC. Staff notes that the MHCC definition of cardiac surgery changed in November of 2015 with the adoption of a replacement Cardiac Surgery Chapter. In addition, the ICD-9 procedure codes were replaced by ICD-10 procedure codes beginning October 1, 2015, and an official crosswalk between the ICD-10 and ICD-9 codes was adopted only recently in the regulations effective January 2019. MHCC staff concludes that PRMC meets the annual volume requirement, by exceeding a volume of 200 cardiac surgery cases for the four most recent fiscal years for which data is available.

## **IV. RECOMMENDATION**

Based on the above analysis and the record in this review, MHCC staff concludes that Peninsula Regional Medical Center meets all of the requirements for a Certificate of Ongoing Performance found in COMAR 10.24.17.07B. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a Certificate of Ongoing Performance that permits Peninsula Regional Medical Center to continue providing cardiac surgery services for the next four years.