IN THE MATTER OF	*	BEFORE THE
	*	
WESTERN MARYLAND REGIONAL	*	MARYLAND HEALTH
	*	
MEDICAL CENTER	*	CARE COMMISSION
	*	
Docket No. 17-01-CP002	*	

* *

STAFF REPORT & RECOMMENDATION

APPLICATION FOR 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 the "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 stakeholder's 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 in August 2014. The Cardiac Surgery Chapter was subsequently replaced in November 2015 and replaced 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' operative mortality rates. MHCC staff was unable to obtain benchmark information for operative mortality rates consistent with the regulations adopted in November 2015, which reflected the recommendations of the CAG. As a result, the standard addressed by applicants was determined to be inapplicable, but information on how hospitals performed relative to the newly adopted mortality standard has been included.

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 specified 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

Western Maryland Regional Medical Center

Western Maryland Regional Medical Center ("WMRMC") is a 200-bed general hospital located in Cumberland (Allegany County). It is an affiliate of Western Maryland Health System, which was established through a merger of Memorial Hospital and Medical Center of Cumberland and Sacred Heart Hospital. WMRMC opened in 2010 as a consolidated replacement hospital for both of the Cumberland hospitals.

Sacred Heart Hospital established a cardiac surgery program in 1999. In accordance with the 1997 Cardiac Surgery Chapter then in effect, the CON granted to Sacred Heart Hospital notes that the Commission may withdraw the authority granted by this Certificate of Need to operate a

cardiac surgery program if the program does not achieve a minimum volume of 200 open heart surgery cases within 24 months of beginning operation and maintain this minimum utilization level in each subsequent year of operation. This condition was removed by the Commission in December 2018.

Health Planning Region

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17. WMRMC is located in the Western Maryland health planning region (HPR). This HPR includes Allegany, Garrett and Washington Counties. There are three hospitals located in this HPR, one in each county. Two of these hospitals, WMRMC and Meritus Medical Center in Hagerstown (Washington County), provide PCI services. WMRMC is the only hospital performing cardiac surgery in this HPR.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

WMRMC filed a Certificate of Ongoing Performance application on October 26, 2017. On February 22, 2018, WMRMC responded to questions from MHCC staff concerning its application for a Certificate of Ongoing Performance by phone.

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.

WMRMC participates in the Society of Thoracic Surgeons' ("STS") adult cardiac surgery data registry ("STS-ACSD") and submits its STS-ACSD data to MHCC staff as required.

Staff Analysis and Conclusion

WMRMC 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 STS. Advanta Government Solutions, the MHCC's contractor, did not identify any concerns regarding the accuracy or completeness of WMRMC's STS-ACSD data for the period

July 1, 2014 through December 31, 2014. MHCC staff concludes that WMRMC 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.

WMRMC performs quality assurance through its quarterly Open Heart Case Review ("OHCR") meetings. WMRMC held seven meetings between January and October of calendar year ("CY") 2017. Members of the OHCR team include the chair of cardiac surgery, the unit cardiac surgeons, cardiac surgery nurses, physician assistants, and data managers. WMRMC provided minutes for all of the formal meetings and a list of attendees for most meetings. The meeting minutes indicate that specific quality measures are reviewed at these meetings. In addition, WMRMC provided a list of other quality assurance activities that were not captured in meeting minutes. WMRMC explained the benchmarks that it adopted and provided information on its performance relative to these benchmarks on a monthly basis for CY 2015, CY 2016, and January through September of 2017.

In addition to the OHCR meetings, the hospital also conducts a quarterly Open Heart Collaborative Care meeting. Members of this group include the cardiac program mid-level professionals. Quality measures such as rates of complications, infections, and readmissions are reviewed. WMRMC does not perform internal peer review because almost all cases are performed by one surgeon. WMRMC reported that no cases were referred for external review that were performed between January 2015 and September 2017.

Barry Ronan, President of Western Maryland Health System, submitted a letter stating that WMRMC is committed to identifying areas of improvement in the quality and outcomes of the WMRMC's cardiac surgery program. He also stated that, annually or upon request, WMRMC will provide a report of the quality assurance activities of the program.

Staff Analysis and Conclusion

WMRMC provided information documenting its quality assurance activities and the actions taken in response to any quality concerns identified. MHCC staff concludes that WMRMC 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 plans of correction.

Staff Analysis and Conclusion

WMRMC 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 overall percentage of the WRMC's volume of cardiac surgery included in the STS ratings. As shown in Table 1, approximately 55 to 77 percent of WMRMC's cardiac surgery volume is included in the STS composite star ratings for the period January 2015 through June 2018. Hospitals with cardiac surgery programs typically perform other types of cardiac surgery and may perform CABG in combination with other surgical procedures, but the STS ratings shown in Table 1 are based only on 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 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: Western Maryland Regional Medical Center's Cardiac Surgery Volume, CABG Volume, and Composite STS Star 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[1]	★★★	★★	★★	★★	★★	★★
Total Isolated CABG Cases Included[2]	92	100	107	105	97	91
Total Cardiac Surgery Volume[3]	166	170	150	136	128	124
Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating	55%	59%	71%	77%	76%	73%

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

[1] The maximum number of stars awarded is three stars. Two stars indicate that a program is neither statistically significantly better nor worse than the national average for cardiac surgery programs participating in the STS-ACSD.

[2] 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.

[3] 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.[1] 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 support by a breathing machine.[2] 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.[2] The fourth component is receipt of all four specific perioperative medications; these medications are believed to improve patient outcomes. The first component, the absence of operative mortality carries the most weight in the overall composite star rating for isolated CABG cases, a weight of approximately 80%.[3] 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.[4]

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 WMRMC performed on the revised standard adopted in regulations that became effective January 14, 2019.

The difference between WMRMC'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, WMRMC's 95% confidence interval ("CI") for its all-cause risk adjusted operative mortality rate for isolated CABG includes the national average, indicating that WMRMC 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 the performance for WMRMC. As shown in Figure 1, the national average falls within the CI for WMRMC's performance in each reporting period. MHCC staff concludes that WMRMC would have met the current performance standard, if it had been applicable between January 2015 and June 2018.[4]

---

[1] Society of Thoracic Surgeons. (2017). STS Public Reporting Online. Retrieved from https://publicreporting.sts.org/cabg-composite-score
[2] Society of Thoracic Surgeons. (2017). STS Public Reporting Online. Retrieved from https://publicreporting.sts.org/cabg-composite-score
[3] Society of Thoracic Surgeons. (June 2018). Report Overview- Risk Adjustment Supplement STS Report- Period Ending 12/31/2017.
[4] 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: WMRMC Comparison to the National Average, by Reporting Period

Reporting Period	All-Cause 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
WMRMC	0.0	1.2	1.3	(0.0 , 4.6)	(0.1 , 6.3)	(0.1 , 6.8)
National Average	2.2	2.1	2.2	--	--	--
Reporting Period	July 2016- June 2017	Jan. 2017- Dec. 2017	July 2017- June 2018	July 2016- June 2017	Jan. 2017- Dec. 2018	July 2017- June 2018
WMRMC	0	1.2	1.2	(0.0, 4.2)	(0.1, 6.1)	(0.1, 6.4)
National Average	2.3	2.3	2.3	--	--	--

Source: STS analysis of data from all Maryland hospitals with cardiac surgery programs.
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.

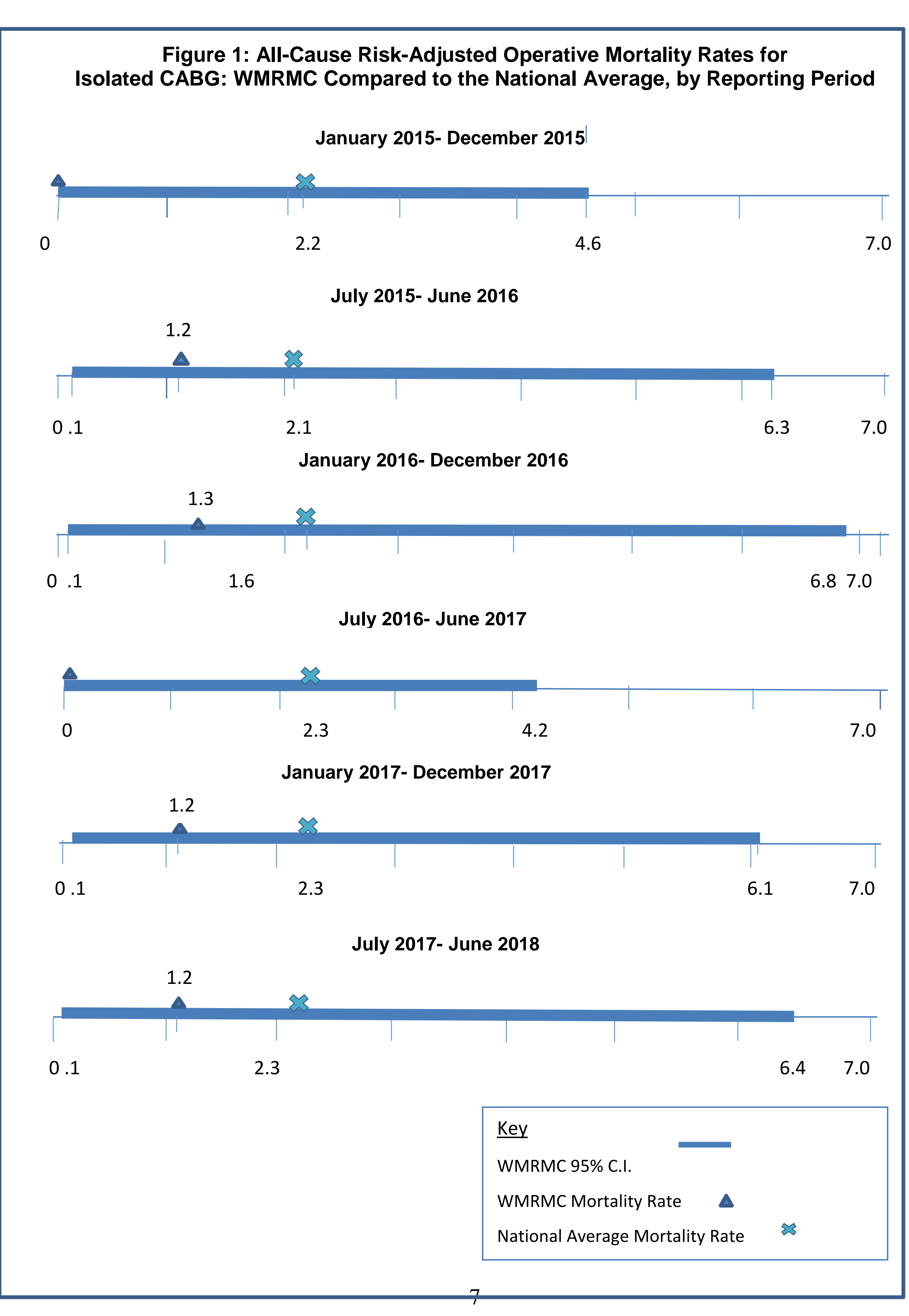
Figure 1: All-Cause Risk-Adjusted Operative Mortality Rates for
Isolated CABG: WMRMC Compared to the National Average, by Reporting Period
January 2015- December 2015
0
2.2
4.6
7.0
July 2015- June 2016
1.2
0 .1
2.1
6.3
7.0
January 2016- December 2016
1.3
0 .1
1.6
6.8 7.0
July 2016- June 2017
0
2.3
4.2
7.0
January 2017- December 2017
1.2
0 .1
2.3
6.1
7.0
July 2017- June 2018
1.2
0 .1
2.3
6.4
7.0
Key
WMRMC 95% C.I.
WMRMC Mortality Rate
National Average Mortality Rate

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 risk adjusted operative mortality rates across most programs and the volume of cases typically performed at individual hospitals, this performance measure cannot be used to meaningfully discriminate 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.

WMRMC has not maintained an annual volume of 200 or more cases in any reporting period from 2015 onward. It reported a volume of 169 cases for calendar year ("CY") 2015, 149 cases for CY 2016, and 99 cases for the period January through September 2017 (MHCC staff estimates that this would be 132 cases on an annualized basis).

Staff Analysis and Conclusion

Based on MHCC staff's analysis of the HSCRC discharge data, WMRMC performed 166 cases in CY 2015, 150 cases in CY 2016, and 128 cases in CY 2017. MHCC staff notes that its case counts are very similar to those of WMRMC. MHCC staff concludes that these counts may differ due to minor differences in the definitions of adult cardiac surgery used by MHCC and WMRMC. 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.

WMRMC did not meet the requirement that it maintain an annual volume of 200 cases or more, failing to reach this target in the last three calendar years for which data is available. The trend has been declining case volume and a continuation of this trend could result in the program falling below an annual case volume of 100 cases for two consecutive years, leading to a focused review to more closely examine the quality of patient care at the program. However, at this time, the hospital is meeting the performance standards for patient outcomes, and the information submitted indicates that the program is performing well.

Staff notes that an annual volume below 200 cases is no longer a trigger for the Commission to request closure of a cardiac surgery program as it was when the WMRMC's cardiac surgery program was authorized over 18 years ago. The comprehensive update of the Cardiac Surgery Chapter undertaken after the 2012 changes to statute involved a reexamination of the relationship between case volume and outcomes in the light of more recent research literature. Although programs are expected to attain an annual volume of 200 cases or more, it also is acceptable for a program to perform less than 200 cases per year, or even less than 100 cases per year, as long as the program demonstrates the provision of high quality care. MHCC staff's review of WMRMC's mortality and morbidity rates suggests that the program continues to provide high quality care. For this reason, MHCC staff concludes that a focused review is not

warranted. If, however, WMRMC performs under 100 cases for two consecutive years, staff will initiate a focused review, as provided in COMAR 10.24.17.07B(6)(c).

IV. RECOMMENDATION

Based on the above analysis and the record in this review, Western Maryland Regional Medical Center meets the requirements for a Certificate of Ongoing Performance defined in COMAR 10.24.17.07B, with the exception of the volume standard that sets a target volume of performing 200 cases or more annually. The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a Certificate of Ongoing Performance that permits Western Maryland Regional Medical Center to continue providing cardiac surgery services for the next three years.