IN THE MATTER OF THE	*	**BEFORE THE**
UNIVERSITY OF MARYLAND CAPITAL	*	**MARYLAND HEALTH**
REGION MEDICAL CENTER	*	**CARE COMMISSION**
Docket No. 24-16-CP052	*	

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STAFF REPORT & RECOMMENDATION

APPLICATION FOR CERTIFICATE OF ONGOING PERFORMANCE FOR CARDIAC SURGERY SERVICES

November 21, 2024

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 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

University of Maryland Capital Region Medical Center

University of Maryland Capital Region Medical Center (UM CRMC) is a 228-bed general acute care hospital located in Prince George's County, Maryland and is part of the University of Maryland Medical System. The hospital's cardiac surgery program was established prior to the requirement for a Certificate of Need to establish a cardiac surgery program.

This is the first time UM CRMC has filed an application for a Certificate of Ongoing Performance because the hospital relocated in June 2021. The Cardiac Services Chapter permits a hospital to operate without a Certificate of Ongoing Performance when the relocated services have been in operation for fewer than 36 months, and COMAR 10.24.01.13A(3) permits a hospital to operate without a Certificate of Ongoing Performance until the Commission acts on the hospital's first application for a Certificate of Ongoing Performance.

Because UM CRMC, formerly Prince George's Hospital Center, relocated and was not required to obtain a Certificate of Ongoing Performance until years after getting established at the new location, MHCC staff did not include in this report a review of quality assurance activities related to cardiac surgeries performed more than two years before the relocation. Instead, staff evaluated the hospital's compliance over the most recent 4.5 years, which aligns with the approximate period of review for most hospitals. Staff notes that the hospital has complied with submitting information as required, and staff considered the hospital's compliance with standards following each submission of information, even though the hospital was not required to obtain a Certificate of Ongoing Performance earlier. The hospital was subject to a focused review due to low volume in CY 2016 and CY 2017. The focused review involved external peer review of all mortalities for isolated Coronary Artery Bypass Graft (CABG) cases in CY 2016 and CY 20107. The focused review did not identify any concerns regarding patient care in those cases.

Health Planning Region

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17. UM CRMC is in the Metropolitan Washington health planning region (HPR). This region includes Calvert, Charles, Frederick, Montgomery, Prince George's, and St. Mary's counties, and the District of Columbia. Two other hospitals in this HPR provide cardiac surgery services for adults: Suburban Hospital and Adventist White Oak Medical Center.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

UM CRMC filed a Certificate of Ongoing Performance application for cardiac surgery services on February 1, 2024. MHCC staff requested additional information on October 4, 2024. The hospital provided additional information on October 25, 2024.

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 Commission. Each cardiac 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.

UM CRMC stated that it 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

UM CRMC has complied with the submission of STS-ACSD data to MHCC in accordance with the established schedule. For cardiac surgery cases performed during the period July 2019 through December 2023, the hospital submitted the required pages from its STS reports. MHCC staff concludes that UM CRMC complies with this standard.

Quality

COMAR 10.24.17.07B(4)

> ***(a) 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.***
>
> ***(b) 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.***

UM CRMC submitted a letter from its chief executive officer, Nathaniel Richardson, dated February 3, 2024, that certifies UM CRMC is committed to adhering to the quality assurance standards set forth by MHCC, including standards pertaining to case review.

The hospital reported that the quality assurance process at UM CRMC involves quarterly meetings of the Cardiac Surgery Continuous Quality Improvement (CQI) committee, which includes all disciplines within the sphere of cardiac surgery patient care. Issues with processes are identified at this meeting and follow-up is completed to handle the concerns identified. One

concern that was identified through the CQI meetings was regarding sacral pressure sores. UM CRMC addressed this by assuring the timely transfer of at-risk patients to specialty beds. The use of sacral border dressings for pressure sore prophylaxis was also integrated into patient care plans and all nursing and provider teams were re-educated on the need for identification of at-risk patients, thorough skin assessment, use of preventative dressings, repositioning, and early mobilization. Another example provided of an improvement stemming from ongoing quality assurance activities was the facility's blood bank changing its inventory of blood products because there was no longer a blood product depot within the hospital walls. UM CRMC submitted meeting minutes documenting the upgrade in the efficiency of its processes to ensure the constant availability of blood products.

UM CRMC also explained that there are data quality meetings, which are conducted at least quarterly between the clinical team and data manager, to review data completeness, accuracy, and quality. In the event of a serious adverse outcome, the case is submitted to the Mortality and Morbidity (M&M) Peer Review Committee, which presents the clinical summary for review. Activities and findings from this meeting are reported to the hospital-wide Medical Staff Quality Oversight Committee (MSQOC).

Staff Analysis and Conclusion

UM CRMC provided information documenting its quality assurance activities and the actions taken in response to quality concerns identified, as described above. MHCC staff reviewed this information and concludes that UM CRMC 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. Applicable performance measures include:

(i) 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, 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. Upon notice from the Executive Director of the Commission, the hospital shall voluntarily relinquish its authority and close its cardiac surgery services in a timely manner.

(ii) The hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

Staff Analysis and Conclusion

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.[7] STS updated the methodology to reflect a three-year period with a 95% credible interval in 2021.

The performance reports for UM CRMC for cardiac surgeries performed between July 2019 and December 2023 show that UM CRMC maintained an STS composite score for CABG surgeries of at least two stars. Staff notes that the STS did no 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.[8]

Table 1 shows the star ratings for each three-year reporting period between July 2019 and December 2023, the volume of isolated CABG cases included in the ratings for each period, and the overall percentage of UM CRMC's volume of cardiac surgery included in the STS ratings. As shown in Table 1, UM CRMC received a three-star STS composite score rating in three of four reporting periods. Approximately 20% of programs received a three-star rating for isolated CABG cases. In addition, isolated CABG cases accounted for between 73.4% and 79.5% of the total adult cardiac surgery volume at UM CRMC in each reporting period.

Hospitals with cardiac surgery programs typically perform other types of cardiac surgery and may perform CABG in combination with other surgical procedures, but the STS ratings shown in Table 1 are based only on isolated CABG procedures. The Cardiac Services Chapter uses isolated CABG as a reference point based on both the recommendation of the CAG 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 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.

[7] 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

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

Table 1: UM CRMC'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
Jul 2019 – Jun 2022	★★★	79	95	73.7%
Jan 2020 – Dec 2022	★★★	93	117	79.5%
Jul 2020 – Jun 2023	★★	116	157	73.9%
Jan 2021 – Dec 2023	★★★	149	203	73.4%

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

[1] The maximum number of stars awarded is three. 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 vary 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 by 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 July 2019 – December 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 that the program did not perform worse or better than the average for all participants in the STS-ACSD, at a statistically significant level.

The STS provides star ratings for each of the four components of the STS composite star rating. The hospital consistently received two or more stars for all components of the STS composite star rating, including the absence of mortality. A rating of two stars or greater for the component that captures the absence of mortality is an indication that the hospital's risk-adjusted mortality rate is consistent with high quality patient care.

MHCC staff concludes that UM CRMC complies with this standard.

COMAR 10.24.17.07B(5)(b) A hospital with an all-cause 30-day risk-adjusted mortality rate for a specific type of cardiac surgery case, 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

UM CRMC'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 below shows the rates for three 12-month periods for which data is available from STS. MHCC staff concludes that UM CRMC 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: UM CRMC Comparison to the National Benchmark, by Reporting Period

	Jan 2020-Dec 2020	Jan 2021 - Dec 2021	Jan 2022 - Dec 2022	Jan 2023 - Dec 2023
STS National Benchmark	2.46	2.47	2.38	2.17
UM CRMC	3.73	0.00	3.42	0.00
95% Confidence Interval	(1.99, 6.45)	(0.00, 5.08)	(0.18, 17.41)	(0.00, 2.30)

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 (CI) 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.

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.

In its application, UM CRMC reported annual volumes of 24 cases for CY 2020, 31 cases for CY 2021, 57 cases for CY 2022, and 115 cases for CY 2023.

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, as calculated based on the definition of cardiac surgery in COMAR 10.24.17, was 26 cases for CY 2020, 34 cases for CY 2021, 57 cases for CY 2022, and 112 cases for CY 2023. 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 UM CRMC, but the counts may differ due to minor differences in the definitions of adult cardiac surgery used by MHCC and UM CRMC. Because the hospital performed over 100 cases in CY 2023, it will not be subject to a focused review.

IV. RECOMMENDATION

Based on the above analysis and the record in this review, UM CRMC meets the requirements for a Certificate of Ongoing Performance defined in COMAR 10.24.17.07B. Staff recommends that the Commission issue a Certificate of Ongoing Performance that permits UM CRMC to continue providing cardiac surgery services for the next three years.