

**IN THE MATTER OF  
JOHNS HOPKINS HOSPITAL**

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

**Docket No.: 17-24-CP009**

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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**

Johns Hopkins Hospital (“JHH”), is a 1,114-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 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 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; Sinai Hospital of Baltimore; and MedStar Union Memorial Hospital.

### **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 JHH's documentation and MHCC staff's analysis of this information follows.

## **II. PROCEDURAL HISTORY**

JHH filed a Certificate of Ongoing Performance application on December 15, 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.*

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

### **Staff Analysis and Conclusion**

JHH 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 JHH's STS data for the period July 1, 2014 through December 31, 2014. 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 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.*

JHH performs quality assurance of its cardiac surgery program through a series of meetings, clinical care reviews, and technical conferences. Peer review meetings held by the

hospital in 2017 included weekly meetings to review cardiac surgery cases with morbidity, mortality, or that resulted in hospital readmissions. Bi-monthly peer review meetings were also held for cases involving ventricular assist devices and heart transplants.

Other quality assurance activities include meetings to address the hospital's performance relative to benchmarks for its cardiac surgery program. This benchmark information is obtained through participation in the STS-ACSD, membership in Vizient, and the Maryland Cardiac Surgery Quality Initiative (MCSQI). The STS-ACSD benchmark information is reviewed quarterly; MCSQI data is reviewed monthly, and Vizient data is reviewed on an ongoing basis, when ad hoc reports are generated. The Vizient data and benchmarks are derived from administrative patient information, and JHH compares its performance with other quaternary institutions. JHH noted that the reports from Vizient are shared monthly with the Chief of Cardiac Surgery and in the group quality meetings for Cardiac Surgery and Anesthesia. The STS report measures include the frequency of intraoperative red blood cell usage, clinical assessment of the use of an internal mammary artery, review of post-operative complications such as prolonged intubation, renal insufficiency, stroke, return for reoperation, and mortality. The data is reviewed by the Director of Quality, the Quality Improvement Team Leader, the Director of Cardiac Surgery Clinical Registries, and the STS data management team.

JHH provided additional information from its STS reports indicating how the hospital's operative mortality rates compare to STS benchmarks for aortic valve replacement cases, mitral valve replacement cases, mitral valve repair cases, combined aortic valve replacement and CABG cases, combined mitral valve replacement and CABG, and combined mitral valve repair and CABG. JHH also provided benchmark and performance information for its heart transplant program and quality improvement initiatives undertaken. JHH provided a list of attendees and minutes for two monthly meetings of its cardiovascular intensive care unit held in 2017. JHH also provided materials used in several other meetings to illustrate its performance on various performance metrics.

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 on the program's quality assurance activities.

## **Staff Analysis and Conclusion**

JHH provided information documenting its quality assurance activities and 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 has consistently maintained an STS 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 overall percentage of JHH’s volume of cardiac surgery included in the STS ratings for isolated CABG cases. As shown in Table 1, approximately 40 to 50 percent of JHH’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 multiple types of cardiac surgery or may perform CABG in combination with other cardiac 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 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: JHH's Cardiac Surgery Volume, Isolated CABG Volume, and Composite STS Star Ratings for Isolated CABG, by Reporting Period**

<b>Reporting Period</b>	<b>Jan. 2015- Dec. 2015</b>	<b>July 2015- June 2016</b>	<b>Jan 2016- Dec 2016</b>	<b>July 2016- June 2017</b>	<b>Jan 2017- Dec 2017</b>	<b>July 2017- June 2018</b>
<b>Composite Star Rating<sup>1</sup></b>						
<b>Total Isolated CABG Cases Included<sup>2</sup></b>	469	421	404	416	401	377
<b>Total Cardiac Surgery Volume<sup>3</sup></b>	1,158	1,046	994	930	799	751
<b>Estimated Percentage of Cardiac Surgery Cases Included in CABG Star Rating</b>	41%	40%	41%	45%	50%	50%

Sources: JHH 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.

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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 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.<sup>1</sup> 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.<sup>2</sup> 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 have been known for more than a decade to function longer than a vein graft.<sup>3</sup> 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 rating, approximately 80%.<sup>4</sup> 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.<sup>5</sup>

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

The difference between JHH'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, JHH's confidence interval for its all-cause risk adjusted operative mortality rate for isolated CABG includes the national average, indicating that JHH performed similar to the national average for all participants in the STS-ACSD. The results are shown

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

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

<sup>3</sup> 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.

<sup>4</sup> Society of Thoracic Surgeons. (June 2018). Report Overview- Risk Adjustment Supplement STS Report- Period Ending 12/31/2017.

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

graphically in Figure 1. In Figure 1, an ‘X’ indicates the national average, and a triangle indicates the performance for JHH. As shown in Figure 1, the national average falls within the CI for JHH’s performance in each reporting period. MHCC staff concludes that JHH would have met the current performance standard, if it had been applicable between January 2015 and June 2018.

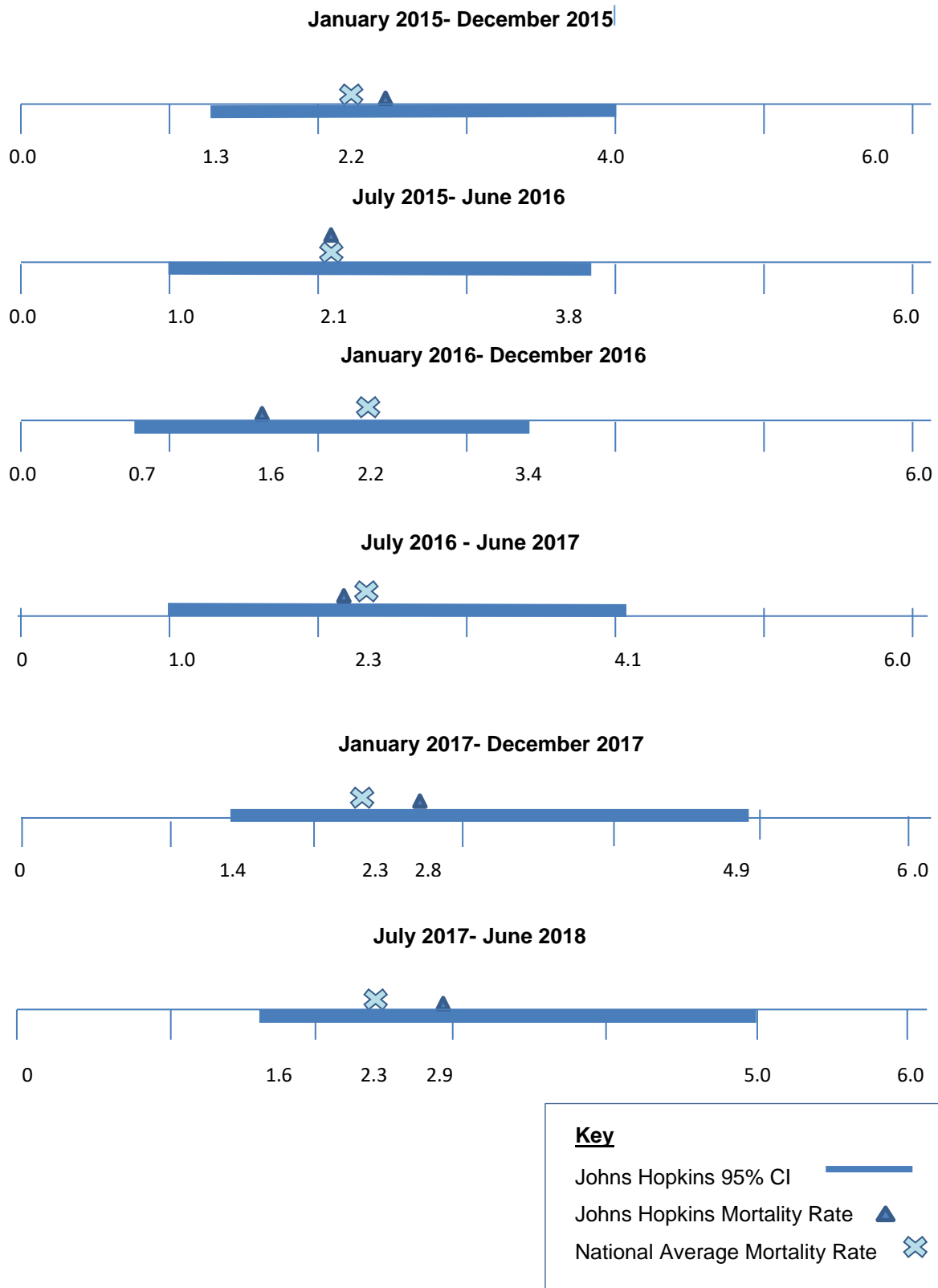
**Table 2: All-Cause Risk Adjusted Operative Mortality Rate for Isolated CABG: John’s Hopkins’s Hospital Comparison to the National Average, by Reporting Period**

Reporting Period	All-Cause Risk-Adjusted Isolated CABG Operative Mortality			95% Confidence Interval (CI)		
	Jan. 2015 - Dec. 2015	Jul 2015 - Jun 2016	Jan. 2016 – Dec. 2016	Jan. 2015 – Dec. 2015	July 2015 - June 2016	Jan. 2016 – Dec. 2016
JHH	2.4	2.1	1.6	(1.3, 4.0)	(1.0-3.8)	(0.7,3.4)
National Average	2.2	2.1	2.2	--	--	--
Reporting Period	July 2016- June 2017	Jan. 2017- Dec. 2017	July 2017- June 2018	July 2016- June 2017	Jan. 2017- Dec. 2017	July 2017- June 2018
JHH	2.2	2.8	2.9	(1.0, 4.1)	(1.4, 4.9)	(1.6, 5.0)
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: Johns Hopkins 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.***

JHH reported a volume of 1,014 cases for calendar year (CY) 2015, 936 cases for CY 2016, and 400 cases from January 1 to June 30, 2017.

### **Staff Analysis and Conclusion**

Based on MHCC staff's analysis of the HSCRC data, JHH performed 1,158 cardiac surgery cases in CY 2015, 994 cases in CY 2016, and 799 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 MHCC, and JHH. 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 JHH 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 Johns Hopkins 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 Johns Hopkins Hospital to continue providing cardiac surgery services for the next four years.