IN THE MATTER OF	*	**BEFORE THE**
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SINAI HOSPITAL OF BALTIMORE	*	**MARYLAND HEALTH**
	*	
Docket No.: 17-24-CP005	*	**CARE COMMISSION**
	*	

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STAFF REPORT & RECOMMENDATION

FOR A CERTIFICATE OF ONGOING PERFORMANCE
FOR CARDIAC SURGERY SERVICES

May 16, 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 stakeholders' 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 effective August 2014. The Cardiac Surgery Chapter was subsequently replaced in November 2015 and 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 to 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 that reflected the recommendations of the CAG. As a result, the standard addressed by applicants was determined to be inapplicable; however, information on how hospitals performed relative to the newly adopted mortality standard is included in staff reports.

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

Sinai Hospital of Baltimore ("Sinai Hospital") is a 340-bed general acute care hospital located in Baltimore City, Maryland. The hospital received a Certificate of Need to establish its cardiac surgery program in 1990.

Health Planning Region

Four health planning regions for adult cardiac surgery services are defined in COMAR 10.24.17. Sinai Hospital 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: University of Maryland St. Joseph's Medical Center; University of Maryland Medical Center; Johns Hopkins Hospital; and MedStar Union Memorial Hospital.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

Sinai Hospital filed a Certificate of Ongoing Performance application on December 11, 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.

Sinai Hospital participates in the Society of Thoracic Surgeons' ("STS") adult cardiac surgery data registry ("STS-ACSD") data submission and also submits STS-ACSD data to MHCC staff as required.

Staff Analysis and Conclusion

Sinai Hospital has complied with the submission of STS data to MHCC in accordance with the established schedule. An audit of the STS data conducted by Advanta Government Solutions, at the request of MHCC, did not identify any concerns regarding the accuracy or completeness of the Hospital's STS data for the period July 1, 2014 through December 31, 2014. MHCC staff concludes that Sinai Hospital is compliant 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.

Sinai Hospital provided the most detailed documentation of its quality assurance activities among all the Certificate of Ongoing Performance applications for cardiac surgery programs. The documentation covers both minutes and materials for quality assurance meetings and evaluations of individual surgeons with respect to specific performance metrics. The hospital also provided information on external case reviews conducted over the review period and detailed information on quality oversight and leadership accountability for the hospital overall. Primarily three separate groups at Sinai Hospital engage in quality assurance activities for cardiac services. These are the Ongoing Professional Practice Evaluation Committee, the Cardiovascular Multidisciplinary Committee, and the Cardiac Surgery Division.

Meetings of the hospital's Ongoing Professional Practice Evaluation Committee ("OPPEC") focus primarily on an overview of the cardiac surgery professional practice volumes, physician performance, and performance improvement opportunities on quality of care. Members of the committee include cardiac surgeons and other staff for the cardiac surgery program. OPPEC meeting are held biannually, and the hospital provided meeting minutes that cover the periods: July 2014 through May 2015; July 2015 through December 2015; January 2016 through June 2016; and January 2017 through June 2017.

Sinai Hospital stated that its Cardiovascular Multidisciplinary Committee ("CVI-MDC") meets to assesses and improve care by aligning measured quality indicators with the quality goals and improvement standards of the hospital. The CVI-MDC reviews patient care process and outcome measures, identifies improvement opportunities unique to cardiovascular services, gathers clinical evidence and best practices from other organizations that can be adapted to Sinai Hospital, and conducts proactive risk assessments to determine the need for changes that will reduce harm and increase process reliability. Additionally, CVI-MDC engages staff in the application of process improvement methods, tests initiatives to validate improvement ideas, and reinforces a culture within service lines that supports performance improvement and patient safety. Sinai Hospital provided meeting minutes for CVI-MDC meetings held between February 2015 and September 2017.

The Cardiac Surgery Division focuses on reviewing cases with morbidity and mortality. Sinai Hospital provided attendance sheets for meetings to discuss cases with morbidity and mortality for the period November 2014 through September 2017.

Jonathan Ringo, the President and Chief Operating Officer of Sinai Hospital, submitted a letter stating that the hospital is committed to identifying areas of improvement in the quality and outcomes of the cardiac surgery program. He also stated that, annually or upon request, Sinai Hospital will provide details of its quality assurance activities.

Staff Analysis and Conclusion

Sinai Hospital provided information documenting its quality assurance activities and the actions taken in response to any quality concerns identified. MHCC staff concludes that Sinai Hospital 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

Sinai Hospital has consistently maintained a composite score for coronary 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 isolated CABG cases included in the ratings for each period, and the estimated overall percentage of Sinai Hospital's volume of cardiac surgery included in the STS ratings. As shown in Table 1, approximately 72 to 85 percent of the hospital'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 and may perform CABG in combination with other types of 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 isolated CABG as a reference point based not only on the recommendations of the 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: Sinai Hospital of Baltimore's Cardiac Surgery Volume, CABG Volume, and Composite STS Star Ratings by Reporting Period

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]	294	285	292	351	353	265
Total Cardiac Surgery Volume	380	382	400	429	416	328
Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating	76%	73%	72%	80%	85%	81%

Sources: Sinai Hospital 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 – June 2018.

[1] The maximum number 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 open-heart 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 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.[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 for the bypass graft, 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.[4] The first component, the absence of operative mortality carries the most weight in the overall composite rating for isolated CABG cases, approximately 80%.[5] Nationally, the vast majority of programs

[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 Study Group #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.

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

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

receive a two-star rating, indicating the program did not perform significantly worse or better than the average for all participants in the STS-ACSD, at a statistically significant level.[6]

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 Sinai Hospital performed on the revised standard adopted in regulations that became effective January 14, 2019.

The difference between Sinai Hospital's all-cause 30-day risk adjusted operative mortality rate for isolated CABG cases and the national average 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, Sinai Hospital's confidence interval for its all-cause risk adjusted operative mortality rate for isolated CABG includes the national average, indicating that Sinai Hospital performed similar to the national average for all participants in the STS-ACSD. The results are shown graphically in Figure 1. In Figure 1, an 'X' indicates the national average, and a triangle indicates the performance for Sinai Hospital. As shown in Figure 1, the national average falls within the CI for Sinai Hospital's performance in each reporting period. MHCC staff concludes that Sinai Hospital would have met the current performance standard, if it had been applicable between January 2015 and June 2018.

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

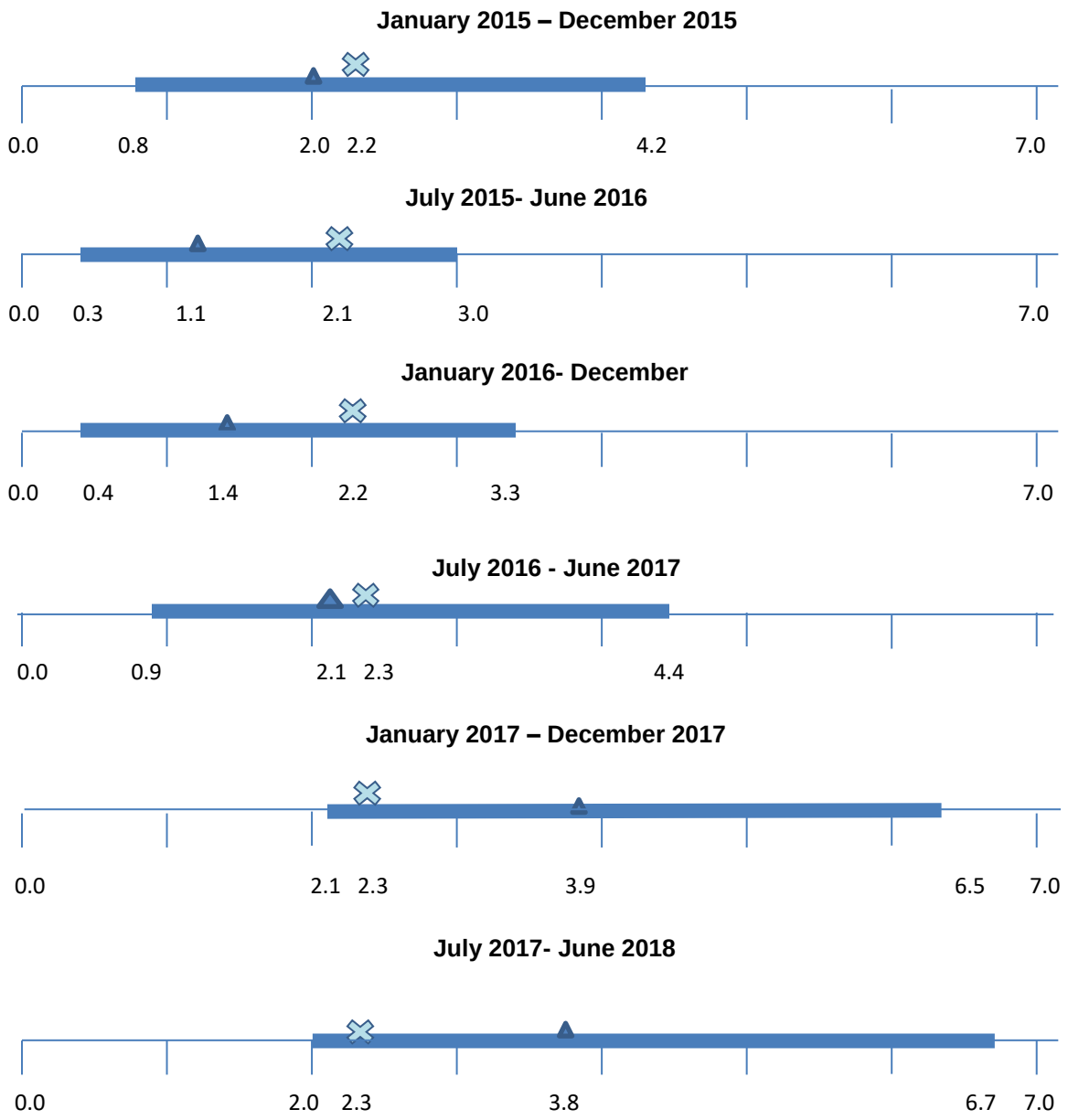
Table 2: All-Cause Risk Adjusted Operative Mortality Rates for Isolated CABG: Sinai Hospital Comparison to the National Average, by Reporting Period

	All-Cause 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
Sinai Hospital	2.0	1.1	1.4	(0.8 , 4.2)	(0.3 , 3.0)	(0.4 , 3.3)
National Average	2.2	2.1	2.2	---	---	---
Reporting Period	July 2016-June 017	Jan. 2017-Dec. 2017	July 2017-June 2018	July 2016 - June 2017	Jan. 2017-Dec. 2017	July 2017-June 2018
Sinai Hospital	2.1	3.9	3.8	(0.9 , 4.4)	(2.1 , 6.5)	(2.0 , 6.7)
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 significantly worse or better relative to 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: Sinai Hospital 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 rates for Maryland cardiac surgery programs ranged from zero to 2.4%; for the 12-month period ending June 30, 2016, the rate range was zero to 2.7%; for CY 2016, the rate range was zero to 3.4%; for the 12-month period ending June 30, 2017, the rate range was zero to 5.8%; for CY 2017, the rate range was 0.4% to 5.2%; and, for the 12-month period ending June 30, 2018, the rate range was 0.4% to 3.8%. Given the relatively low rates for risk adjusted operative mortality across most programs and the volume of cases typically performed at individual hospitals, this performance measure cannot be used to discriminate meaningfully among programs, except to identify outliers relative to the national average.

Volume Requirements

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

Sinai Hospital reported a volume of 385 cardiac surgery cases for calendar year ("CY") 2015, 403 cases for CY 2016, and 211 cases for the period January through June 2017.

Staff Analysis and Conclusion

MHCC staff analyzed the HSCRC data for Sinai Hospital, and the information reported to the STS-ACSD by the hospital. Based on MHCC staff's analysis of the HSCRC data, Sinai Hospital performed a total of 380 cardiac surgery cases in CY 2015, 400 cases in CY 2016, and 416 cases in CY 2017. MHCC staff concludes that these case counts may differ due to minor differences in the definitions of adult cardiac surgery used by STS, MHCC, and Sinai Hospital. 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 was adopted only recently in the regulations effective January 2019. MHCC staff concludes that Sinai Hospital meets the annual volume requirement, by exceeding a volume of 200 cardiac surgery cases for the four most recent fiscal years for which data is available.

IV. RECOMMENDATION

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