

**IN THE MATTER OF**

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**BEFORE THE**

**ADVENTIST HEALTHCARE**

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**MARYLAND HEALTH**

**WHITE OAK MEDICAL CENTER**

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**CARE COMMISSION**

**Docket No. 22-15-CP041**

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**STAFF REPORT & RECOMMENDATION**

**APPLICATION FOR CERTIFICATE OF ONGOING PERFORMANCE  
FOR CARDIAC SURGERY SERVICES**

**January 19, 2023**

## 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).<sup>1</sup> The law also directed MHCC to incorporate several specific requirements in its regulations.

The Cardiac Surgery Chapter, COMAR 10.24.17, 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 specified by the Commission that cannot exceed five years.<sup>2</sup> At the end of the authorized period, the hospital must again demonstrate that it continues to meet the requirements in COMAR 10.24.17.07B for the Commission to renew the hospital's authorization to provide cardiac surgery services. While the Cardiac Surgery Chapter includes cardiac surgery volume standards, MHCC waived these standards for two years, either calendar year (CY) 2020 and CY 2021 or fiscal year (FY) 2020 and FY 2021, depending on whether a hospital measures volumes by calendar year or fiscal year.<sup>3</sup> This Staff Report and Recommendation accounts for this limited waiver.

### B. Applicant

#### **Adventist HealthCare White Oak Medical Center**

Adventist Healthcare, Inc. d/b/a Adventist HealthCare White Oak Medical Center (WOMC), formerly Washington Adventist Hospital, is a 213-bed general hospital previously located in Takoma Park, Montgomery County. The Commission granted WOMC a Certificate of Need in December 2015 to relocate the hospital to the White Oak area of Silver Spring in Montgomery County and the replacement hospital became operational in 2020.

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<sup>1</sup> Md. Code Ann., Health-Gen. §19-120.1

<sup>2</sup> COMAR 10.24.17.07B(1).

<sup>3</sup> MHCC, *Bulletin-21: Changes to the Evaluation of Compliance with Performance Standards for Percutaneous Coronary Intervention (PCI) and Cardiac Surgery Programs for the Period Between January 2020 and December 2021* (Aug. 27, 2021),

[https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs\\_cardiaccare/documents/MHCC%20bulletin\\_20210827.pdf](https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiaccare/documents/MHCC%20bulletin_20210827.pdf).

## **Health Planning Region**

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17. WOMC is in the Metropolitan Washington Health Planning Region (HPR). This HPR includes Calvert, Charles, Frederick, Montgomery, Prince George's, and St. Mary's Counties in Maryland, and the District of Columbia. There are five other hospitals in this HPR that provide cardiac surgery services for adults. Two of these hospitals, Suburban and the University of Maryland Capital Region Medical Center, are in Maryland. The other three hospitals—MedStar Washington Hospital Center, George Washington University Hospital, and Howard University Hospital—are in the District of Columbia. A fourth hospital, Children's National Medical Center, operates a pediatric cardiac surgery program in the District of Columbia.

### **C. Staff Recommendation**

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

## **II. PROCEDURAL HISTORY**

WOMC filed a Certificate of Ongoing Performance application for cardiac surgery services on August 3, 2022. On September 16, 2022, WOMC submitted additional information to support its application. On November 29, 2022, and December 16, 2022, WOMC responded to questions from MHCC staff concerning its application.

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

### **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.*

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

### **Staff Analysis and Conclusion**

WOMC has substantially complied with the submission of data to the STS-ACSD and to MHCC in accordance with the established schedule. For the period between January 2018 and December 2020, the hospital submitted select information from STS reports for rolling 12-month periods, except for the period from July 2019 through June 2020. Due to a lack of staff resources,

the hospital was not able to finish data entry and review for the first two harvests for CY 2020.<sup>4</sup> STS switched to three-year reporting periods in 2021. WOMC provided one of two required three-year reports for the period from January 2019 through December 2021. WOMC did not participate in the second harvest period for 2021 due to the departure of a key staff member and the timing of replacement with a new staff member.<sup>5</sup> However, because WOMC submitted most of the reports in accordance with the established schedule and demonstrated a commitment to cooperate with the data collection requirements, MHCC staff recommends the Commission find that WOMC complies with this standard.

## **Quality**

***COMAR 10.24.17.07B(4)(a) and (b) The chief executive officer of the hospital shall certify upon request by 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. A hospital's application for a Certificate of Ongoing Performance shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.***

WOMC performs quality assurance through its quarterly morbidity and mortality meetings. Those staff included in morbidity and mortality review meetings include the cardiothoracic surgeons, intensivists, anesthesiologists, nurses, quality director, perfusionists, advanced practice providers, and hospital leadership. Hospital leadership participants may include the Chief Operating Officer and the Chief Medical Officer. The hospital provided the slides and sign-in sheets for attendees at the morbidity and mortality review meetings conducted from 2019 through September 2022. The meeting slides indicate that cases with mortalities and significant morbidities are reviewed at these meetings with opportunities for quality improvement identified and discussed.

In order to track progress on several quality outcomes, WOMC uses a standard management approach that includes comparing its performance to benchmarks from the STS and internally established goals. Some of the quality measures tracked include readmission rates and average length of hospital stay for its cardiac surgery patients.

WOMC provided a detailed algorithm for internal peer reviews including a protocol for escalation of cases for external reviews. One external review was conducted during this review period. The internal peer review process occasionally involves a Professional Practice Evaluation Committee (PPEC), and the hospital shared redacted minutes from the PPEC meetings conducted.

Anthony Stahl, President of the WOMC, submitted a letter stating that WOMC is committed to identifying areas of improvement in the quality and outcomes of the hospital's cardiac surgery program. He also stated that, annually or upon request, WOMC will provide a report of the quality assurance activities of the program.

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<sup>4</sup> Email correspondence to Eileen Fleck from Jennifer Bobbitt on September 9, 2020.

<sup>5</sup> Email correspondence to Eileen Fleck from Denise Stimpson on May 27, 2021.

## Staff Analysis and Conclusion

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

WOMC maintained an STS composite score for coronary artery bypass graft (CABG) surgeries of two stars or higher during the period from January 2018 through December 2021, as shown in Table 1. Recently, the STS noted that declining volumes of isolated CABG cases and increasing case-mix severity make it difficult to differentiate the performance levels of hospitals given STS's use of a conservative 98% credible interval in its CABG composite measure methodology.<sup>6</sup> STS updated the methodology to reflect a three-year period with a 95% credible interval in 2021. For this reason, STS also did not generate a benchmark or reports for CY 2021. It should also be noted that there were no performance reports generated for hospitals participating in the STS registry for the 12-month period ending in June 2021 due to the transition of the data warehouse for STS from one vendor to another in early 2020.<sup>7</sup>

Table 1 shows the star ratings for each of five overlapping 12-month periods and two three-year periods, the volume of isolated CABG cases included in the ratings for each period, and the overall percentage of WOMC's volume of cardiac surgery included in the STS ratings. As shown in Table 1, WOMC received a three-star STS CABG composite score rating for the periods July 2018 through June 2021, January 2019 through December 2019, and January 2019 through December 2021. In addition, isolated CABG cases accounted for between 45% and 62% of the total adult cardiac surgery volume at WOMC in each reporting period.

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. The Cardiac Surgery Chapter uses isolated CABG as a reference point based on the recommendation of both the Clinical Advisory Group and

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<sup>6</sup> The Society of Thoracic Surgeons, STS Quality Webinar Series: STS Measure Development and NQF Endorsement (Dec 2021), [https://www.youtube.com/watch?v=3\\_Gmtdtm9\\_I](https://www.youtube.com/watch?v=3_Gmtdtm9_I)

<sup>7</sup> Email correspondence between MHCC staff and STS staff on August 29, 2022.

the Cardiac Services Advisory Committee, which includes cardiac surgeons and interventional cardiologists. For an individual patient who requires a different type of cardiac surgery, the information included in Table 1 may not be relevant. However, 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: Adventist WOMC’s Cardiac Surgery Volume, Isolated CABG Volume, and Composite STS Star Ratings for CABG, by Reporting Period**

Reporting Period	Composite Star Rating <sup>1</sup>	Total Isolated CABG Cases Included <sup>2</sup>	Total Cardiac Surgery Volume <sup>3</sup>	Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating
Jan 2018 - Dec 2018	★ ★	153	312	49.0%
Jul 2018 - Jun 2019	★ ★	128	282	45.4%
Jan 2019 - Dec 2019	★ ★ ★	159	315	50.5%
Jul 2019 - Jun 2020	★ ★	N/A	301	N/A
Jan 2020 - Dec 2020	★ ★	217	349	62.2%
Jul 2018 - Jun 2021	★ ★ ★	N/A	1,042	N/A
Jan 2019 - Dec 2021	★ ★ ★	662	1,122	59.0%

Sources: MHCC compilation of information submitted by WOMC and analysis of HSCRC discharge data.

<sup>1</sup> WOMC submitted copies of its star ratings and CABG volume to MHCC for each period shortly after receiving the information from STS. The maximum number of stars awarded is three stars. Two stars indicate that a program performed similar to the national average for cardiac surgery programs participating in the STS-ACSD. N/A means the information was not available

<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 cardiac surgery in COMAR 10.24.17, effective in January 2019, and using the procedure date to categorize cases by reporting period; total cardiac surgery volume is based on MHCC staff analysis of HSCRC discharge abstract for January 2018 - December 2021. The number of isolated CABG cases included in the star ratings for July 2019 – June 2020 and July 2018 – June 2021 was not available.

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. The second component is the absence of major morbidity; major morbidity is defined to include any one of the following: reoperation, stroke, kidney failure, deep sternal infection or mediastinitis, and prolonged ventilation. 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. 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%. Nationally, most 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.

MHCC staff recommends that the Commission find WOMC complies with this standard.

***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 national 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**

WOMC’s all-cause 30-day risk-adjusted mortality rate for isolated CABG cases was similar to the national average in all reporting periods; it did not statistically significant differ from the national average for STS registry participants. Table 2 and Figure 1 below show the rates for the five 12-month periods for which data is available from the STS. MHCC staff concludes that WOMC met this performance standard and maintained a risk-adjusted mortality rate consistent with high quality patient care.

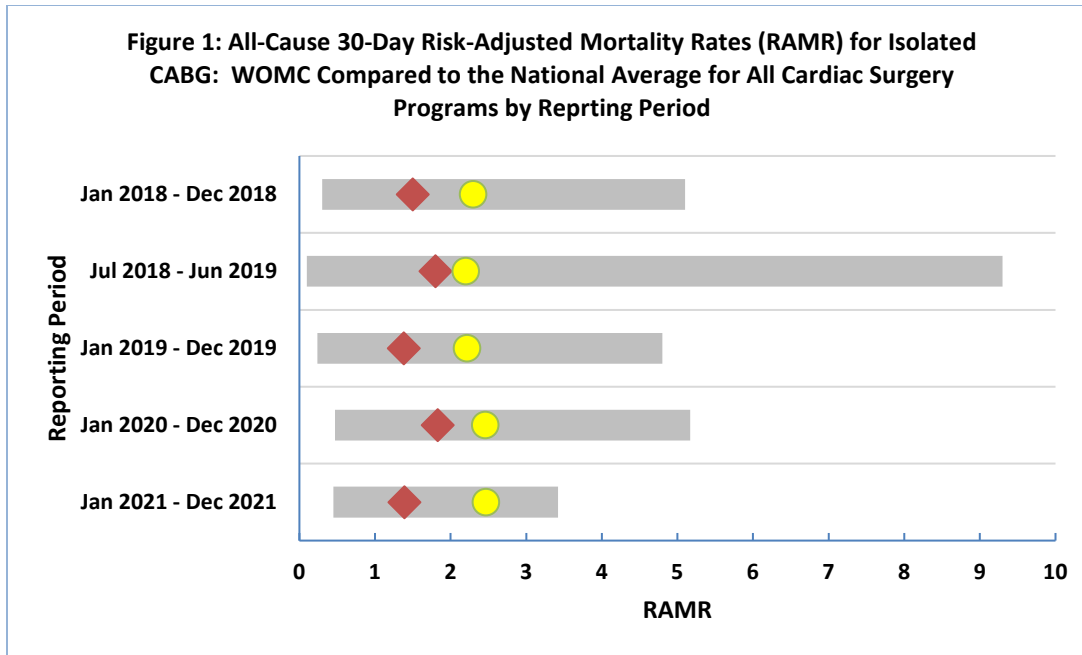
**Table 2: 30-Day All-Cause Risk-Adjusted Mortality Rates for Isolated CABG: WOMC Comparison to the National Benchmark, by Reporting Period**

	Jan 2018 - Dec 2018	Jul 2018- Jun 2019	Jan 2019- Dec 2019	Jul 2019- Jun 2020*	Jan 2020- Dec 2020	Jul 2020- Jun 2021*	Jan 2021- Dec 2021
<b>STS National Benchmark</b>	2.3	2.2	2.22		2.46		2.47
<b>WOMC</b>	1.5	1.8	1.38		1.83		1.39
<b>95% CI</b>	(0.3,5.1)	(0.1,9.3)	(0.24,4.8)		(0.47,5.17)		(0.45,3.42)

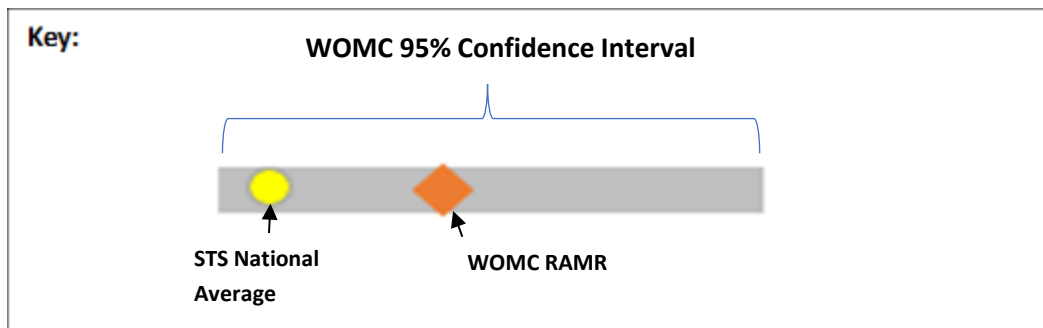
Source: STS analysis of data from all Maryland hospitals with cardiac surgery programs.

Notes: The all-cause 30-day risk-adjusted mortality rate and confidence intervals only provide information on whether a hospital has performed worse or better relative to the national average mortality rate at a statistically significant level. The mortality rates include in-hospital patient deaths following isolated CABG surgery and deaths for any reason within 30 days of isolated CABG surgery.

\* STS national benchmark data not available for these periods



Source: MHCC staff compilation of STS reports provided directly to MHCC.



**Volume Requirements**

*COMAR 10.24.17.07B(6)(a) A cardiac surgery program shall maintain an annual volume of 200 or more cases. (b) A cardiac surgery program that fails to reach an annual volume of 100 cardiac surgery cases for two consecutive years will be subject to a focused review. (c) A cardiac surgery program that fails to reach an annual volume of 100 cases for three or more consecutive years will be subject to a focused review for cases performed in the 12-month period following the prior focused review, unless the Executive Director determines that a 24-month period is appropriate, based upon considerations that include the results of the prior focused review, patient outcomes for morbidity and mortality, and the cardiac surgery program’s most recent STS star ratings.*

WOMC has maintained an annual volume of 200 or more cases in every reporting period from January 2018 through December 2021. It reported a volume of 304 cases for calendar year



(CY) 2018, 317 cases for CY 2019, 338 cases for CY 2020, 454 cases for CY 2021, and 192 cases for the period January through June 2022.

### **Staff Analysis and Conclusion**

As stated in the updated MHCC Bulletin dated August 27, 2021, although a hospital's actual performance for the period between January 2020 and December 2021 will be included in staff reports for Certificates of Ongoing Performance, compliance with case volume standards will be waived for two years (CY 2020 and CY 2021 or FY 2020 and FY 2021). WOMC reported that it performed 304 cases for CY 2018, 317 cases for CY 2019, 338 cases for CY 2020, 454 cases for CY 2021, and 192 cases for the period from January through June 2022. MHCC staff's analysis of case volume based on the Health Services Cost Review Commission discharge abstract data case counts are similar to those of WOMC; 312 cases for CY 2018, 315 cases for CY 2019, 349 cases for CY 2020, and 458 cases for CY 2021. MHCC staff concludes that these counts may differ due to minor differences in the definitions of adult cardiac surgery used by MHCC and WOMC.

### **IV. RECOMMENDATION**

Based on the above analysis and the record in this review, Commission staff recommends that the Commission find that WOMC meets the requirements for a Certificate of Ongoing Performance defined 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 WOMC to continue providing cardiac surgery services for the next four years.