IN THE MATTER OF	*	**BEFORE THE**
UNIVERSITY OF MARYLAND	*	**MARYLAND**
ST. JOSEPH MEDICAL CENTER	*	**HEALTH CARE**
	*	**COMMISSION**
Docket No.: 17-03-CP007	*	

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STAFF REPORT & RECOMMENDATION

CERTIFICATE OF ONGOING PERFORMANCE FOR CARDIAC SURGERY SERVICES

April 18, 2019

I. INTRODUCTION

A. Background

In 2012, the Maryland legislature passed a law directing the Maryland Health Care Commission ("MHCC" or "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"). The law also directed MHCC to incorporate several specific requirements in its regulations.

After extensive discussion with the CAG comprised of national and regional experts and considering the CAG's and other stakeholder's recommendations, COMAR 10.24.17, the Cardiac Surgery and PCI Services chapter ("Cardiac Surgery Chapter") of the State Health Plan for Facilities and Services ("State Health Plan") was replaced in August 2014. The Cardiac Surgery Chapter was subsequently replaced in November 2015 and replaced again in January 2019. The primary changes to the Cardiac Surgery Chapter that affect cardiac surgery programs have been an evolving definition of cardiac surgery that may affect a hospital's compliance with volume standards for a Certificate of Ongoing Performance for cardiac surgery and a change in the benchmark used to evaluate hospitals' risk adjusted mortality rates. MHCC staff was unable to obtain benchmark information for risk adjusted mortality rates consistent with the regulations adopted in November 2015, which reflected the recommendations of the CAG. As a result, one standard addressed by applicants was determined to be inapplicable, but information on how applicants performed relative to the newly adopted mortality standard has been included.

The Cardiac Surgery Chapter 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 of time specified by the Commission that cannot exceed five years. At the end of the time period, the hospital must again demonstrate that it continues to meet the requirements in COMAR 10.24.17.07B for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide cardiac surgery services.

B. Applicant

The University of Maryland St. Joseph Medical Center ("UM-SJMC") is a 218-bed general acute care hospital located in Towson (Baltimore County) and is part of the University of Maryland Medical System. St. Joseph Medical Center received a Certificate of Need to establish its cardiac surgery program in December 1981, and in 2012 became part of the University of Maryland Health System.

Health Planning Region

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17. SJMC is located in the Baltimore/Upper Shore health planning region. This region includes Anne Arundel, Baltimore, Caroline, Carroll, Cecil, Harford, Howard, Kent, Queen

Anne's, and Talbot Counties, and Baltimore City. Four other hospitals in this health planning region provide cardiac surgery services for adults: Johns Hopkins Hospital; University of Maryland Medical Center; Sinai Hospital of Baltimore; and MedStar Union Memorial Hospital.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

UM-SJMC filed a Certificate of Ongoing Performance application on December 14, 2017.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

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.

UM-SJMC participates in the Society of Thoracic Surgeons' adult cardiac surgery data registry ("STS-ACSD") and included a signed copy of its data-sharing license agreement in the application. UM-SJMC also submits STS data to MHCC staff as required.

Staff Analysis and Conclusion

UM-SJMC has complied with the submission of STS data to MHCC in accordance with the established schedule. In 2015, MHCC staff conducted an audit of the STS data for each Maryland hospital to validate that all hospitals submitted accurate and complete information to STS-ACSD. Advanta Government Solutions, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of UM-SJMC's STS data for the period July 1, 2014 through December 31, 2014. MHCC staff concludes that UM-SJMC complies with this standard.

Quality

COMAR 10.24.17.07B(4)(a) and (b) The chief executive officer of the hospital shall certify annually to 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. The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance process.

UM-SJMC provided notes for the quarterly Comprehensive Unit Based Safety Program ("CUSP") meetings in 2016 and 2017 and four of the monthly Cardiac Surgery Integrated Care

("CSIC") meetings in 2017 as partial documentation of its quality assurance activities. UM-SJMC also provided notes for one patient safety committee meeting in 2016. Participants at the CUSP committee meetings include physicians and nurses from multiple disciplines. The CSIC meetings are also multidisciplinary, and focus on patient outcomes following cardiac surgery. The CSIC meetings include a review of performance metrics provided in STS reports and plans for addressing any areas for improvement identified. Copies of slides from two presentations provide additional information on quality improvement initiatives undertaken by UM-SJMC between 2015 and 2017. Lastly, UM-SJMC provided a spreadsheet with brief descriptions of cardiovascular operating room events in 2015 and 2016 that violate standard protocols, before, during, or after a scheduled surgical case, whether an injury occurred or not.

Thomas Smyth, President and CEO of UM-SJMC, submitted a letter stating that UM-SJMC is committed to identifying areas for improvement in the quality and outcomes of its cardiac surgery program. He also stated that annually or upon request, UM-SJMC will provide a report of the program's quality assurance activities.

Staff Analysis and Conclusion

UM-SJMC provided information documenting its quality assurance activities and the actions taken in response to any quality concerns identified. MHCC staff concludes that UM-SJMC 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 plan of correction.

Staff Analysis and Conclusion

UM-SJMC has consistently maintained a composite score for coronary artery bypass graft (CABG) surgeries of two stars or higher, as required. Table 1 shows the star ratings for each of six overlapping 12-month periods, the volume of CABG cases included in the ratings for each period, and the overall percentage of UM-SJMC's volume of cardiac surgery included in the STS ratings. As shown in Table 1, approximately 64 to 71 percent of UM-SJMC's cardiac surgery volume is included in the composite STS star ratings for the period January 2015 through June 2018. Hospitals with cardiac surgery programs typically perform many other types of surgeries or may perform CABG in combination with other surgical procedures, but the STS ratings shown in Table 1 are based on only isolated CABG procedures. For an individual patient who requires a different type of cardiac surgery, the information included in Table 1 may not be relevant. However, the Cardiac Surgery Chapter uses CABG as a reference point based not only on the recommendations of its Clinical Advisory Group but also on the continued advice of its current Cardiac Services Advisory Committee, which includes cardiac surgeons and interventional cardiologists. Isolated CABG is one of the most common cardiac surgery 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: UM-SJMC's Cardiac Surgery Volume, CABG Volume, and Composite STS Star Ratings for CABG by Reporting Period

12-Month Reporting Period	Jan. 2015 Dec. 2015	July 2015- June 2016	Jan 2016- Dec 2016	July 2016- June 2017	Jan 2017- Dec 2017	July 2017- June 2018
Composite Star Rating[1]	★★	★★	★★★	★★	★★	★★★
Total Isolated CABG Cases Included[2]	293	328	347	342	343	340
Total Cardiac Surgery Volume[3]	458	490	510	489	493	481
Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating	64%	67%	68%	70%	70%	71%

Sources: UM-SJMC submitted copies of its star ratings and CABG volume to MHCC for each time period shortly after receiving the information from STS; total cardiac surgery volume is based on MHCC staff analysis of HSCRC discharge abstract for January 2015- September 2018.

[1] The maximum number of stars awarded is three stars. Two stars indicates that a program is neither 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 November 2015, and using the procedure date to categorize cases by reporting period.

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 this surgery, if discharged.[1] The second component is the absence of major morbidity, which is defined to include any one of the following: reoperation; stroke; kidney failure; infection of the chest wound from surgery; or prolonged support by a breathing machine.[2] 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, which has been known for more than a decade to function longer than a vein graft.[3] The fourth component is receipt of all four specific perioperative medications that 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 CABG,

[1] Society of Thoracic Surgeons. (2017). STS Public Reporting Online. Retrieved from https://publicreporting.sts.org/cabg-composite-score

[2] Society of Thoracic Surgeons. (2017). STS Public Reporting Online. Retrieved from https://publicreporting.sts.org/cabg-composite-score

[3] Cameron, A., Davis, K.B., Green. G., Schaff, H.V. (1996). Coronary bypass surgery with internal-thoracic-artery grafts – effects on survival over a 15-year period. *New England Journal of Medicine*, 334(4):216-9; Goldman, S., Zadina, K., Moritz, T., Ovitt, T., Sethi G, Copeland, JG, . . . VA Cooperative StudyGroup #207/297/364 (2004). Long-term patency of saphenous vein and left internal mammary artery grafts after coronary artery bypass surgery: results from a Department of Veterans Affairs Cooperative Study. *Journal of the American College of Cardiology*, 44(11):2149-56. https://doi.org/10.1016/j.jacc.2004.08.064; Loop, F,D. (1996). Internal-thoracic-artery grafts. Biologically better coronary arteries. *New England Journal of Medicine*, 334(4):263-5.

approximately 80%.[4] Nationally, the vast majority of programs receive a two-star rating, indicating the program did not perform significantly worse or better than the national average at a statistically significant level.[5]

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 statewide 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

This standard is not applicable because hospitals and MHCC staff were not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality. However, MHCC staff has provided information below on how UM-SJMC performed on the revised standard adopted in regulations that became effective January 14, 2019.

The difference between UM-SJMC's all-cause 30-day risk adjusted operative mortality rate for isolated CABG cases and the average rate for all Maryland cardiac surgery programs is not statistically significant in any of the 12-month reporting periods between January 2015 and June 2018. A hospital's performance on this measure is acceptable as long as the hospital's risk adjusted operative mortality rate is similar or better than the national average for participants in the STS-ACSD. As shown in Table 2, for each of the six reporting periods, UM-SJMC's confidence interval for its all-cause risk adjusted operative mortality rate for isolated CABG includes the national average in four reporting periods, indicating that UM-SJMC performed similar to the national average for all participants in the STS-ACSD. In two reporting periods, the ones ending June 2017 and December 2017, UM-SJMC performed better than the national average at a statistically significant level. The results are shown graphically in Figure 1. In Figure 1, an 'X' indicates the national average, and a triangle indicates the performance for UM-SJMC. MHCC staff concludes that UM-SJMC would have met the current performance standard, if it had been applicable between January 2015 and June 2018.

[4] Society of Thoracic Surgeons. (June 2018). Report Overview- Risk Adjustment Supplement STS Report- Period Ending 12/31/2017.
[5] Society of Thoracic Surgeons. (June 2018). Report Overview- Risk Adjustment Supplement STS Report- Period Ending 12/31/2017.

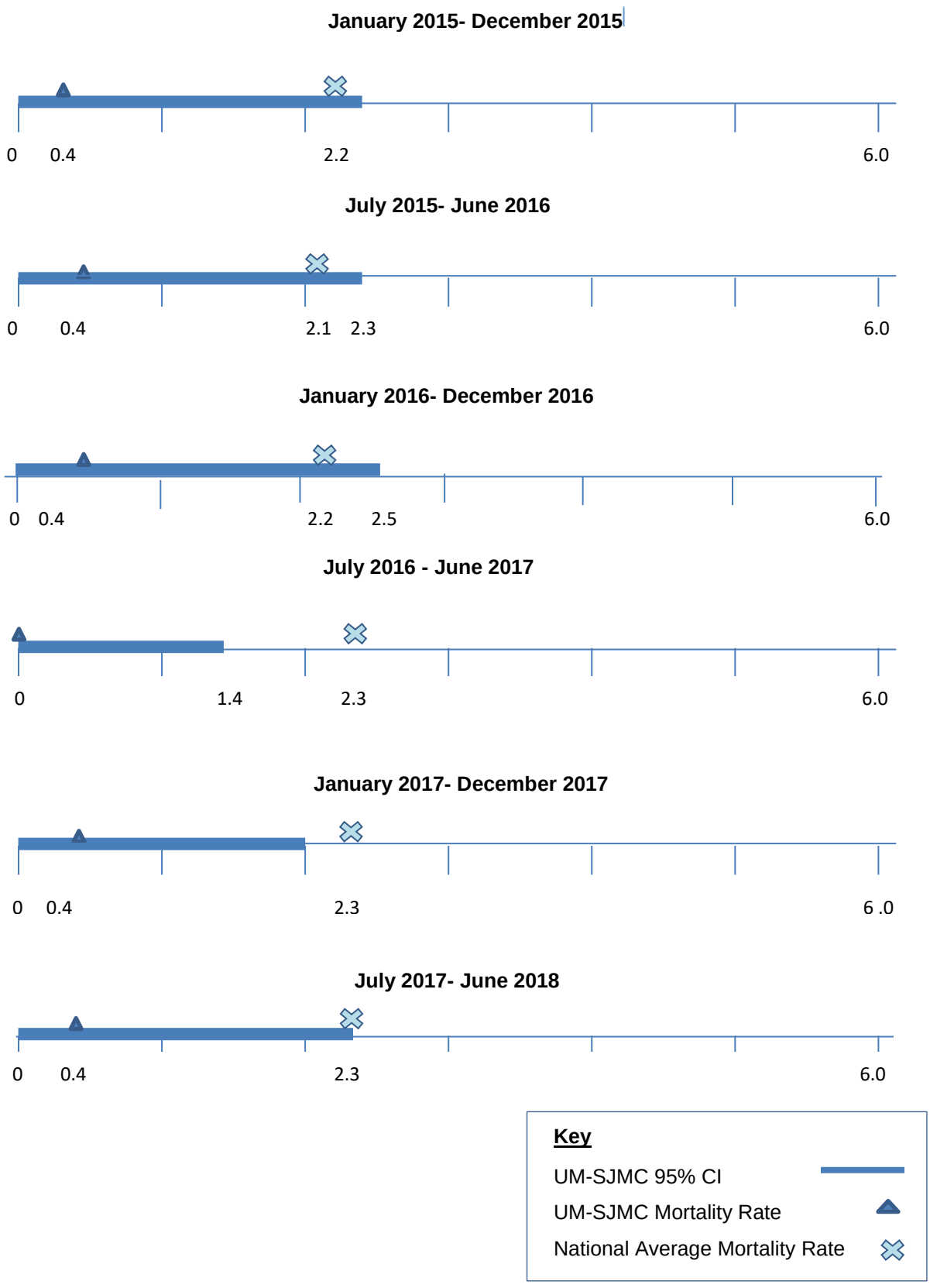
Table 2: All-Cause Risk Adjusted Operative Mortality for Isolated CABG: UM-SJMC Comparison to the National Average, by Reporting Period

	Risk-Adjusted Isolated CABG Operative Mortality			95% Confidence Interval (CI)		
Reporting Period	Jan. 2015 – Dec. 2015	July 2015 - June 2016	Jan. 2016 – Dec. 2016	Jan. 2015 – Dec. 2015	July 2015 - June 2016	Jan. 2016 – Dec. 2016
UM-SJMC	0.4	0.4	0.4	(0.0 , 2.3)	(0.0 , 2.3)	(0.0 , 2.5)
National Average	2.2	2.1	2.2	---	---	---
Reporting Period	July 2016 - June 2017	Jan. 2017 – Dec. 2017	July 2017 - June 2018	July 2016 - Jun 2017	Jan. 2017 – Dec. 2017	July 2017 - June 2018
UM-SJMC	0.0	0.4	0.4	(0.0 , 1.4)	(0.0 , 2.0)	(0.0 , 2.3)
National Average	2.3	2.3	2.3	---	---	---

Source: STS analysis of data collected in the STS-ACSD.

Notes: It is not valid to compare Maryland hospitals to each other and rank them based on the risk-adjusted operative mortality rates for individual hospitals. The risk-adjusted operative mortality rates and confidence intervals only provide information on whether a hospital has performed worse or better than the national average operative mortality rate at a statistically significant level. Operative 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 Risk-Adjusted Operative Mortality Rates for Isolated CABG: UM-SJMC Compared to the National Average by Reporting Period



Across all Maryland hospitals, the all-cause risk adjusted operative mortality rates for isolated CABG fall within a relatively narrow range. For the 12-month period January 2015 to December 2015, the performance of Maryland cardiac surgery programs ranged from zero to 2.4%. For the 12-month period July 2015 to June 2016, the performance of Maryland cardiac surgery programs ranged from zero to 2.7%. For the 12-month period January 2016 to December 2016, the performance of Maryland cardiac surgery programs ranged from zero to 3.4%. Given the very low-level of operative mortality across most programs and the volume of cases typically performed at individual hospitals, this performance measure cannot be used to discriminate among programs, except to identify outliers relative to the average for all Maryland cardiac surgery programs.

Volume Requirements

COMAR 10.24.17.07B(6)(a) A cardiac surgery program shall maintain an annual volume of 200 or more cases.

UM-SJMC reported a volume of 461 adult cardiac surgery cases in calendar year (CY) 2015, 546 cases in CY 2016, and 491 cases for January 2017 through November 2017.

Staff Analysis and Conclusion

Based on MHCC staff's analysis of the HSCRC data, UM-SJMC performed 458 cardiac surgery cases in CY 2015, 510 cases in CY 2016, and 493 cases in CY 2017. MHCC staff concludes that these case counts differ from UM-SJMC reported counts due to minor differences in the definitions of adult cardiac surgery used by MHCC and UM-SJMC. Staff notes that the MHCC definition of cardiac surgery changed in November of 2015 with the adoption of a replacement Cardiac Surgery Chapter. In addition, the ICD-9 procedure codes were replaced by ICD-10 procedure codes beginning October 1, 2015, and an official crosswalk between the ICD-10 and ICD-9 codes has not yet been adopted by the Commission. MHCC staff concludes that UM-SJMC meets the annual volume requirement, by exceeding a volume of 200 cardiac surgery cases for the three most recent calendar years for which data is available.

IV. RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff concludes that UM-SJMC meets all of the requirements for a Certificate of Ongoing Performance found 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 UM-SJMC to continue providing cardiac surgery services for four years.