

**IN THE MATTER OF THE
SINAI HOSPITAL OF BALTIMORE**

Docket No. 22-24-CP037

*** BEFORE THE
* MARYLAND HEALTH
* CARE COMMISSION**

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

April 18, 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 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 temporary waiver.

B. Applicant

Sinai Hospital of Baltimore

The Sinai Hospital of Baltimore (Sinai Hospital) is a 424-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

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.

The Cardiac Surgery Chapter defines four health planning regions for adult cardiac surgery services. Sinai Hospital 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: The University of Maryland Medical Center, University of Maryland St. Joseph Medical Center, The Johns Hopkins Hospital, MedStar Union Memorial Hospital, and Luminis Anne Arundel Medical Center.

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 the information provided by Sinai Hospital and MHCC staff's analysis of this information follows.

II. PROCEDURAL HISTORY

Sinai Hospital first received a Certificate of Ongoing Performance for cardiac surgery services on May 16, 2019, for four years. Sinai Hospital filed a Certificate of Ongoing Performance application for cardiac surgery services on September 9, 2022. MHCC staff requested additional information on November 3, 2022, December 1, 2022, and April 1, 2024. The hospital provided additional information on November 17, 2022, December 15, 2022, and April 2, 2024. MHCC staff also notified Sinai Hospital that its Certificate of Ongoing Performance was extended by six-months on May 10, 2023 and November 3, 2023. These extensions were granted because MHCC staff needed additional time to complete a focused review of the program.

Sinai Hospital received a copy of the preliminary focused review report on June 13, 2023. MHCC staff met with staff from Sinai Hospital to discuss the results of the focused review on August 24, 2023. MHCC staff sent follow-up questions to Sinai Hospital on August 25, 2023, and a response was submitted by Sinai Hospital on September 7, 2023. A final focused review report was issued on November 22, 2023. Subsequently, MHCC staff contracted with a cardiologist to review EKGs in some cases to resolve conflicting interpretations of EKGs by Sinai Hospital, an external reviewer hired by Sinai Hospital, and the external reviewer hired by MHCC staff. The report with the results of the EKG reviews was finalized on February 14, 2024, and MHCC staff sent the results to Sinai Hospital on February 20, 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 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) and submits its STS-ACSD data and select STS report information to MHCC staff.

Staff Analysis and Conclusion

Sinai Hospital 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. Sinai Hospital submitted the required pages for the three-year reports, which together cover the period from July 2018 through June 2023.

MHCC staff concludes that Sinai Hospital 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.

Sinai Hospital provided detailed documentation of its quality assurance activities. The documentation covers both minutes and materials for quality assurance meetings and the performance of individual surgeons with respect to specific quality metrics, including in-hospital mortality, out-of-hospital mortality, number of cases with an opportunity for improvement identified, and patient experience complaints. The hospital also provided information on external case reviews conducted over the review period and detailed information on quality oversight. This information indicates that Sinai Hospital is conducting internal and external peer review of cardiac surgery cases routinely. Primarily Sinai Hospital engages in quality assurance activities for cardiac services through the Cardiovascular Institute (CVI) Peer Review Committee, the CVI Vasculature Multidisciplinary Committee (MDC), and the Chair for the Division of Cardiac Surgery.

The CVI Peer Review Committee is authorized by the hospital's Medical Executive Committee to conduct peer review. This Committee monitors and evaluates practitioners on an ongoing basis. The Committee also makes recommendations to Department Chairs for actions to take in response to concerns identified. When system issues are identified they are shared with the CVI Vasculature MDC. There is a Quality Oversight Committee (QOC) that receives reports from the CVI Vasculature MDC and provides accountability. Sinai Hospital provided minutes from the QOC meetings for the period from September 2018 through April 2022. The minutes reference cardiac surgery and other cardiac services. The hospital also provided a detailed flow chart explaining the process for the handling of external peer review of cases.

Sinai Hospital provided examples of process improvement initiatives that include improving early extubation of patients following cardiac surgery, reducing readmissions of cardiac surgery patients, decreasing blood utilization for cardiac surgery patients, and increasing referrals for cardiac rehabilitation. Sinai Hospital provided data on its annual performance for the period from January 2017 through December 2021 and the first six months of 2022, which shows the hospital has improved on the percentage of patients with early extubation, as well as decreased the percentage of patients with prolonged vent hours, which is defined as greater than 24 hours. With respect to readmissions, the hospital explained that it has redesigned discharge education for patients to promote patient safety, patient satisfaction, and to potentially reduce readmissions. Sinai Hospital did not provide information on the trend over time in readmissions. However, the hospital did provide trend information on its blood utilization for isolated coronary artery bypass graft (CABG) surgeries between CY 2018 and CY 2021. This information shows the hospital has decreased its use of operative and post-operative blood products. With respect to increasing referrals to outpatient cardiac rehabilitation, Sinai Hospital explained that it participated in a national initiative funded by the Agency for Health Care Research and Quality (AHRQ). Staff received 12 months of training, coaching, and technical support. The hospital reported that patient referral rates for cardiac rehabilitation services has increased since implementing the practices learned through the AHRQ initiative.

As will be described later in this report, Sinai Hospital's performance on a measure of mortality for isolated CABG cases for the period from January to December 2019 triggered a focused review because the hospital's performance was statistically significantly worse than the national average for participants in the STS data registry. Sinai Hospital addressed concerns raised in the focused review by explaining the actions that it had taken in CY 2020 as well as additional changes in later years.

Amy Schlossman, President and Chief Operating Officer of Sinai Hospital, submitted a letter stating that Sinai Hospital is committed to identifying areas of improvement in the quality and outcomes of the hospital's cardiac surgery program. Previously, a letter was submitted by the former president for the hospital, Daniel Blum.

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 reviewed this information and 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

plans of correction.

Sinai Hospital submitted select information from its STS performance reports as required that include the star ratings for CABG cases and other performance measures for cardiac surgery cases.

Staff Analysis and Conclusion

Sinai Hospital maintained an STS composite score for coronary artery bypass graft (CABG) surgeries of two stars during the period from January 2018 through June 2022. 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.⁴ STS updated the methodology to reflect a three-year period with a 95% credible interval in CY 2021. For this reason, STS also did not generate a benchmark or reports for CY 2021. The three-year period reports for Sinai Hospital also show an overall rating of two stars. 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 three three-year periods, the volume of isolated CABG cases included in the ratings for each period, and the overall percentage of Sinai Hospital’s volume of cardiac surgery included in the STS ratings. As shown in Table 1, Sinai Hospital received a two-star STS CABG composite score rating in each reporting period. In addition, isolated CABG cases accounted for between 75% and 79% of the total adult cardiac surgery volume at Sinai Hospital 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 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.

Table 1: Sinai Hospital’s Cardiac Surgery Volume, Isolated CABG Volume, and Composite STS Star Ratings for CABG, by Reporting Period

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.

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	★ ★	238	303	78.5%
Jul 2018 - Jun 2019	★ ★	243	307	79.2%
Jan 2019 - Dec 2019	★ ★	230	290	79.3%
Jul 2019 - Jun 2020	★ ★	158	210	75.2%
Jan 2020 - Dec 2020	★ ★	126	162	77.8%
Jul 2018 - Jun 2021	★ ★	543	706	76.9%
Jan 2019 - Dec 2021	★ ★	502	645	77.8%
Jul 2019 - Jun 2022	★ ★	473	613	77.2%
Jan 2020 – Dec 2022	★ ★	455	580	78.4%
Jul 2020 - Jun 2023	★ ★	502	625	80.3%

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

¹ Sinai Hospital 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 range 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 – June 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 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 Sinai Hospital 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

Sinai Hospital’s all-cause 30-day risk-adjusted mortality rate for isolated CABG cases was similar to the national average in all reporting periods, except in CY 2019. With the exception of CY 2019, the hospital’s risk adjusted mortality rate 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 STS. MHCC staff concludes that Sinai Hospital 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: Sinai Hospital Comparison to the National Benchmark, by Reporting Period

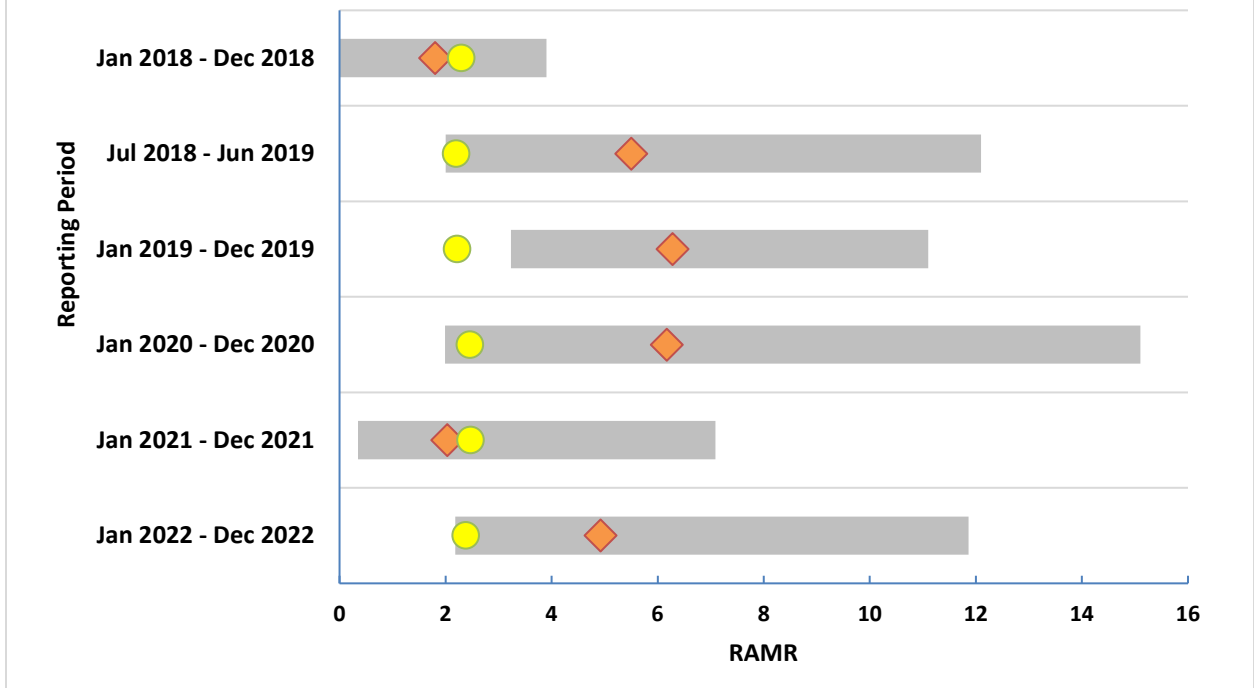
	Jan 2018 - Dec 2018	Jul 2018- Jun 2019	Jan 2019- Dec 2019	Jan 2020- Dec 2020	Jan 2021- Dec 2021	Jan 2022- Dec 2022
STS National Benchmark	2.3	2.2	2.22	2.46	2.47	2.38
Sinai Hospital	1.8	5.5	6.28	6.17	2.03	4.92
95% CI	(0.6,4.5)	(2.0,12.1)	(3.23,11.1)	(1.99,15.1)	(0.35,7.09)	(2.18,9.68)

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

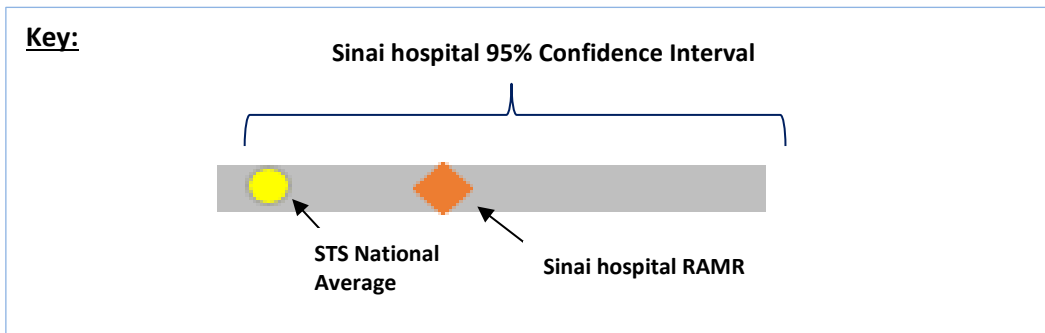
Notes: The all-cause 30-day risk-adjusted mortality rate and confidence intervals only provide information on whether a hospital has performed worse or better relative to the national average mortality rate at a statistically significant level. The mortality rates include in-hospital patient deaths following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

* STS analysis of data not available for July 2019 - June 2020 or July 2020 - June 2021.

Figure 1: All-Cause 30-Day Risk-Adjusted Mortality Rates (RAMR) for Isolated CABG: Sinai Hospital Compared to the National Average for All Cardiac Surgery Programs by Reporting Period



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



Sinai Hospital’s performance on the mortality metric for isolated CABG cases in CY 2019 triggered a focused review because the hospital performed statistically significantly worse than the national average for STS registry participants. The initiation of the focused review was delayed because of a longer than usual lag in getting the performance metric information from STS and delays with establishing who would conduct the focused review. A preliminary report with the results of the focused review was provided to Sinai Hospital on June 13, 2023. The hospital initially responded on July 10, 2023, requesting to meet with MHCC staff. MHCC staff and representatives for Sinai Hospital met to discuss the focused review on August 24, 2023. Following this meeting, MHCC staff sent a list of questions to Sinai Hospital that pertained to the conclusions of the focused review. Sinai Hospital responded to these questions on September 7, 2023. Based on this

information, the focused review report was revised, and a final report was issued on November 22, 2022. For details regarding the focused review, Commissioners should refer to Appendix 1. This information is confidential and protected by MHCC's status as a medical review committee.

Based on the hospital's acceptable performance on the mortality metric for isolated CABG cases in CY 2020, CY 2021, and CY 2022, and the hospital already having taken action to address key concerns identified in the focused review, MHCC staff recommends that the Commission find that Sinai Hospital complies with this standard.

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.

Sinai Hospital has maintained an annual volume of 309 cases for CY 2018, 289 cases for CY 2019, 154 cases for CY 2020, 190 cases for CY 2021, and 121 cases for the period from January to June 2022.

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 303 cases for CY 2018, 290 cases for CY 2019, 162 cases for CY 2020, 193 cases for CY 2021, and 225 cases for CY 2022. MHCC staff's analysis of case volume based on the Health Services Cost Review Commission discharge abstract data case counts are similar to the case counts from Sinai Hospital. These case counts may differ due to minor differences in the definitions of adult cardiac surgery used by MHCC staff and Sinai Hospital.

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 programs performing 200 or more cases per year are more likely to have better outcomes. Sinai Hospital performed over 200 cardiac surgery cases annually from January 2018 through December 2022 for all years when the case volume standard is applicable.

MHCC staff concludes that Sinai Hospital complies with this standard.

IV. RECOMMENDATION

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