

**IN THE MATTER OF**

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**BEFORE THE**

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**ADVENTIST HEALTHCARE**

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**MARYLAND HEALTH**

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**WASHINGTON ADVENTIST HOSPITAL**

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**CARE COMMISSION**

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**Docket No. CP-17-15-001**

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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 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 in 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, which reflected the recommendations of the CAG. As a result, one standard addressed by applicants was determined to be inapplicable, but information on how applicants 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 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**

#### **Washington Adventist Hospital**

Adventist HealthCare (“AHC”) Washington Adventist Hospital (“WAH”) is a 191-bed general hospital located in Takoma Park (Montgomery County). WAH established its cardiac surgery program in 1962. The Commission granted WAH a Certificate of Need in December 2015 to relocate the hospital to the White Oak area of Silver Spring in Montgomery County. The replacement hospital is under construction and is expected to be operational in 2020.

## **Health Planning Region**

For adult cardiac surgery services, there are four health planning regions defined in COMAR 10.24.17. WAH is located 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 (D.C.). There are five other hospitals in this health planning region that provide cardiac surgery services for adults. Two of these hospitals, Suburban and the University of Maryland Prince George’s Hospital Center, are located in Maryland. The other three hospitals, MedStar Washington Hospital Center, George Washington University Hospital, and Howard University Hospital are located in the District of Columbia. A fourth D.C. hospital, Children’s National Medical Center, operates a pediatric cardiac surgery program. Two D.C. hospitals in this HPR have a very low volume of adult cardiac surgery cases: (1) Children’s National Medical Center, which primarily serves pediatric patients, performed less than 30 adult cardiac surgeries, as defined in COMAR 10.24.17, in calendar year (“CY”) 2017. The second hospital with low volume is Howard University Hospital, which performed fewer than ten adult cardiac surgery cases in CY 2017.

### **C. Staff Recommendation**

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

## **II. PROCEDURAL HISTORY**

WAH filed a Certificate of Ongoing Performance application on October 25, 2017. On January 30, 2018, WAH submitted responses to questions, additional information requested by MHCC staff, 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.*

WAH participates in the Society of Thoracic Surgeons’ adult cardiac surgery data registry (“STS-ACSD”) and submits STS-ACSD data to MHCC staff as required.

## Staff Analysis and Conclusion

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

WAH described its quality assurance activities for cardiac services as including monthly meetings. In CY 2015, meetings were held in ten of the 12 months. In CY 2016, a meeting occurred each month. In CY 2017, meetings were held only seven times; five meetings were canceled. The participants invited to these meetings include cardiac surgeons, the Director for the Cardiac and Vascular Intensive Care Unit ("CVICU"), cardiovascular nurse practitioners, the Director of Anesthesiology, the Lead Cardiovascular Circulator, the Director of Radiology, the CVICU Clinical Nurse Specialist, a perfusionist, the Chief Medical Officer, and a CVICU intensivist. WAH does not record meeting minutes or attendance, but it provided the dates for quality meetings for cardiac services held in 2015 through 2017. WAH also provided copies of some of the materials presented for discussion in these meetings.

WAH explained that slides reviewed at the monthly quality meetings are based on the hospital's own data, with rolling 12-month periods updated monthly. Rather than providing a repetitious set of slides, WAH provided data for calendar year periods in its Certificate of Ongoing Performance application. At quarterly meetings, WAH reviews its Society of Thoracic Surgeons' ("STS") data, which includes: the bi-annual STS composite quality ratings with quarterly risk adjusted rates for all composite elements and in-hospital and operative mortality for major procedures; preoperative conditions such as chronic lung disease, emergency status, salvage status, and cardiogenic shock; blood use, both intraoperative and postoperative; extubation within six hours and in the operating room; complications; length of stay less than six days; length of stay greater than 14 days; and readmissions. WAH provided slides with some redaction of information on the benchmarks used, which are proprietary STS information.

WAH responded to MHCC staff's request for information on the findings and follow-up from any external reviews conducted over the review period with documentation of the findings from these reviews. In addition, WAH described its general peer review process, as follows. Adverse outcomes are reported to Adventist Risk Management. Cases are reviewed by the Chair of the Surgery Department and Medical Staff President or Chief Medical Officer, if warranted. If a case requires further evaluation, it is sent to the Chair of the Professional Practice Evaluation

Committee (“PPEC”). A written response from the physician under evaluation is requested. The PPEC reviews the case and the physician’s response. The discussion of the case is documented in meeting minutes. The minutes are reviewed by the Medical Executive Committee (“MEC”) and the Board. In addition, a response is filed in the physician’s quality file, and a letter is sent to the physician with the MEC’s decision. An educational or policy related addendum may be included with the letter sent to the physician.

The President of WAH, Erik Wangness, submitted a letter stating that the hospital is committed to identifying areas of needed improvement in the quality and outcomes of WAH’s cardiac surgery program. He also stated that WAH will provide annually or upon request a report of the quality assurance activities of the program.

### **Staff Analysis and Conclusion**

WAH provided sufficient information to document its quality assurance activities and the actions taken in response to any quality concerns identified. MHCC staff concludes that WAH 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**

WAH has consistently maintained an STS composite score for coronary 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 WAH’s volume of cardiac surgery included in the STS ratings. As shown in Table 1, approximately 63 to 70 percent of WAH’s cardiac surgery volume is included in the composite STS star ratings for the period January 2015 through June 2018. Hospitals with cardiac surgery programs typically perform multiple types of cardiac surgery or may perform CABG in combination with other 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 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: WAH's Cardiac Surgery Volume, Isolated CABG Volume, and Composite STS Star Ratings for Isolated 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>	187	187	160	166	166	167
Total Cardiac Surgery Volume <sup>3</sup>	265	246	229	244	252	253
Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating	71%	76%	70%	68%	66%	66%

Sources: WAH 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.

<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 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 two decades to function longer than a saphenous vein graft.<sup>3</sup> The fourth component is receipt of all four specific perioperative medications; these medications are believed to improve patient

<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.

outcomes.<sup>4</sup> 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%.<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 national average, 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 WAH performed on the revised standard adopted in regulations that became effective January 14, 2019.

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

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

<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: WAH Comparison to the National Average, by Reporting Period**

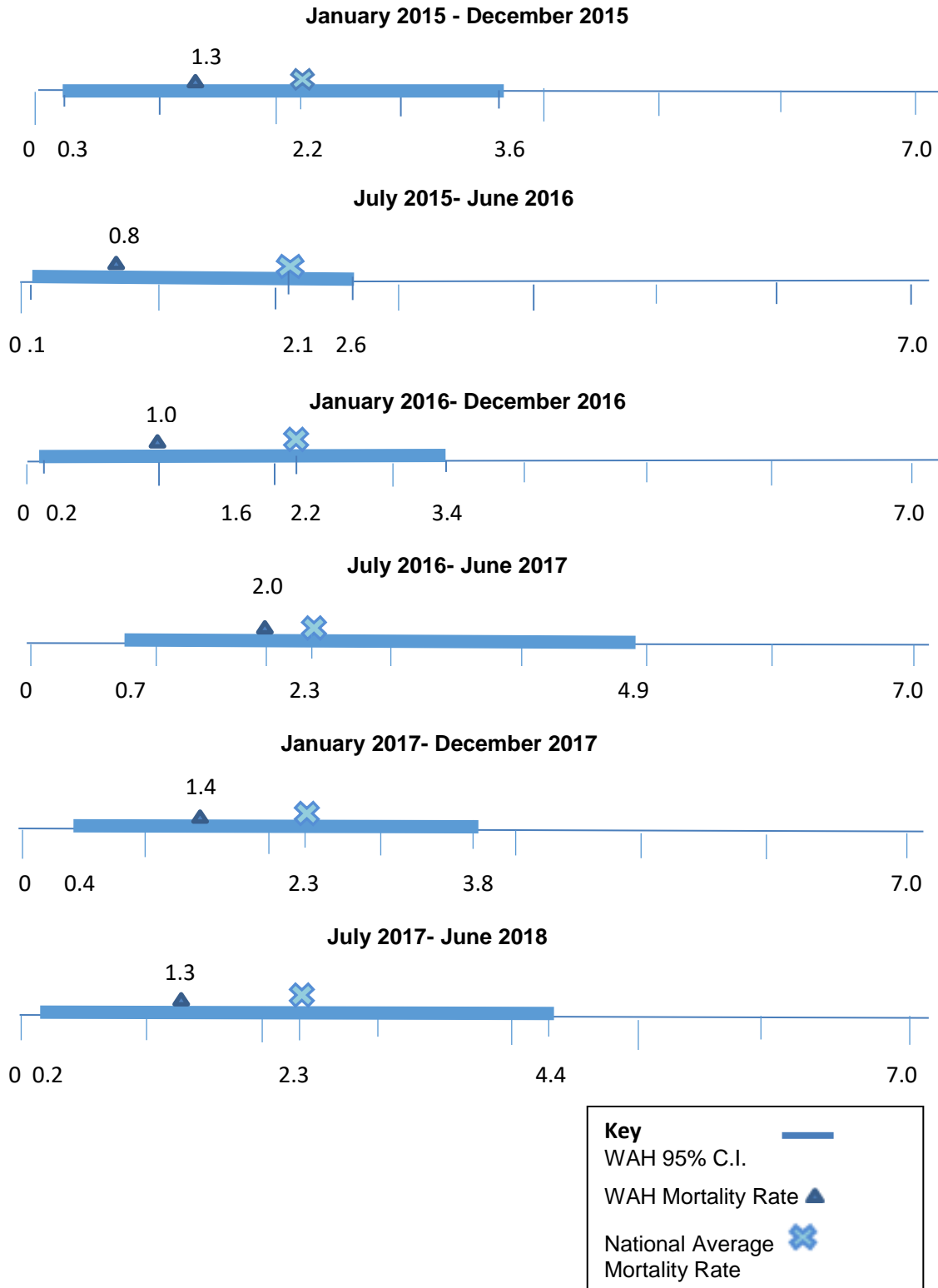
Reporting Period	All-Cause Risk-Adjusted Isolated CABG Operative Mortality			95% Confidence Interval		
	Jan 2015 - Dec 2015	Jul 2015 - Jun 2016	Jan 2016 - Dec 2016	Jan 2015 - Dec 2015	July 2015 - Jun 2016	Jan 2016 - Dec 2016
WAH	1.3	0.8	1.0	(0.3, 3.6)	(0.1, 2.6)	(0.2, 3.4)
National Average	2.2	2.1	2.2	--	--	--
<b>Reporting Period</b>	July 2016- June 2017	Jan. 2017- Dec. 2017	July 2017- June 2018	July 2016- June 2017	Jan. 2017- Dec. 2017	July 2017- June 2018
WAH	2.0	1.4	1.3	(0.7, 4.9)	(0.4, 3.8)	(0.2, 4.4)
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 than 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: WAH 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 of 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.

**Additional Information on WAH’s Performance**

MHCC staff provided each hospital that submitted an application for a Certificate of Ongoing Performance in October 2017 with the opportunity to voluntarily include additional information on composite star ratings developed by the Society of Thoracic Surgeon’s for inclusion in this MHCC staff report. MHCC staff only required that hospitals provide the composite star ratings from STS for isolated CABG cases in their applications for Certificates of Ongoing Performance and their periodic submissions of STS data and select information on their performance from STS reports. The inclusion of additional STS composite star ratings provides a fuller picture of the performance of a hospital across multiple types of cases.

In order to develop statistically valid ratings for a comparison of hospitals, a critical volume of cases is required. STS determined that three years of data for aortic valve replacement (AVR) surgeries should be combined for its composite star ratings of AVR cases, combined CABG and AVR cases, and mitral valve repair or replacement (MVRR) cases. As a result, there is only one set of ratings available for the time period considered for WAH’s Certificate of Ongoing Performance application. Table 3 shows the composite star ratings for AVR, combined CABG and AVR cases, and MVRR cases, for the 36-month reporting period for cases performed between July 2014 and June 2017. As shown in Table 3, WAH performed similar to the national average for both AVR and combined CABG and AVR cases, achieving two stars for both categories. For MVRR cases, WAH performed achieved three stars, indicating its performance on these cases was superior to the national average.

**Table 3: WAH’s Composite Star Ratings for AVR, AVR +CABG, and MVRR for July 2014 through June 2017**

Category	Composite Star Rating <sup>1</sup>
AVR	★★
AVR+CABG	★★
MVRR	★★★

Source: Select pages from WAH’s STS reports provided to MHCC staff.

<sup>1</sup> The maximum number 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. The specific criteria that determine the star ratings for each category of cases (AVR, AVR+CABG, MVRR) varies.

The specific components of the STS composite star ratings vary, as described in the STS report overview that is included with individual hospitals' performance reports.<sup>7</sup> Isolated CABG composite star ratings include four domains, covering both processes and outcomes. In contrast, the AVR, combination AVR and CABG, and MVRR composite star ratings include two outcome domains, risk-adjusted mortality, and risk-adjusted morbidity. Morbidity includes the same complications as those included in other composite star ratings, such as CABG. For AVR, combination AVR and CABG, and MVRR composite scores, a hospital with at least a 97.5% probability that its performance was higher or lower than average receives three stars or one star, respectively. Programs that perform too few cases in a specific category do not receive a composite star rating because STS sets volume thresholds for these ratings.

### **Volume Requirements**

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

WAH reported that the STS database with cardiac surgery cases performed at WAH between June 30, 2015 and June 30, 2017, includes 557 cases. WAH explained that one case that is included in the Health Services Cost Review Commission ("HSCRC") database is not included in the STS database because the STS does not require that a hospital enter a single case for a surgeon who does not practice at the hospital regularly. WAH also noted that 13 other discharges are not included in the STS database because the patients' ages were all under 18. The STS database for adult cardiac surgery only includes patients who are 18 years or older. In addition, 11 other discharges are not included in the STS database because the procedures were stand-alone procedures that the STS does not include, such as lead insertions, generator changes, intra-aortic balloon pump placement, and video-assisted thoracoscopic surgery.

### **Staff Analysis and Conclusion**

MHCC staff analyzed the HSCRC data for WAH, and the information reported to the STS-ACSD by WAH. MHCC staff's analysis of the HSCRC data showed that WAH performed 273 cases in fiscal year ("FY") 2015, 246 cases in FY 2016, 244 cases in FY 2017, and 253 cases in FY 2018. Although the total number of cases calculated by MHCC staff for the period between July 1, 2015 and June 30, 2017 is less than the volume reported by WAH for virtually the same period of time, MHCC staff notes that the definition of cardiac surgery changed in November of 2015 with the adoption of revised regulations, COMAR 10.24.17. 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 WAH meets the annual volume requirement, by exceeding a volume of 200 cardiac surgery cases for the three most recent fiscal years for which data is available.

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<sup>7</sup> Society of Thoracic Surgeons. (June 2018). Report Overview- Risk Adjustment Supplement STS Report- Period Ending 12/31/2017.

#### **IV. RECOMMENDATION**

Based on the above analysis and the record in this review, MHCC staff concludes that AHC Washington Adventist Hospital meets all of the requirements for a Certificate of Ongoing Performance 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 for a four-year period that permits AHC Washington Adventist Hospital to continue providing cardiac surgery services.