IN THE MATTER OF	*	**BEFORE THE**
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UPMC WESTERN	*	**MARYLAND HEALTH**
	*	
MARYLAND	*	**CARE COMMISSION**
	*	
Docket No. 22-01-CP034	*	

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STAFF REPORT & RECOMMENDATION

APPLICATION FOR CERTIFICATE OF ONGOING PERFORMANCE FOR CARDIAC SURGERY SERVICES

November 17, 2022

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"). Md. Code Ann., Health-Gen. §19-120.1 The law also directed MHCC to incorporate several specific requirements in its regulations.

The Cardiac Surgery Chapter, COMAR 10.24.17, contains standards for evaluating the performance of established cardiac surgery services in Maryland and determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for cardiac surgery authorizes a hospital to continue to provide these services for a period specified by the Commission that cannot exceed five years. COMAR 10.24.17B(1). 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 imposes cardiac surgery volume standards on hospitals, MHCC waived these standards for CY 2020 and 2021 or FY 2020 and 2021, depending on whether the respective hospitals measure volumes by calendar year or a fiscal year beginning in June.[1] This Staff Report and Recommendation will reflect this limited waiver.

B. Applicant

UPMC Western Maryland

UPMC Western Maryland is a 200-bed general hospital located in Cumberland (Allegany County). In February 2020, the Western Maryland Health System (WMHS) integrated with the UPMC system created by the University of Pittsburgh Medical Center (UPMC) to become UPMC Western Maryland (UMPC Western Maryland). The hospital continues to provide services for Allegany and Garrett Counties as well as the surrounding counties in West Virginia and Pennsylvania.

Health Planning Region

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17. UPMC Western Maryland is in the Western Maryland Health Planning Region (HPR). This HPR includes Allegany, Garrett, and Washington Counties. There are three hospitals located in this HPR, one in each county. Two of these hospitals, UPMC Western Maryland and Meritus

[1] 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.

Medical Center in Hagerstown (Washington County), provide PCI services. UPMC Western Maryland is the only hospital performing cardiac surgery in this HPR.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

UPMC Western Maryland filed a Certificate of Ongoing Performance application for cardiac surgery services on July 13, 2022. On October 4, 2022, the hospital submitted additional information, as requested by MHCC staff. On October 11, 2022, UPMC Western Maryland also responded to questions from MHCC staff concerning its application for a Certificate of Ongoing Performance by phone.

III. 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.

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

Staff Analysis and Conclusion

UPMC Western Maryland has complied with the submission of STS-ACSD data to MHCC in accordance with the established schedule. For the period between January 2018 and December 2020, the hospital submitted the required select pages from reports for rolling 12-month periods. STS switched to three-year reporting periods in 2021. UPMC Western Maryland submitted the required select pages for both reports, which together cover the period from July 2018 through December 2021. MHCC staff concludes that UPMC Western Maryland 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.

UPMC Western Maryland performs quality assurance through its quarterly Open Heart Case Review (OHCR) meetings. UPMC Western Maryland held five meetings (January, July, and October 2020; April and July 2021) between January 2020 and December 2021. The scheduled meetings for April 2020 as well as January and October 2021 were cancelled due to the COVID surge. Members of the OHCR team include the chair of cardiac surgery, cardiologists, cardiac surgery nurses, physician assistants, perfusionists and data managers. The hospital provided the minutes and a list of attendees for all meetings conducted. The meeting minutes indicate that specific quality measures are reviewed at these meetings. In addition, the hospital provided a detailed list of other quality assurance activities that were not captured in meeting minutes. UPMC Western Maryland explained the benchmarks that it adopted and provided information on its performance relative to these benchmarks monthly for CY 2018, CY 2019, CY 2020, CY 2021, and the first quarter (January through March) of 2022. The results show how the hospital performed compared to STS National benchmarks.

In addition to the OHCR meetings, the hospital also conducted quarterly Open Heart Collaborative Care Team meetings. Members of this group include the cardiac program mid-level professionals including staff from the Cardiovascular unit (CVU), Cardiac rehabilitation unit, dieticians, and respiratory therapists. Quality measures such as rates of complications, infections, and readmissions were reviewed. UPMC Western Maryland did not perform an internal peer review because almost all cases were performed by one surgeon. However, the hospital also reported that in late December 2021, due to the affiliation with the UPMC Heart and Vascular Institute, the cardiac surgeon at UPMC Western Maryland can participate in peer review with surgeons from UPMC Heart and Vascular Institute for any case with adverse outcomes. Because there have been no cardiac surgery cases with mortality since this opportunity for peer review has been put in place, it has not yet been utilized though. UPMC Western Maryland also reported that that no cases performed between January 2020 and March 2022 were referred for external review.

Michele R. Martz, President of the UPMC Western Maryland, submitted a letter stating that UPMC Western Maryland is committed to identifying areas of improvement in the quality and outcomes of the UPMC Western Maryland's cardiac surgery program. She also stated that, annually or upon request, UPMC Western Maryland will provide a report of the quality assurance activities of the program.

Staff Analysis and Conclusion

UPMC Western Maryland provided information documenting its quality assurance activities and the actions taken in response to any quality concerns identified. Peer review of cases with mortality and morbidity is essential for compliance with MHCC's regulations. Therefore, it is critical that UPMC Western Maryland participate in this activity through its affiliation with the UPMC Heart and Vascular Institute or through another mechanism. MHCC staff concludes that UPMC Western Maryland 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

UPMC Western Maryland maintained an STS composite score for coronary artery bypass graft ("CABG") surgeries of two stars or higher during the period from January 2018 through December 2021. Recently, the STS noted that declining volumes of isolated CABG cases and increasing case mix severity make it difficult to discriminate levels of performance given STS's use of a conservative 98% credible interval in its CABG composite measure methodology.[2] 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. UPMC Western Maryland received a three-star STS CABG composite score rating for the period July 2018 through June 2021 as reflected in Table 1 below. It should also be noted that there were not performance reports generated for hospitals participating in the STS registry for the 12-month period ending in June 2021 due to the transition of the data warehouse for STS from one vendor to another in early 2020.[3]

Table 1 shows the star ratings for each of five overlapping 12-month and two 3-year periods, the volume of isolated CABG cases included in the ratings for each period, and the overall percentage of the UPMC Western Maryland's volume of cardiac surgery included in the STS ratings. 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. In addition, 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 the Cardiac Services Advisory Committee, which includes cardiac surgeons and interventional cardiologists. For an individual patient who requires a different type of cardiac surgery, the information included in Table 1 may not be relevant. However, isolated CABG is one of the most common procedures performed, which allows for a consistent and fair basis for comparing programs and evaluating the overall performance of hospitals, with respect to one type of cardiac surgery.

[2] 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

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

Table 1: UPMC Western Maryland'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	★★	88	147	59.9%
Jul 2018 - Jun 2019	★★	76	125	60.8%
Jan 2019 - Dec 2019	★★	82	113	72.6%
Jul 2019 - Jun 2020	★★	76	102	74.5%
Jan 2020 - Dec 2020	★★	64	94	68.1%
Jul 2018 - Jun 2021	★★★	217	331	65.6%
Jan 2019 - Dec 2021	★★	208	308	67.5%

Sources: MHCC compilation of information submitted by UPMC Western Maryland and analysis of HSCRC discharge data.

UPMC Western Maryland 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.

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

[3] Cardiac surgery case volume is based on counting discharges with any procedure code that is included in the definition of open-heart surgery in COMAR 10.24.17, effective in November 2015, and using the procedure date to categorize cases by reporting period; total cardiac surgery volume is based on MHCC staff analysis of HSCRC discharge abstract for January 2018 - December 2021.

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 UPMC Western Maryland 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

UPMC Western Maryland's all-cause 30-day risk-adjusted mortality rate for isolated CABG cases was similar to the national average in all reporting periods, not differing by 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 the STS. MHCC staff concludes that UPMC Western Maryland met this performance standard and maintained a risk-adjusted mortality rate consistent with high quality patient care.

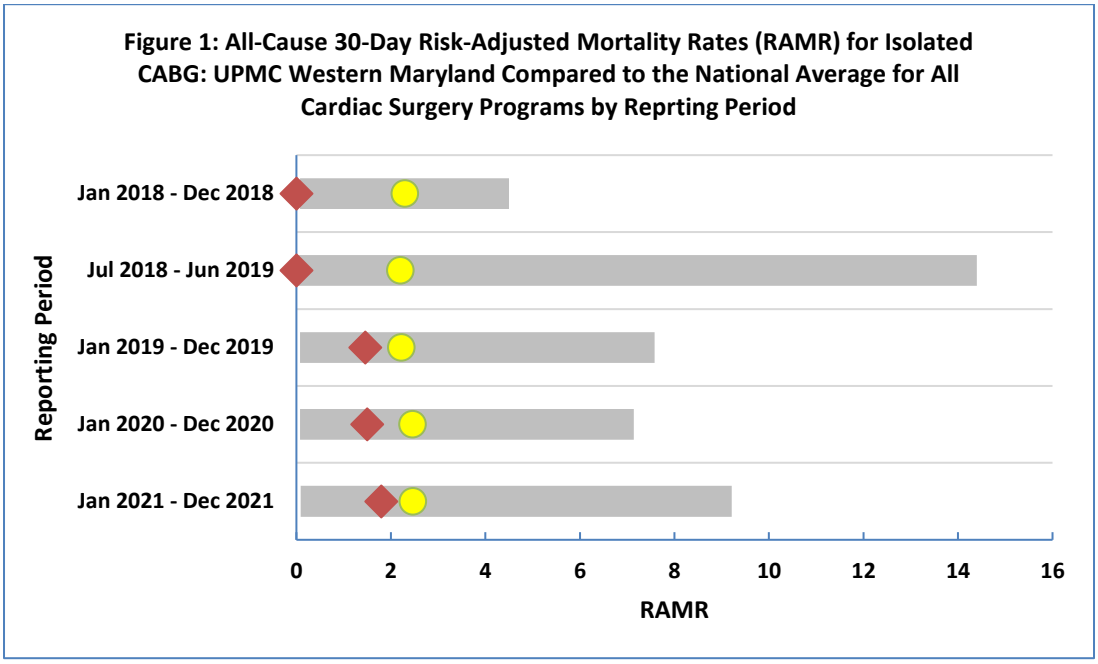
Table 2: 30-Day All-Cause Risk-Adjusted Mortality Rates for Isolated CABG: UPMC Western Maryland Comparison to the National Benchmark, by Reporting Period

	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
UPMC Western MD	0.0	0	1.46		1.45		1.8
95% CI	(0.0,4.5)	(0.0,14.4)	(0.08,7.58)		(0.08,7.14)		(0.09,9.21)

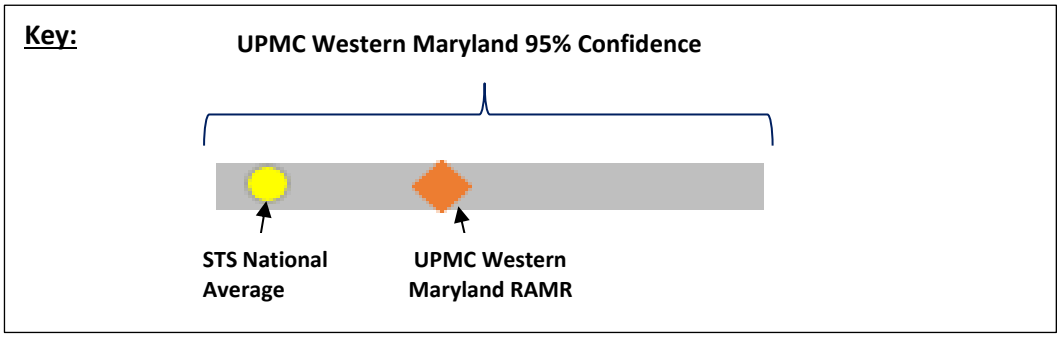
Source: STS analysis of data from all Maryland hospitals with cardiac surgery programs.

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

* STS national benchmark data not available for these periods



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



Volume Requirements

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

UPMC Western Maryland has not maintained an annual volume of 200 or more cases in any reporting period from January 2018 through December 2021. It reported a volume of 142 cases for calendar year (CY) 2018, 111 cases for CY 2019, 93 cases for CY 2020, 102 cases for CY 2021, and 70 cases for the period January through June 2022.

Staff Analysis and Conclusion

As stated in the updated MHCC Bulletin dated August 27, 2021, although a hospital's actual performance for the period between January 2020 and December 2021 will be included in staff reports for Certificates of Ongoing Performance, compliance with case volume standards will be waived for CY 2020 and CY 2021. UPMC Western Maryland reported that it performed 142 cases for CY 2018, 111 cases for CY 2019, 93 cases for CY 2020, 102 cases for CY 2021, and 70 cases for the period from January through June 2022. MHCC staff's analysis of case volume based on the HSCRC discharge abstract data case counts are similar to those of UPMC Western Maryland; 147 cases for CY 2018, 113 cases for CY 2019, 94 cases for CY 2020, and 101 cases for CY 2021. MHCC staff concludes that these counts may differ due to minor differences in the definitions of adult cardiac surgery used by MHCC and UPMC Western Maryland.

UPMC Western Maryland did not meet the requirement that it maintain an annual volume of 200 cases or more for the four years (2018-2021) for which data was provided. 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 program with volume of 200 cases or greater are more likely to have better outcomes. However, the hospital still performed over 100 cases in each year of the review period, except for CY 2020, when the volume standard has been waived. It is only if a hospital performs less than 100 cases for two consecutive years that a focused review will be triggered. In addition, the information available shows UPMC Western Maryland continues to provide safe and high-quality care.

IV. RECOMMENDATION

Based on the above analysis and the record in this review, UPMC Western Maryland meets the requirements for a Certificate of Ongoing Performance defined in COMAR 10.24.17.07B, except for the volume standard that sets a target volume of performing 200 cases or more annually. UPMC Western Maryland is required to participate in peer review and submit documentation upon request as part of the application process for a Certificate of Ongoing Performance.

The Executive Director of the Maryland Health Care Commission recommends that the Commission issue a Certificate of Ongoing Performance that permits UPMC Western Maryland to continue providing cardiac surgery services for the next four years.