IN THE MATTER OF	*	**BEFORE THE**
MEDSTAR UNION MEMORIAL	*	**MARYLAND HEALTH**
HOSPITAL	*	**CARE COMMISSION**
DOCKET NO. 22-24-CP035	*	

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STAFF REPORT & RECOMMENDATION

APPLICATION FOR CERTIFICATE OF ONGOING PERFORMANCE FOR CARDIAC SURGERY SERVICES

March 16, 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).[1] The law also directed MHCC to incorporate several specific requirements in its regulations.

The Cardiac Surgery Chapter of the State Health Plan, 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.[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.

While the Cardiac Surgery Chapter includes cardiac surgery volume standards, the 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.[3] This Staff Report and Recommendation accounts for this temporary waiver.

B. Applicant

Medstar Union Memorial Hospital

Medstar Union Memorial Hospital (MUMH) is a 191-bed acute general hospital located in Baltimore City and is part of the Medstar Health System. Medstar Health has two cardiac surgery programs, one at MUMH and the other at Medstar Washington Hospital Center. MUMH has been providing cardiac surgery services since 1994, after the Commission granted the hospital a Certificate of Need in 1991.

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[1] Md. Code Ann., Health-Gen. §19-120.1.
[2] COMAR 10.24.17.07B(1).
[3] MHCC, *Bulletin 21-01: 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.

Health Planning Region

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17.03. MUMH is in the Baltimore/Upper Shore health planning region (HPR). This HPR includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen Anne's, and Talbot Counties in Maryland, as well as Baltimore City. There are five other hospitals in this HPR that provide cardiac surgery services for adults: The Johns Hopkins Hospital; University of Maryland Medical Center; University of Maryland St. Joseph Medical Center, Sinai Hospital of Baltimore; and Luminis Anne Arundel Medical Center. Two of the five hospitals, The Johns Hopkins Hospital and University of Maryland Medical Center, also operate pediatric cardiac surgery programs.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

MUMH filed an application for a Certificate of Ongoing Performance for cardiac surgery services on September 6, 2022. On February 3, 2023, the hospital provided the missing STS reports that had been requested by MHCC staff. The hospital provided additional information on February 14, 2023.

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 Commission. Each cardiac surgery program shall also cooperate with the data collection requirements deemed necessary by the Commission to assure a complete, accurate, and fair evaluation of Maryland's cardiac surgery programs.

MUMH participates in the Society of Thoracic Surgeons' (STS) adult cardiac surgery data (STS-ACSD) registry and submits its STS-ACSD data and select STS report information to MHCC staff as required. The hospital has a dedicated team of cardiac and critical care nurses, who are dedicated to collecting, entering, and reporting data required for all mandated and voluntary registries.

Staff Analysis and Conclusion

MUMH has complied with the submission of data to the STS-ACSD registry and to MHCC in accordance with the established schedule. For the period between January 2018 and December

2020, the hospital submitted the required select information from STS reports for rolling 12-month periods. STS switched to three-year reporting periods in CY 2021. MUMH provided the required select pages for all three of the required three-year reports, which together cover the period from July 2018 through June 2022. MHCC staff concludes that MUMH 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 Commission staff 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 each concern identified through its quality assurance processes.

MUMH performs quality assurance through its monthly multidisciplinary performance improvement committee meetings. These meetings include the cardiac surgeons, surgical assistants, intensivists, and advance practice clinicians, as well as the STS data team leader and a data analyst. In addition, at least one representative from cardiac anesthesia, perfusion, operating room nursing, cardiovascular intensive care nursing, cardiovascular step-down nursing, and administration attends. The hospital provided the meeting minutes and attendance sheets for those present at the performance improvement meetings conducted from January 2018 through June 2022. Meeting minutes indicate that opportunities for quality improvements are identified and discussed.

MUMH also provided meeting minutes and attendance sheets for monthly cardiology service line meetings held between January 2019 and May 2022. Representatives present included staff from cardiology, cardiac surgery, the cardiac catheterization laboratory, the critical care unit, and the cardiovascular recovery unit. In addition to improvements indicated in meeting minutes, the hospital reports implementation of a lung ultrasound and thoracentesis protocol in January 2022, with an aim to decrease readmissions.

All mortalities are reviewed both internally and externally. Physicians at the Cleveland Clinic Foundation conduct reviews of all mortalities. During the reporting period, the Cleveland Clinic Foundation did not identify any deaths as avoidable, and the findings were consistent with internal Mortality and Morbidity meetings conducted by the Medstar Health System.

MUMH also monitors its performance and the need for additional quality improvement measures for its cardiac surgery program by comparing itself to benchmarks available through its participation in the STS-ACSD and the Maryland Cardiac Surgery Quality Initiative (MCSQI). Key performance measures tracked for its cardiac surgery patients include blood product usage, discharge disposition, and readmission rates.

Bradley Chambers, President and Chief Operating Officer of MUMH, submitted a letter stating that MUMH is committed to continuing a diligent approach to quality improvement,

striving to provide all patients with the best possible outcome.

Staff Analysis and Conclusion

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

Performance Standards

COMAR 10.24.17.07B(5)(a) and (c) A cardiac surgery program shall meet all performance standards established in statute or in State regulations. Applicable performance measures include: 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 rating cycles, the program will be subject to a focused review. If the composite score for CABG from the STS-ACSD is one star, or if a hospital fails to receive a star rating, 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

MUMH maintained an STS composite score for coronary artery bypass graft (CABG) surgeries of two stars or higher during the period from January 2018 through June 2022, as shown in Table 1. 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.[4] Therefore, STS updated the methodology to reflect a three-year period with a 95% credible interval in 2021. For this reason, STS 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 STS data warehouse from one vendor to another in early 2020.[5]

Table 1 shows the star ratings for each of five overlapping 12-month periods and three overlapping 3-year periods, the volume of isolated CABG cases included in the ratings for each period, and the overall percentage of MUMH's volume of cardiac surgery included in the STS ratings. As shown in Table 1, MUMH received a three-star STS CABG composite score rating for the periods from July 2018 through June 2019, January 2019 through December 2019, July 2019 through June 2020, July 2018 through June 2021, January 2019 through December 2021, and July 2019 through June 2022. In addition, isolated CABG cases accounted for between 56% and 71% of the total adult cardiac surgery volume at MUMH in each reporting period.

[4] 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.
[5] Email correspondence between MHCC staff and STS staff on August 29, 2022.

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 of the State Health Plan uses isolated CABG as a reference point based on the recommendation of both the CAG and the Cardiac Services Advisory Committee, which include cardiac surgeons and interventional cardiologists. For an individual patient who requires a different type of cardiac surgery, the information 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: MUMH's Cardiac Surgery Volume, Isolated CABG Volume, and Composite STS Star Ratings for CABG, by Reporting Period

Reporting Period	Composite Star Rating[1]	Total Isolated CABG Cases Included[2]	Total Cardiac Surgery Volume[3]	Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating
Jan 2018 - Dec 2018	★★	342	518	66.0%
Jul 2018 - Jun 2019	★★★	315	441	71.4%
Jan 2019 - Dec 2019	★★★	281	431	65.2%
Jul 2019 - Jun 2020	★★★	222	391	56.8%
Jan 2020 - Dec 2020	★★	223	339	65.8%
Jul 2018 - Jun 2021	★★★	746	1,157	64.5%
Jan 2019 - Dec 2021	★★★	676	1,066	63.4%
Jul 2019 - Jun 2022	★★★	613	1,023	59.9%

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

[1] MUMH submitted copies of its star ratings and CABG volume to MHCC for each period. The maximum number of stars awarded is three stars. Two stars indicate that a program performed similarly to the national average for cardiac surgery programs participating in the STS-ACSD.
[2] Isolated CABG cases are cases in which only CABG is performed. The number of eligible procedures ranges within the components of the star rating; the number in the table reflects the number of eligible procedures for the mortality component.
[3] Cardiac surgery case volume is based on counting discharges with any procedure code that is included in the definition of 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 the HSCRC discharge abstract for January 2018 – June 2022.

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, which 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, which 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 MUMH 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, 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

MUMH'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 2 and Figure 1 below show the rates for the five 12-month periods for which data is available from STS. MHCC staff concludes that MUMH met this performance standard and maintained a risk-adjusted mortality rate consistent with high quality patient care.

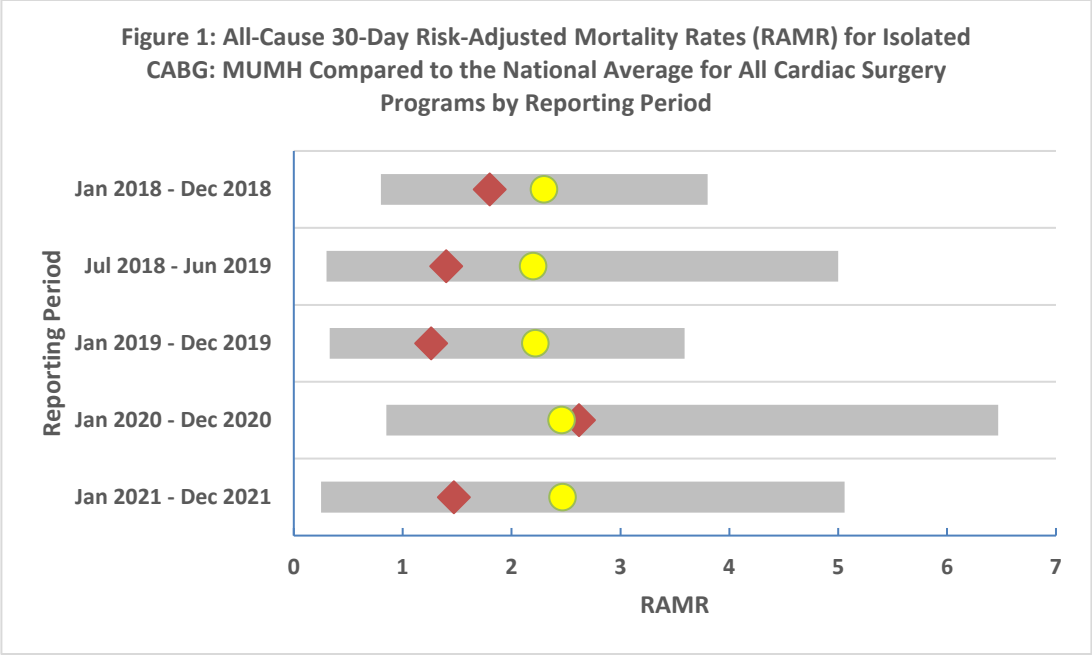
Table 2: 30-Day All-Cause Risk-Adjusted Mortality Rates for Isolated CABG: MUMH Comparison to the National Benchmark, by Reporting Period

	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
STS National Benchmark	2.3	2.2	2.22		2.46		2.47
MUMH	1.8	1.4	1.26		2.62		1.47
95% CI	(0.8,3.8)	(0.3,5.0)	(0.33,3.59)		(0.85,6.47)		(0.25,5.06)

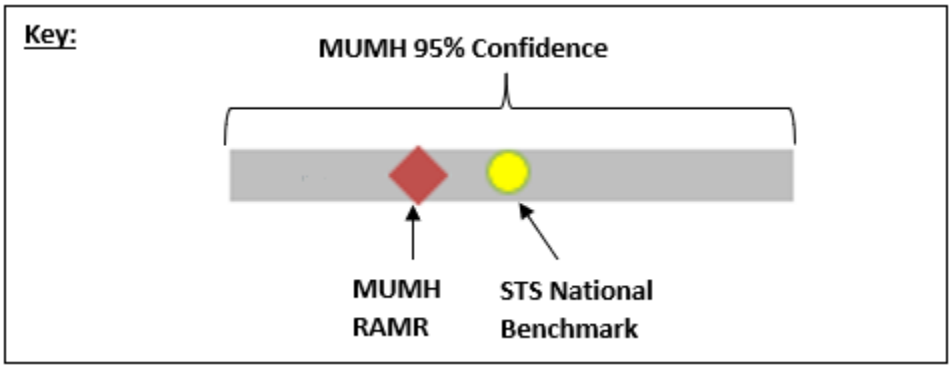
Source: STS analysis of data from all Maryland hospitals with cardiac surgery programs.

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 cardiac surgery 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.

MUMH 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 548 cases for CY 2018, 459

cases for CY 2019, 338 cases for CY 2020, 285 cases for CY 2021, and 194 cases for the period January through June 2022. These counts are derived from the cases entered into the STS-ACSD registry for cardiac surgery patients aged 18 years or older and exclude transcatheter aortic valve replacement (TAVR) cases. STS has a separate registry for TAVR cases, and these cases only sometimes count toward volume requirements in MHCC's regulations.

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). MHCC staff's analysis of annual case volume, based on the definition of cardiac surgery in COMAR 10.24.17, does not differ significantly from the case counts reported by MUMH: 518 cases for CY 2018, 431 cases for CY 2019, 339 cases for CY 2020, 296 cases for CY 2021, and 174 cases for the period January through June 2022. MHCC staff concludes that the minor differences seen in these counts are the result of differences in the definitions of adult cardiac surgery used by MHCC and MUMH. Staff concludes that MUMH complies with this standard.

IV. RECOMMENDATION

Based on the above analysis and the record in this review, Commission staff concludes that MUMH 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 MUMH to continue providing cardiac surgery services for the next four years.