IN THE MATTER OF THE	*	**BEFORE THE**
LUMINIS ANNE ARUNDEL	*	**MARYLAND HEALTH**
MEDICAL CENTER	*	**CARE COMMISSION**
Docket No. 23-02-CP043	*	

* *

STAFF REPORT & RECOMMENDATION

APPLICATION FOR CERTIFICATE OF ONGOING PERFORMANCE FOR CARDIAC SURGERY SERVICES

January 16, 2025

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 MHCC established a process and minimum standards for obtaining and maintaining a Certificate of Ongoing Performance that incorporates recommendations on standards for cardiac surgery services and PCI services from a Clinical Advisory Group (CAG).[1]

The Cardiac Services 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, unless an extension is granted by the Executive Director.[2] 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.

In between renewals for a Certificate of Ongoing Performance, if a hospital is not in compliance with certain standards, a focused review must be conducted. Commission staff also have the authority to conduct a focused review based on reported patient safety concerns, aberrations in data, or failure to meet quality standards established in State and federal regulations.[3] A hospital that is identified as failing to meet one or more of the requirements for a Certificate of Ongoing Performance must receive a detailed list of deficiencies identified in the focused review and submit a plan of correction to Commission staff within 30 days of receipt of the list of deficiencies.[4] If a hospital does not submit a plan of correction that addresses the deficiencies cited or successfully complete a plan of correction, the hospital shall, upon notice of the Executive Director of the Commission, voluntarily relinquish its authority to perform cardiac surgery or emergency or elective PCI services, as applicable.[5]

While the Cardiac Services 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 CY or FY.[6] This Staff Report and Recommendation accounts for this temporary waiver.

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[1] Md. Code Ann., Health-Gen. §19-120.1
[2] COMAR 10.24.17.07B(1).
[3] COMAR 10.24.17.07B(2)(a), .07C(2)(a), and .07D(2)(a).
[4] COMAR 10.24.17.07B(2)(c), .07C(2)(c), and .07D(2)(c).
[5] COMAR 10.24.17.07B(2)(e), .07C(2)(e), and .07D(2)(e).
[6] 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.

B. Applicant

Luminis Anne Arundel Medical Center

The Luminis Anne Arundel Medical Center (AAMC) is a 377-bed general acute care hospital located in Anne Arundel County, Maryland. The hospital applied for its cardiac surgery Certificate of Need (CON) on February 20, 2015.[7] On December 30, 2016, the MHCC reviewer recommended approval of AAMC's application to introduce cardiac surgery services with conditions. An interested party, the University of Maryland Baltimore Washington Medical Center, filed exceptions to the recommended decision on January 11, 2017. Ultimately, a revised recommended decision was approved by MHCC on March 3, 2017. On April 11, 2017, a lawsuit was filed, in the Circuit Court of Maryland for Prince George's County, appealing MHCC's decision to grant a CON for cardiac surgery to AAMC. That lawsuit was subsequently withdrawn by the appellant, and the lawsuit was dismissed, in May of 2019. AAMC's cardiac surgery program began in late December 2020.

Health Planning Region

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17. AAMC is in the Baltimore/Upper Shore Health Planning Region (HPR). This region includes Baltimore City and Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot counties. Five other hospitals in this HPR provide cardiac surgery services for adults: The University of Maryland Medical Center; University of Maryland St. Joseph Medical Center; The Johns Hopkins Hospital; MedStar Union Memorial Hospital; and Sinai Hospital of Baltimore.

C. Staff Recommendation

MHCC staff recommends that the Commission approve AAMC's application for a Certificate of Ongoing Performance to continue providing cardiac surgery services for four years with two conditions. A description of the information provided by AAMC and MHCC staff's analysis follows.

II. PROCEDURAL HISTORY AND COMPLIANCE WITH CON CONDITIONS

AAMC filed a Certificate of Ongoing Performance application for cardiac surgery services on November 3, 2023. Staff requested additional information on March 4 and December 13, 2024. AAMC provided responses on March 26, 2024, and December 23, 2024. MHCC staff allowed several months to pass before asking additional questions because we did not have the ability to verify the volume of cardiac surgery cases for CY 2023 until June of 2024, and we wanted to allow more time to see whether plans that were expected to lead to higher volumes of cardiac surgery appeared to be effective. The questions posed to AAMC pertained to compliance with conditions

[7] At that time, AAMC was not part of the Luminis hospital system. The original 2015 proposal was for AAMC to develop a cardiac surgery, research, and training program in partnership with Johns Hopkins Medicine.

on its CON for the cardiac surgery program. There were four conditions on AAMC's CON for the cardiac surgery program:

> *1. If the cardiac surgery program at Anne Arundel Medical Center fails to achieve a volume of at least 200 cardiac surgery cases in its second year of operation, Anne Arundel Medical Center will fully cooperate with the Maryland Health Care Commission's required evaluation of closure of the program, under COMAR 10.24.17.04B(1)(b).*
>
> *2. The Johns Hopkins Hospital will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has as any part of its basis, the lost revenue generated by cardiac surgery services that have shifted to Anne Arundel Medical Center.*
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> *3. Anne Arundel Medical Center will not approach the Health Services Cost Review Commission to request an increase in global budgeted revenue that has, as any part of its basis, the objective of obtaining additional revenue from the provision of cardiac surgery services.*
>
> *4. Anne Arundel Medical Center's cardiac surgery program and cardiothoracic surgeons will participate in the Society of Thoracic Surgeons National Database and provide the required data set from its STS Database submissions to Maryland Health Care Commission for use in on-going performance review of its cardiac surgery program.*

The second condition is no longer applicable because the partnership with Johns Hopkins Hospital (JHH) ended before AAMC began its program. For the third condition, staff notes that AAMC has not received an increase in its global budgeted revenue because the HSCRC staff is aware of the CON condition and supports the criteria set by the MHCC. For the fourth condition, AAMC has been submitting the required data.

AAMC did not meet the first condition of its CON because it failed to achieve a volume of at least 200 cases in its first two years of operation. During the first year of operation, the annual cardiac surgery volume standard was waived for all hospitals due to the COVID-19 pandemic. However, in the two subsequent years, approximately CY 2022 and CY 2023, the hospital also did not achieve a volume of over 200 cases.

In accordance with the condition, MHCC staff evaluated whether AAMC's cardiac surgery program should be required to close. The evaluation was based on whether the benefits expected to be realized by awarding AAMC a CON for its cardiac surgery program were achieved or seem likely to be achieved. Those benefits include the provision of high-quality cardiac surgery, improved access, and lower costs relative to other cardiac surgery programs. MHCC staff also considered whether the hospital would likely achieve a volume of 200 or more cases within the next year, approximately five years after initiating the program.

The volume of cardiac surgery cases at AAMC in 2021, 2022, and 2023 was 117, 106, and 93 cases respectively. The volume standards for cardiac surgery programs in COMAR 10.24.17 were waived for 2020 and 2021 due to the COVID-19 pandemic.[8] AAMC explained its challenges with achieving a volume of 200 cardiac surgery cases annually by the end of 2022 and 2023 and its plans and progress towards reaching the standard in its responses to staff questions in March and December 2024. In March 2024, AAMC noted that one cardiac surgeon left, and with only one other cardiac surgeon, there were limited opportunities to expand access to cardiac surgery. AAMC had only one cardiac surgeon for about a year. AAMC explained that it was able to recruit a new cardiac surgeon who would begin performing cardiac surgeries in May 2024. AAMC also explained that it initiated a transcatheter aortic valve replacement (TAVR) program in June 2023, and this program is expected to result in higher cardiac surgery case volume for AAMC for CY 2024.

AAMC has reported significant progress towards achieving an annual volume of 200 cardiac surgery cases in the past year. AAMC reported that 180 cardiac surgery cases, as defined in MHCC's regulations, have been performed between December 2023 and November 2024. AAMC attributes the growth in case volume to the addition of a new Chief of Cardiac Surgery, David Caparrelli, M.D., in May 2024. This new cardiac surgeon uses new techniques that distinguish AAMC from other cardiac surgery programs. AAMC explained that Dr. Caparrelli has introduced cryo nerve block therapy, an adjunct technique that provides long-lasting pain relief to patients who have open heart surgery, allowing for reduced patient recovery and reduced or eliminated use of narcotics post-open-heart procedure. AAMC reported that it is currently the only center in Maryland offering this innovative approach to pain control. AAMC also attributed its progress increasing cardiac surgery volume to its collaboration with Kaiser Permanente, which has resulted in 56 cardiac surgeries between December 2023 and November 2024.

AAMC noted another reason for the recent increase in case volume that is anticipated to positively impact future program development. AAMC is able to provide surgery to higher risk patients with the addition of the Impella heart pump assistive support device. The hospital explained that being able to treat higher risk patients reduces the hospital's reliance on transfers to regional academic or out-of-state centers. Further, AAMC expects that it will be able to achieve a higher volume of cardiac surgeries because it is working on developing a comprehensive center for the treatment of atrial fibrillation, a large subset of patients that AAMC reports are currently undertreated.

Staff concludes that while AAMC has not achieved a volume of 200 cases, the hospital has reported credible efforts to grow volume and significant progress in growing the volume of cardiac surgery performed at the hospital. Staff is not able independently verify the volume of cardiac surgery cases at AAMC yet, but AAMC has provided credible reasons for growth in its cardiac surgery case volume. AAMC also appears to have credible plans for continuing to grow its cardiac surgery case volume over the next few years.

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[8] 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.

III. IMPACT OF AAMC PROGRAM ON ACCESS, QUALITY, and COST

In addition to considering AAMC's compliance with the CON conditions to establish a cardiac surgery program, MHCC staff's evaluation considered the impact of AAMC's program on access, quality, and cost of cardiac surgery services, in determining whether to recommend that AAMC's cardiac surgery program be closed. As reflected in the final staff report for the CON decision (Docket No. 15-02-2360), the Commission expected that approval of AAMC's CON to establish a cardiac surgery program would improve access to cardiac surgery services while maintaining good quality care at a reduced cost.

Access

Approval of AAMC's cardiac surgery program was expected to improve access to cardiac surgery services for residents of the Eastern Shore by reducing travel times.[9] AAMC also stated that access would be improved for residents of Anne Arundel County and residents of other counties in its service area, including Prince George's County.

MHCC staff reviewed HSCRC discharge data to assess AAMC's success in expanding cardiac surgery access to residents of the Eastern Shore. As shown in Table 1, the total volume of cases for residents of the Eastern Shore declined by 21.2% in CY 2023 as compared to 2019. Staff compared the volume of cases in 2019 to CY 2023 instead of using CY 2020 because of the COVID-19 pandemic in 2020, which led many hospitals to primarily perform emergency or urgent cardiac surgeries.

Table 1: Cardiac Surgery Volume for Residents of the Eastern Shore, by Location, CY 2019-CY 2023

Location	2019	2020	2021	2022	2023	Average Annual Case Volume 2021-2023	Percent Change 2019-2023
All Maryland Hospitals	391	297	375	402	323	367.0	-21.2%
AAMC	N/A	0	20	19	11	16.6	N/A

Source: MHCC staff analysis of HSCRC discharge abstract data, CY 2019, CY 2021-CY 2023.
Notes: Due to the COVID-19 pandemic, cardiac surgery volume was lower in 2020 than it likely otherwise would have been. N/A means not applicable.

In March 2024, AAMC stated that it planned to provide a stronger presence in Kent Island. However, AAMC reported in December 2024 that it deferred the expansion of its ambulatory access plans for the Eastern Shore because of strong growth in its cardiac surgery program the latter half of CY 2024. AAMC reported that it performed 12 cardiac surgeries for residents of the Eastern Shore between December 2023 and November 2024. This case volume is lower than the average number of cardiac surgery cases that AAMC appears to have performed on residents of the Eastern Shore between CY 2021 and CY 2023, an average of 16.6 cases each year, as shown in Table 1.

[9] Revised Recommended Decision Cardiac Surgery Review for the Baltimore/Upper Shore Region. Docket Nos.: 15-02-2360 and 15-02-2361. March 3, 2017.

In terms of access for residents of Prince George's County, there has been an increase of about 30 to 35 cardiac surgery cases in each calendar year from 2021 through 2023, as compared to CY 2019, as shown in Table 2. Across those three years, about half of the increase in the number of cardiac surgeries performed above the baseline number for Prince George's County residents in 2019 was performed at AAMCs (54 of 100) or an average of 16.6 cardiac surgery cases each year. Staff consider CY 2019 the baseline for determining a change in cardiac surgery volume because it is the most recent year available prior to the implementation of AAMC's cardiac surgery program that is reliable. CY 2020 is not a reliable year for comparison to CY 2023 cardiac surgery volumes because of the statewide reduction in cardiac surgeries in 2020 due to the COVID-19 pandemic.

Table 2: Cardiac Surgery Volume for Residents of Prince George's County, by Location, CY 2019-CY 2023

Location	2019	2020	2021	2022	2023	Average Annual Case Volume 2021-2023	Percent Change 2019-2023
All Maryland Hospitals	194	177	226	231	225	227.3	13.8%
AAMC	0	0	14	28	8	16.6	N/A

Source: MHCC staff analysis of HSCRC discharge abstract data, CY 2019, CY 2021-CY 2023.
Notes: Due to the COVID-19 pandemic, cardiac surgery volume was lower in 2020 than it likely otherwise would have been. N/A means not applicable.

There are some measures that AAMC reported that may have led to an increase in cardiac surgery for Prince George's County residents. In June 2023, AAMC established an ambulatory office for cardiology services at Doctor's Community Hospital as part of establishing an ambulatory access point for residents of Prince George's County. Also, in December 2024, AAMC opened a new Greenbelt multi-specialty practice, which includes space designated for cardiovascular services as well as primary care and other medical specialty services. AAMC reported that between December 2023 and November 2024, a total of 27 cardiac surgeries performed at AAMC were on residents of Prince George's County. This is a significant increase compared to the average number of cardiac surgeries performed on Prince George's County residents from CY 2021 through CY 2023, 16.6 cases on average annually.

Staff concludes that there is evidence that AAMC has expanded access to cardiac surgery for Prince George's County residents but has not increased access for residents of the Eastern Shore, based patient origin information for patients who had cardiac surgery at a Maryland hospital. Staff concludes that AAMC has partially met the goal of expanding access to cardiac surgery for Maryland residents.

Quality

As will be discussed later in this report in greater detail, on pages 11-14, AAMC has continuously met the quality standards that cardiac surgery programs in Maryland must achieve from inception in December 2020, through the present. AAMC's performance on quality metrics developed by the Society of Thoracic Surgeons (STS) that are referenced in the Cardiac Services Chapter, has been statistically similar to national benchmarks.

Staff concludes that AAMC's cardiac surgery program is providing quality care because the program performs statistically similar to other programs on key performance metrics from STS. These metrics include a composite star rating that has components for morbidity, mortality, appropriate medications, and a recognized surgical best-practice, as well as the star ratings for each of those components. The hospital's operative mortality rates over 12-month periods for isolated coronary artery bypass graft cases have also been statistically similar to the national benchmark for this metric.

Cost

In addition to improving access, another basis for AAMC's CON approval was the opportunity to provide more cost-effective care, by shifting cardiac surgery cases from higher cost programs to a lower cost program. The reviewer specifically stated the following on pages 121 and 122 of the recommended CON decision issued March 3, 2017:

> *As health care delivery technologies evolve, it is important that the health system reduce the costs of technologies and this is one important option that allows taxpayers to receive the financial benefit of innovation that reduces costs. It has been an important health policy objective in Maryland to search for strategies to improve the cost-effectiveness of care in the hospital setting. I believe this type of project is a strong positive cost-effective strategy for developing cardiac surgery in Maryland at this point in time.*

For FY 2023, AAMC's cardiac surgery program had a charge per case that falls in the middle as compared to other Maryland cardiac surgery programs. As shown in Table 3, for FY 2023, half of the other cardiac surgery programs have higher average charges per case and half have a lower average charge per case.

Table 3: Number of Cardiac Surgery Cases by Hospital, Total Charges, and Average Charges Per Case, FY 2023

Hospital	Number of Cardiac Surgery Cases	Total Charges	Average Charge Per Case
University of Maryland (UM) Medical Center	710	138,775,754	195,459

The Johns Hopkins Hospital	968	136,931,653	141,458
MedStar Union Memorial Hospital	237	24,925,373	105,170
UM Capital Regional Medical Center	97	9,614,679	99,120
UPMC Western Maryland	98	7,213,924	73,611
Luminis Anne Arundel Medical Center	106	7,796,794	73,555
Sinai Hospital	236	16,542,835	70,097
Suburban Hospital	240	16,451,633	68,548
UM St. Joseph Medical Center	523	34,983,811	66,891
Adventist White Oak Medical Center	311	19,468,206	62,599
TidalHealth Peninsula Regional	269	16,790,667	62,419

Source: HSCRC and MHCC staff analysis of HSCRC discharge abstract data for FY 2023.
Notes: Cardiac surgeries included are those records defined as cardiac surgery in COMAR 10.24.17.

AAMC's analysis of the FY 2024 data for Maryland cardiac surgery programs shows that its average charge per case is $69,020, which is $42,500 less than the state average of $111,517 and less than half the average charge of the highest cost centers in the state, as shown in Table 4. However, AAMC has advised MHCC that the hospital's current regulated rates are inadequate to cover its operational costs.

Table 4: AAMC's Analysis of Adult Cardiac Surgery Volume, Charges, and Average Length of Stay (ALOS), FY 2024

Hospital	Cases	Avg Charge	ALOS
University of Maryland Medical Center	623	$ 198,741	15.97
Johns Hopkins Hospital	963	$ 126,509	14.07
UM Capital Region	134	$ 116,006	10.16
MedStar Union Memorial	382	$ 108,679	10.21
Suburban Hospital	204	$ 81,362	9.47
Western MD Health System	113	$ 77,707	8.37
Lifebridge Sinai Hospital	202	$ 72,059	7.35
UM Saint Joseph	537	$ 70,989	7.68
Adventist HealthCare White Oak Medical Center	263	$ 70,848	8.22
Anne Arundel Medical Center	**116**	**$ 69,020**	**7.72**
Peninsula Regional	293	$ 67,267	8.40
Total (All Hospitals)	**3,830**	**$ 111,517**	**11.17**
Average Without UMMC & JHH	**2,244**	**$ 80,867**	**8.59**

Source: AAMC's response to additional questions, December 23, 2024.

Staff concludes that AAMC is providing quality cardiac surgery services at a lower cost than several other Maryland hospitals. The goal of providing more cost-effective care to Maryland residents is being achieved.

Recommendation

Based on AAMC's achievement in providing quality cardiac surgery at a lower cost, staff recommends that AAMC's cardiac surgery program be allowed to continue to operate, despite not achieving a volume of 200 cases within the first two years of operation. There is evidence that AAMC has expanded cardiac surgery access to residents of Prince George's County, but not for residents of the Eastern Shore. Staff recommends that the following condition be included on the hospital's Certificate of Ongoing Performance, if approved by the Commission:

> AAMC shall continue efforts to improve access to cardiac surgery services for Maryland residents in Prince George's County and the Eastern Shore. AAMC shall report annually by December 31 each year on its progress improving access to cardiac surgery services, until the MHCC releases the hospital from this condition.

Although AAMC appears to have a credible plan for achieving a volume of 200 cardiac surgery cases within the next year or two, staff also recommends that a condition be included on the hospital's Certificate of Ongoing Performance for additional reporting on its plans to achieve a volume of 200 cardiac surgery cases, if AAMC is not able to achieve a volume of 200 cardiac surgery cases by the end of CY 2025. Staff recommends that the following condition be included on the hospital's Certificate of Ongoing Performance, if approved by the Commission:

> If AAMC fails to achieve an annual volume of 200 cardiac surgery cases by the end of CY 2025, then AAMC shall report by June 30, 2026, on its strategic plan for achieving a volume of 200 cardiac surgery cases annually, by June 30th each year, until AAMC achieves an annual volume of 200 cardiac surgery cases or is released from this condition by the MHCC. The strategic plan should address why strategies previously expected to increase cardiac surgery volume have not been successful and describe new strategies for achieving a volume of 200 cardiac surgery cases annually.

IV. PROJECT CONSISTENCY WITH REVIEW STANDARDS

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.

AAMC 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.

Staff Analysis and Conclusion

AAMC has complied with the submission of STS-ACSD data to MHCC in accordance with the established schedule. For the period between December 2021 and June 2024, the hospital

submitted the required subset of information from its STS reports. MHCC staff concludes that AAMC 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.

AAMC provided detailed documentation of the quality assurance activities associated with its cardiac surgery program. The documentation includes minutes and materials for quality assurance meetings and evaluations of individual surgeons with respect to specific performance metrics. The hospital also provided detailed information on quality oversight and leadership accountability for the hospital overall. AAMC uses a 3-pronged process to engage in quality assurance activities for cardiac services. These are as follows:

(1) Surgical Services Quality Forum (SSQF)
(2) Surgical Peer Review Committee (SPRC)
(3) Cardiovascular Steering Committee

The SSQF is a monthly forum in which operational and core-quality metrics are presented for review and discussion with the hospital's surgical teams and includes a rotational program review led by the Surgical Service Line Chiefs / Program Directors, a monthly Morbidity & Mortality discussion, and a grand rounds presentation.

The SPRC is a multi-step, multi-disciplinary process. The first step consists of case reviews completed by the Department of Surgery, led by the Associate Chair for Surgical Quality. Cases identified for review are compiled and data is obtained about the cases from multiple sources. Any cases identified though this initial monthly review that involve process or behavioral concerns are addressed separately by the appropriate leadership team. Conversely, cases that are identified to have a quality concern are elevated to an additional step, which is a review by one of the members of the SPRC, and then discussed at a monthly meeting by all committee members. If the SPRC believes it would benefit from additional expertise not available through the members of the committee, that expertise is sought from other physicians within the institution that are appropriate subject matter experts. If not available internally, external expertise can be sought. At the conclusion of the committee's review, cases are voted on with either an adjudication being made with directions communicated back to the involved parties, or with the case being escalated to the Medical Staff Quality Review Council (MSQRC). Cases are discussed within the MSQRC, and the medical staff member(s) involved are invited to discuss the case with the committee. Results of the discussions at MSQRC are reported through the hospital Medical Executive Council.

The AAMC Cardiovascular Steering Committee meets quarterly and reviews all operational and quality issues pertaining to the delivery of Cardiovascular services. Cardiac Surgery quality

data is presented on a routine basis including Society of Thoracic Surgeons data, infection reports, interoperative red blood cell usage, and ICU trends related to prolonged intubation.

Dr. Sherry Perkins, President of AAMC, submitted a letter, dated October 27, 2023, reaffirming that AAMC remains committed to ensuring the highest level of quality and patient outcomes in its Cardiac Surgery Program. She also stated that, annually or upon request, AAMC will provide a report of the quality assurance activities of the program.

Staff Analysis and Conclusion

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

AAMC maintained an STS composite score for coronary artery bypass graft (CABG) surgeries of two stars during the period from December 2020 through December 2023. Recently, 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.[10] 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. The three-year period reports for AAMC also show an overall rating of two stars. It should also be noted that STS did not generate performance reports 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.[11]

Table 5 shows the star ratings for each of three 3-year periods, the volume of isolated CABG cases for each rating period, and the overall percentage of AAMC's volume of cardiac surgery included in the STS ratings. As shown in Table 5, AAMC received a two-star STS CABG composite score rating in each reporting period. In addition, isolated CABG cases accounted for

[10] 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
[11] Email correspondence between MHCC staff and STS staff on August 29, 2022.

between 60.7% and 73.8% of the total adult cardiac surgery volume at AAMC 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 5 are based only on isolated CABG procedures. The Cardiac Surgery Chapter uses isolated CABG as a reference point based on both the recommendation of the Clinical Advisory Group and 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 5 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 5: AAMC's Cardiac Surgery Volume, Isolated CABG Volume, and Composite STS Star Ratings for CABG, by Reporting Period

Reporting Period[1]	Composite Star Rating[2]	Total Isolated CABG Cases Included[3]	Total Cardiac Surgery Volume[4]	Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating
Jan 2019 – Dec 2021	☆☆	85	128	66.4%
Jul 2019 – Jun 2022	☆☆	108	174	62.1%
Jan 2020 – Dec 2022	☆☆	167	223	74.9%
Jul 2020 – Jun 2023	☆☆	206	280	73.6%
Jan 2021 – Dec 2023	☆☆	225	316	71.2%

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

[1] Although the STS reporting period is 3 years, due to the timing of the opening of AAMC's cardiac surgery program, the only reporting period with 3 full years of data is the Jan. 2021 through Dec. 2023 report.

[2] AAMC 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.

[3] Isolated CABG cases are cases in which only CABG is performed. The number of eligible procedures range within the components of the star rating; the number in the table reflects the number of eligible procedures for the mortality component.

[4] 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; total cardiac surgery volume is based on MHCC staff analysis of HSCRC discharge abstract for January 2019 – June 2023.

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 concludes that AAMC 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

AAMC'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 differ to a statistically significant degree from the national average for STS registry participants. Table 6 and Figure 1 below show the rates for the two 12-month periods, and one 6-month period, for which data is available from STS. MHCC staff concludes that AAMC hospital met this performance standard and maintained a risk-adjusted mortality rate consistent with high quality patient care.

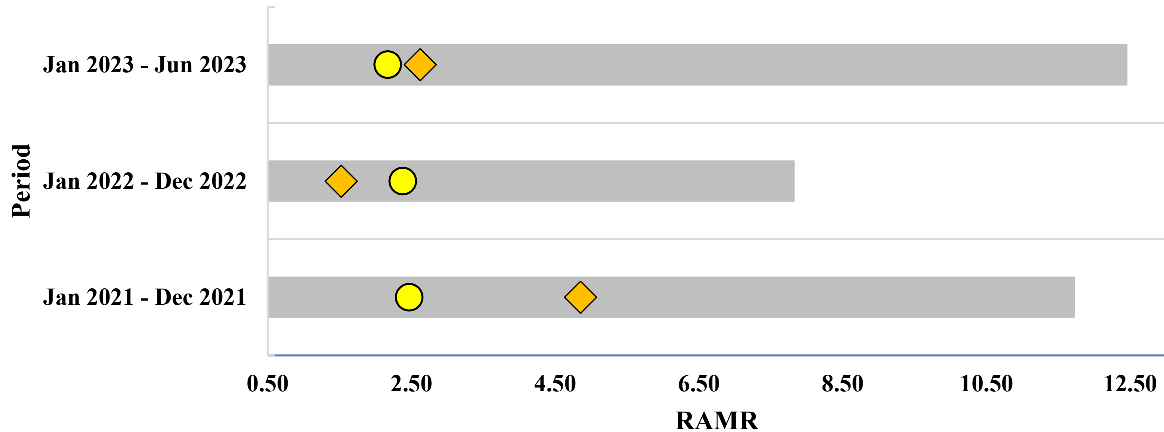
Table 6: 30-Day All-Cause Risk-Adjusted Mortality Rates for Isolated CABG: AAMC Comparison to the National Benchmark, by Reporting Period

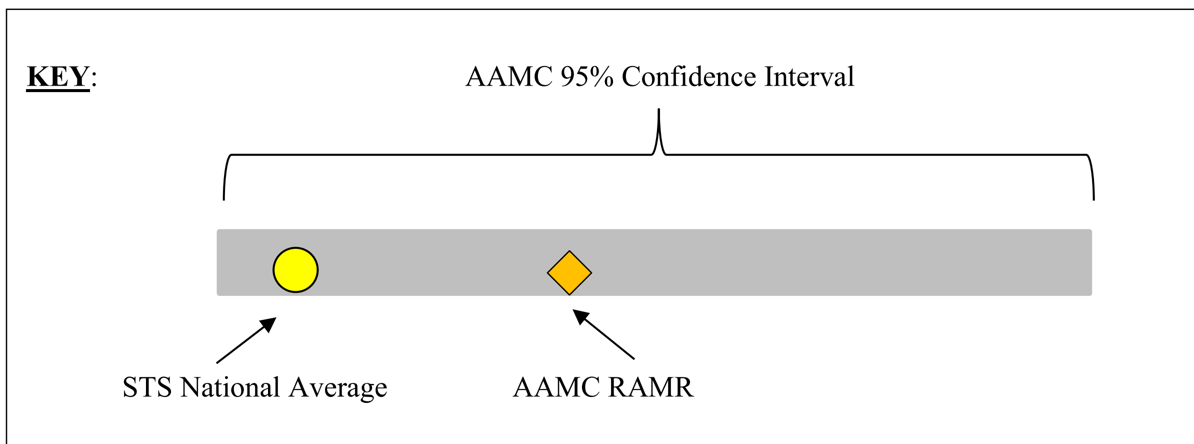
	Jan 2021 - Dec 2021	Jan 2022 - Dec 2022	Jan 2023 - Dec 2023
STS National Benchmark	2.47	2.38	2.17
AAMC	4.85	1.52	3.54
95% Confidence Interval	(1.28, 13.01)	(0.08, 7.91)	(0.62, 11.48)

Source: STS analysis of data from all National 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.

Figure 1: All-Cause 30-Day Risk-Adjusted Mortality Rates (RAMR) for Isolated CABG: AAMC Compared to the National Average for All Cardiac Surgery Programs by Reporting Period





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.

In its application, AAMC reported annual volumes of 63 cases for fiscal year (FY) 2021, 112 cases for FY 2022 and 105 cases for CY 2023. In response to questions from MHCC staff in December 2024, AAMC reported that it has performed 180 cardiac surgery cases for the period from December 2023 to November 2024.

Staff Analysis and Conclusion

As stated in the updated MHCC Bulletin dated August 27, 2021, although a hospital's actual annual cardiac surgery volume for the period between January 2020 and December 2021 will be included in staff reports for Certificates of Ongoing Performance, the case volume standards were waived for CY 2020 and CY 2021. MHCC staff's analysis of cardiac surgery case volume for AAMC, calculated based on the definition of cardiac surgery in COMAR 10.24.17, was seven cases for CY 2020, 117 cases for CY 2021, 106 cases for CY 2022 and 93 cases for CY 2023. MHCC staff is not able to verify the number of cases reported by AAMC for December 2023 through November 2024. MHCC staff's analysis of case volume based on the Health Services Cost Review Commission (HSCRC) discharge abstract data case counts are similar to those of AAMC for the period from CY 2021 through CY 2023. Staff concludes that MHCC staff's and AAMC's case counts may differ due to minor differences in the definitions of adult cardiac surgery used by MHCC and AAMC.

A volume requirement exists because at the time the regulations were developed, the CAG considered research on the relationship between volume and outcomes. This research suggested that cardiac surgery programs performing 200 or more cases per year are more likely to have better outcomes. However, a cardiac surgery program with a low volume of cases may still be providing quality care. Although AAMC performed less than 200 cases in each calendar year from 2021 to 2023, the hospital's performance on quality metrics indicates the hospital provides high quality care that is similar to other programs participating in the STS registry.

For established cardiac surgery programs, MHCC staff has not previously recommended a condition related to volume for hospitals performing less than 200 cases annually that are providing quality care. However, the annual volume requirement for a new cardiac surgery program is different. COMAR 10.24.17.04B(1)(b) states that "A new cardiac surgery program that fails to achieve a volume of at least 200 cardiac surgery cases, in its second year of operation will be evaluated for closure by the Commission." Staff is not recommending closure of AAMC's cardiac surgery program for reasons that include the hospital appears to have significantly increased its cardiac surgery volume during CY 2024 and has credible plans for continuing to increase its volume, as discussed on page 4 of this report. However, based on the expectation that a new cardiac surgery program achieve a volume of 200 cardiac surgery cases annually, staff is recommending a condition, as explained on page 9 of this report. This condition is included in the recommendation below.

V. RECOMMENDATION

Based on the above analysis and the record in this review, AAMC 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 AAMC to continue providing cardiac surgery services for the next four years with the following conditions:

> AAMC shall continue to strive to improve access to cardiac surgery services for Maryland residents in Prince George's County and the Eastern Shore. AAMC shall report annually by December 31 each year on its progress

improving access to cardiac surgery services, until the MHCC releases the hospital from this condition.

If AAMC fails to achieve an annual volume of 200 cardiac surgery cases by the end of CY 2025, then AAMC shall report by June 30, 2026, on its strategic plan for achieving a volume of 200 cardiac surgery cases annually, by June 30th each year, until AAMC achieves an annual volume of 200 cardiac surgery cases or is released from this condition by the MHCC. The strategic plan should address why strategies previously expected to increase cardiac surgery volume have not been successful and describe new strategies for achieving a volume of 200 cardiac surgery cases annually.