

IN THE MATTER OF

*** BEFORE THE**

JOHNS HOPKINS HOSPITAL

*** MARYLAND HEALTH**

Docket No.: 22-24-CP039

*** CARE COMMISSION**

STAFF REPORT & RECOMMENDATION
APPLICATION FOR CERTIFICATE OF ONGOING PERFORMANCE
FOR CARDIAC SURGERY SERVICES

Date: January 19, 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, 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, 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 limited waiver.

B. Applicant

Johns Hopkins Hospital

The Johns Hopkins Hospital (JHH) is a 1,079 bed acute care general hospital located in Baltimore City and is part of the Johns Hopkins Health System. As an academic medical center, JHH provides both tertiary and quaternary care. JHH established its cardiac surgery program prior to the establishment of the requirement for a cardiac surgery program to obtain a Certificate of Need.

Health Planning Region

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

¹ Md. Code Ann., Health-Gen. §19-120.1

² COMAR 10.24.17.07B(1).

³ 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.

Maryland Medical Center; Sinai Hospital of Baltimore; MedStar Union Memorial Hospital, and Luminis Anne Arundel Medical Center.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

JHH filed a Certificate of Ongoing Performance application for cardiac surgery services on September 9, 2022, the deadline for its application. JHH provided a replacement application on September 19, 2022, November 2, 2022, and November 9, 2022, due to inadvertently sending the wrong file multiple times. The hospital submitted other additional information on December 20, 2022, and January 5, 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 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.

JHH participates in the Society of Thoracic Surgeons' adult cardiac surgery data registry (STS-ACSD) and submits its STS-ACSD data and select STS report information to MHCC staff as required.

Staff Analysis and Conclusion

JHH 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 STS report information for rolling 12-month periods. STS switched to three-year reporting periods in 2021. JHH submitted the required select pages for both three-year reports, which together cover the period from July 2018 through December 2021. MHCC staff concludes that JHH 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.

JHH's quality assurance processes include a series of weekly morbidity and mortality review meetings as well as other meetings held on a monthly, quarterly, or annual basis. The hospital submitted meeting minutes for the monthly meetings, slides for quarterly meetings, and slides for a few other meetings. The attendees for monthly and quarterly meetings included physicians, nurses, and quality improvement staff. The minutes for the monthly meetings included lists of all attendees and sufficient detail to demonstrate that specific quality measures were reviewed during the meetings. JHH also provided a detailed list of other quality assurance activities that were not captured in meeting minutes such as initiatives to decrease the need for blood transfusions and to minimize acute kidney injuries.

JHH also monitors its performance and the need for additional quality improvement measures for its cardiac surgery program through comparing itself to benchmarks available through its participation in the STS-ACSD and the Maryland Cardiac Surgery Quality Initiative (MCSQI). It also relies on Vizient data and benchmarks that are derived from administrative patient information from other comparable institutions to JHH.

The hospital has an internal, three-level, review process for evaluating all cardiac surgery mortalities. A Level 1 review is conducted by an internal team consisting of direct care providers including surgeons, and nurses. If there are concerns about the quality of care, there is a Level 2 mortality review. The Level 2 mortality review is conducted by leadership representatives from the departmental level including physicians, nurses, quality and safety, quality improvement, risk management, and advance practice providers. The Level 2 review team determines if a case should be further escalated to a Level 3 review. The Level 3 review team includes a large multidisciplinary committee consisting of representatives from Medicine, Surgery, Anesthesia, Palliative Care, Pharmacy, Nursing, Advanced Practice Nursing, and Risk Management; this team excludes the direct care team. The Level 3 review team makes a final determination on a case. JHH does not have a protocol for conducting external peer review of cases.

Redonda G. Miller, President of JHH, submitted a letter stating that the hospital is committed to identifying areas of improvement in the quality and outcomes of JHH's cardiac surgery program. She also stated that, annually or upon request, JHH will provide a report of the quality assurance activities of the program.

Staff Analysis and Conclusion

JHH described its quality assurance activities and provided documentation of these activities, including the actions taken in response to any quality concerns identified. MHCC staff concludes that JHH 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

JHH maintained an STS composite score for coronary artery bypass graft (CABG) surgeries of two stars 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 differentiate the performance levels of hospitals, given STS's use of a conservative 98% credible interval in its CABG composite measure methodology.⁴ 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. 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 data warehouse for STS from one vendor to another in early 2020.⁵

Table 1 shows the star ratings for each of five overlapping 12-month periods and two three-year periods, the volume of isolated CABG cases included in the ratings for each period, and the overall percentage of the JHH's volume of cardiac surgery included in the STS ratings. As shown in Table 1, JHH received a two-star STS CABG composite score rating in each reporting period. In addition, isolated CABG cases accounted for between 42% and 54% of the total adult cardiac surgery volume at JHH 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 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 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.

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.

Table 1: JHH’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	★ ★	379	894	42.4%
Jul 2018 - Jun 2019	★ ★	397	887	44.8%
Jan 2019 - Dec 2019	★ ★	446	850	52.5%
Jul 2019 - Jun 2020	★ ★	374	693	54.0%
Jan 2020 - Dec 2020	★ ★	318	630	50.5%
Jul 2018 - Jun 2021	★ ★	1,082	2,257	47.9%
Jan 2019 - Dec 2021	★ ★	1,055	2,234	47.2%

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

¹JHH 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 is neither statistically significantly better nor worse than 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 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 JHH 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

JHH’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 the STS. MHCC staff concludes that JHH met this performance standard and maintained a risk-adjusted mortality rate consistent with high quality patient care.

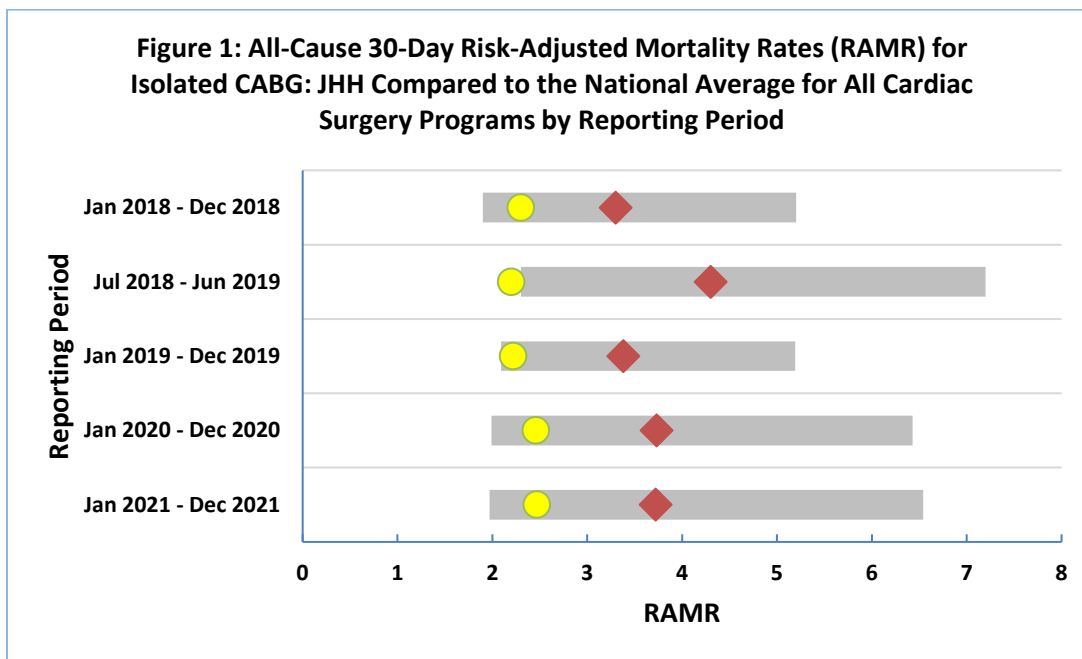
Table 2: 30-Day All-Cause Risk-Adjusted Mortality Rates for Isolated CABG: JHH Comparison to the National Average, by Reporting Period

	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 (Average)	2.3	2.2	2.22		2.46		2.47
JHH	3.3	4.3	3.38		3.73		3.72
95% CI	(1.9,5.2)	(2.3,7.2)	(2.09,5.19)		(1.99,6.43)		(1.97,6.54)

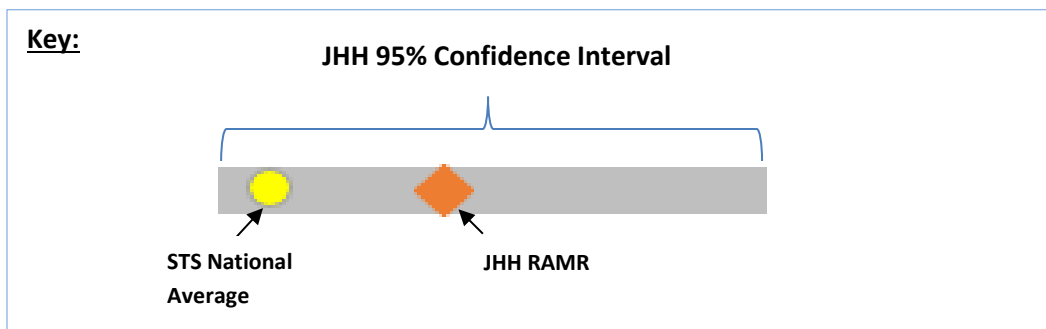
Source: STS analysis of data from all Maryland hospitals with cardiac surgery programs.

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 data not available for these years



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.

JHH maintained an annual volume of 200 or more cases in every reporting period from January 2018 through December 2021. JHH provided the number of cardiac surgeries for patients age 18 and older who had surgery while on a cardio-pulmonary bypass pump between CY 2018 and CY 2021 as follows: 816 cases for CY 2018, 751 cases for CY 2019, 571 cases for CY 2020, and 725 cases for CY 2021.

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 a cardiac surgery in COMAR 10.24.17, using the Health Services Cost Review Commission discharge abstract data indicates JHH performed 898 cases in CY 2018, 843 cases in CY 2019, 632 cases in CY 2020, and 732 cases in CY 2021.

MHCC staff's count of cardiac surgery cases is a bit higher than the approximate volume provided by JHH in all years. JHH acknowledged that some cases may have been inappropriately excluded because in some cases cardiac surgery may not have been performed while a patient was on cardiac pulmonary bypass for the operation. MHCC staff's case count would also capture patients regarded as pediatric patients by JHH, those age 15, 16, and 17. However, when MHCC staff recalculated the cardiac surgery volume for discharges age 18 and over, it only reduced case counts by between one and 12 cases, leaving about a 10% difference in the case counts of MHCC compared to JHH for three of four years.

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. MHCC staff concludes that JHH meets the annual volume requirement, by exceeding a volume of 200 cardiac surgery cases for the four most recent calendar years for which data is available.

IV. RECOMMENDATION

Based on the above analysis and the record in this review, JHH 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 JHH to continue providing cardiac surgery services for the next four years.