

IN THE MATTER OF

SINAI HOSPITAL

OF BALTIMORE

Docket No.: 19-03-CP023

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BEFORE THE

MARYLAND HEALTH

CARE COMMISSION

**STAFF REPORT AND RECOMMENDATION
CERTIFICATE OF ONGOING PERFORMANCE
FOR PRIMARY & ELECTIVE PERCUTANEOUS CORONARY INTERVENTION
SERVICES**

December 17, 2020

I. INTRODUCTION

A. Background

Percutaneous coronary intervention (PCI), commonly known as coronary angioplasty, is a non-surgical procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing. Primary (or emergency) PCI programs provide emergency PCI intervention in the event of a heart attack shortly after it begins. Elective (or non-primary) PCI programs provide interventions that revascularize coronary arteries that are substantially blocked but have not yet resulted in an immediate cardiac event.

For many years, only Maryland hospitals with on-site cardiac surgery services could provide PCI. However, in the 1990s, Maryland began allowing some hospitals to perform primary PCI services without cardiac surgery on-site, first as part of research trials evaluating the safety of providing primary PCI at such hospitals and, later, as a regular clinical service, based on the research findings. The Commission issued waivers to hospitals in order to exempt these hospitals from the co-location requirement of PCI services with cardiac surgery. In the following decade, similar research evaluated the safety of providing elective PCI services at hospitals without on-site cardiac surgery.

The nine Maryland hospitals that obtained waivers to provide elective PCI services participated in a multi-site clinical trial, C-PORT E, a study that was approved by the Commission upon the recommendation of its Research Proposal Review Committee. This non-inferiority study provided evidence that elective PCI could be performed safely and effectively at hospitals without on-site cardiac surgery. In 2012, the Maryland legislature passed a law directing the Commission to establish a process and minimum standards for a hospital to obtain and maintain Certificates of Ongoing Performance for the provision of cardiac surgery and PCI. The legislation required the Commission to establish a Clinical Advisory Group (CAG) to advise the agency on development of regulations to implement the new law.

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 revised in November 2015 and again in January 2019. The main change in these revisions to the Cardiac Surgery Chapter that affects PCI programs has been a change to the benchmark used to evaluate hospitals' risk-adjusted mortality rates. Commission 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 PCI services in Maryland and for determining whether a hospital should be granted a Certificate of Ongoing Performance. A Certificate of Ongoing Performance for PCI services

authorizes a hospital to continue to provide PCI services, either primary or both primary and elective (nonprimary) PCI 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 demonstrate that it continues to meet the requirements in COMAR 10.24.17 for a Certificate of Ongoing Performance in order for the Commission to renew the hospital's authorization to provide PCI services.

B. Applicant

Sinai Hospital of Baltimore

Sinai Hospital of Baltimore (Sinai) is a 348-bed general hospital located in Baltimore (Baltimore City). Sinai has a cardiac surgery program on site.

Health Planning Region

Four health planning regions for adult cardiac services are defined in COMAR 10.24.17. Sinai 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. Fourteen hospitals in this health planning region provide PCI services. One program has only provided primary PCI services since its inception; the other programs all provide both primary and elective PCI services. Five of the fourteen hospitals also provide cardiac surgery services, and one additional hospital in this region has a Certificate of Need to establish a cardiac surgery program and is expected to begin operating in December 2020.

C. Staff Recommendation

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

II. PROCEDURAL HISTORY

Sinai filed a Certificate of Ongoing Performance application on June 21, 2019. MHCC staff reviewed the application and requested additional information on April 24, 2020, August 14, 2020, and December 9, 2020. MHCC received additional information on May 18, 2020, September 1, 2020, September 8, 2020, September 10, 2020, November 10, 2020, and December 10, 2020.

III. PROJECT CONSISTENCY WITH REVIEW CRITERIA

Data Collection

10.24.17.07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACCF NCDR registry, with submission of duplicate information to the Maryland Health Care Commission. Each elective PCI 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 PCI

programs.

Sinai responded that there are currently no deficiencies in data collection or reporting that have been identified by MHCC staff. Sinai abstracts and submits data to the ACC-NCDR CathPCI Registry and submits this information to MHCC through a secure site. Sinai reported that the hospital also submits the quarterly CathPCI outcome report to MHCC.

Staff Analysis and Conclusion

Sinai has complied with the submission of the ACC-NCDR data to MHCC in accordance with the established schedule. In 2014, MHCC staff conducted an audit of ACC-NCDR data to validate that hospitals submitted accurate and complete information. Advanta Government Services, MHCC's contractor for the audit, did not identify any concerns regarding the accuracy or completeness of Sinai's data reported during the audit period.

MHCC staff concludes that Sinai complies with this standard.

Institutional Resources

10.24.17.07D(4)(a) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction 24 hours per day, seven days per week.

Sinai responded that there were not times in which cardiac catheterization laboratory (CCL) downtime prevented delivery of PCI services. As shown in Table 1, Sinai submitted a log of downtime by CCL room for calendar year (CY) 2015 through CY2018.

Table 1: Sinai CCL Downtime by Room, CY 2015- CY 2018

Room	Date	Duration	Reason
6	10/15/2015	36 hours	Preventative maintenance
5	12/08/2015	24 hours	Preventative maintenance
1	12/1/2016	1 month	Lab replaced
5	05/02/2017	24 hours	Preventative maintenance
1	5/15/2017	10.5 hours	Hemodynamic system replacement
2	5/15/2017	24 hours	Hemodynamic system replacement
3	5/16/2017	24 hours	Hemodynamic system replacement
4	5/16/2017	24 hours	Hemodynamic system replacement
5	5/17/2017	24 hours	Hemodynamic system replacement
6	5/17/2017	24 hours	Hemodynamic system replacement
1	6/1/2018	1 month	Lab replaced
2	10/15/2018	48 hours	Preventative maintenance/equipment repairs

Source: Sinai application and updated Q2 response.

Sinai also stated that Lab 3 renovation was initiated at the end of May 2019, noting that the flow of the CCL would not be interrupted because Lab 6 would be utilized during construction.

Staff Analysis and Conclusion

MHCC staff reviewed the information on CCL room downtime and determined that it is unlikely that all three rooms were unavailable simultaneously. MHCC staff concludes that Sinai complies with this standard.

10.24.17.07D(4)(b) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

Sinai provided a signed statement from Neil M. Meltzer, President and Chief Executive Officer of LifeBridge Health, affirming that Sinai commits to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital for at least 75% of cases. The statement also affirms that Sinai commits to tracking and improving door-to-balloon (DTB) times for transfer cases. As shown in Table 2A, Sinai provided quarterly median DTB times from January 2015 through December 2019.

Table 2A: Sinai Reported Compliance with DTB Benchmark by Quarter, January 2015 - December 2019

Quarter	Total Primary PCI Volume	Cases with DTB <= 90 minutes	Percent of Cases With DTB <=90 minutes
CY2015 Q1	13	13	100%
CY2015 Q2	23	23	100%
CY2015 Q3	11	11	100%
CY2015 Q4	19	18	95%
CY2016 Q1	18	17	94%
CY2016 Q2	14	13	93%
CY2016 Q3	10	9	90%
CY2016 Q4	17	14	82%
CY2017 Q1	13	12	92%
CY2017 Q2	22	22	100%
CY2017 Q3	17	16	94%
CY2017 Q4	9	8	89%
CY2018 Q1	21	21	100%
CY2018 Q2	6	6	100%
CY2018 Q3	16	14	88%
CY2018 Q4	14	14	100%
CY2019 Q1	17	17	100%
CY2019 Q2	18	18	100%
CY2019 Q3	17	17	100%
CY2019 Q4	18	18	100%

Source: Sinai application, Q4, updated Q4.

Sinai provided DTB information for primary PCI transfer cases. Between January 2015 and December 2019, Sinai received 81 primary PCI transfer cases and 67.9% (n = 55) had a DTB time of 120 minutes or less. Sinai also explained the steps that it has taken to improve DTB times for transfer primary PCI patients. Sinai has a partnership with the hospital that is the source of most transferred primary PCI patients and consistently collaborates with this hospital to improve processes.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data for non-transfer STEMI cases, as shown in Table 2B. MHCC staff found that the quarterly percentage of patients with a DTB time of 90 minutes or less ranged from 82.4% to 100%. MHCC staff's analysis may differ from the information provided by the hospital because the ACC-NCDR reports exclude certain cases from this performance metric, such as when there is a non-system reason for delay, whereas MHCC includes all cases. Because failure to meet this standard in each quarter may not be attributable to any shortcomings of the hospital, MHCC staff considers a hospital's performance over longer periods. Over rolling eight quarter periods, Sinai complied with this standard, with between 82% and 90% of primary PCI cases meeting the DTB time standard, as shown in Table 2B.

Table 2B: Sinai Hospital Non-Transfer Primary PCI Case Volume and Percentage of Cases With DTB Less Than or Equal to 90 Minutes, by Time Period

Time Period	Quarter			Rolling Eight-Quarters		
	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes	Total Primary PCI Volume	Cases With DTB<=90 Minutes	Percent of Cases With DTB <=90 Minutes
2015q1	21	17	81.0%			
2015q2	19	18	94.7%			
2015q3	14	12	85.7%			
2015q4	18	16	88.9%			
2016q1	21	17	81.0%			
2016q2	17	13	76.5%			
2016q3	12	9	75.0%			
2016q4	17	14	82.4%	139	116	83%
2017q1	16	13	81.3%	134	112	84%
2017q2	22	21	95.5%	137	115	84%
2017q3	20	17	85.0%	143	120	84%
2017q4	10	7	70.0%	135	111	82%
2018q1	24	21	87.5%	138	115	83%
2018q2	9	7	77.8%	130	109	84%
2018q3	19	15	78.9%	137	115	84%
2018q4	13	12	92.3%	133	113	85%
2019q1	18	17	94.4%	135	117	87%
2019q2	22	21	95.5%	135	117	87%
2019q3	19	18	94.7%	134	118	88%
2019q4	20	18	90.0%	144	129	90%

Source: MHCC staff' analysis of ACC NCDR CathPCI data, CY 2015-CY 2019.

MHCC staff concludes that Sinai complies with this standard.

10.24.17.07D(4)(c) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to patients with acute myocardial infarction 24 hours per day, seven days per week.

Sinai provided the number of physicians, nurses, and technicians who were available to provide cardiac catheterization services to patients as of June 14, 2019, a week before the due date of the application.

Table 3A: Total Number of CCL Physician, Nursing, and Technical Staff

Category	Number/FTEs	Cross Training (S/C/M)*
Physician	N = 13	
Nurse	7.0	M,C
Technician	10	S,M

Source: Sinai application, Q6a, updated Q6a.

*Scrub (S), circulate (C), monitor (M)

Staff Analysis and Conclusion

MHCC staff compared the staff levels reported by Sinai to information reported by three other existing programs in their Certificate of Ongoing Performance applications. As shown in Table 3B, Sinai’s 2018 PCI volume was greater than the volume reported by the University of Maryland (UM) Medical Center and the UM Upper Chesapeake Medical Center, but less than TidalHealth Peninsula Regional. The number of full-time equivalent (FTE) nurses reported by Sinai was less than the FTEs reported by University of Maryland Medical Center, UM Upper Chesapeake Medical Center, and TidalHealth Peninsula Regional. The number of technician FTEs reported for Sinai was greater than University of Maryland Medical Center and UM Upper Chesapeake Medical Center; the technician FTEs were less than TidalHealth Peninsula Regional.

Table 3B: CCL Staff Levels for Sinai and Other Select Hospitals

Hospital & Year Reported	2018 PCI Case Volume	Number (N) of Interventionalists or FTEs	Nurse FTEs	Technician FTEs
Sinai 2019	632	N = 13	7.0	10.0
University of Maryland Medical Center 2019	515	N = 8	11.0	7.5
UM Upper Chesapeake Medical Center 2019	517	N = 4	12.1	6.9
TidalHealth Peninsula Regional 2019	695	N = 10	13.5	10.7

Sources: Sinai 2019 PCI Certificate of Ongoing Performance application; University of Maryland Medical Center 2019 PCI Certificate of Ongoing Performance application; UM Upper Chesapeake Medical Center 2019 PCI Certificate of Ongoing Performance application; TidalHealth Peninsula Regional 2019 PCI Certificate of Ongoing Performance application.

*Volumes for either fiscal or calendar year

MHCC staff concludes that Sinai has adequate nursing and technical staff to provide services.

10.24.17.07D(4)(d) The hospital president or Chief Executive Officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.

Sinai provided a signed letter of commitment from Jonathan Ringo, M.D., Senior Vice President of LifeBridge Health and President and Chief Operating Officer of Sinai Hospital of Baltimore, acknowledging that Sinai will provide primary PCI services in accord with the requirements established by the Commission.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that Sinai meets this standard.

10.24.17.07D(4)(e) The hospital shall maintain the dedicated staff necessary for data management, reporting, and coordination with institutional quality improvement efforts.

Sinai stated that its Performance Improvement/Quality Management Associate (1.5 FTE) is responsible for data abstractions for the ACC-NCDR CathPCI, Get With the Guidelines-Coronary Artery Disease (GWTG-CAD), and ACC-ACTION registries. This individual is also responsible for STEMI abstraction and chest pain audits. Sinai also has a Cardiac Quality Program Coordinator (one FTE) who oversees data abstraction by the Performance Improvement/Quality Management Associate in seven cardiac registries. This individual is also responsible for data abstraction, monthly STEMI and vasculature multidisciplinary committees, submission of data to MHCC, monthly updates and dashboards to multidisciplinary committees, quarterly dashboards, and communication with the STEMI team, Northwest Hospital¹ team, and emergency medical services as well as maintaining cardiac intensive care verification.

Staff Analysis and Conclusion

MHCC staff concludes that Sinai complies with this standard.

10.24.17.07D(4)(f) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

Charles Cummings, M.D., is the Physician Director of the CCL. He has held this position since July 1, 2011. Sinai stated that Dr. Cummings is responsible for the medical direction of the CCL including planning and implementation of performance improvement programs, scheduling physicians, planning and implementation of the continuing education program, co-chairing the cardiac catheterization multi-disciplinary committee, and reviewing credentials of all cardiologists.

¹ Northwest Hospital is a general hospital in Western Baltimore County that, like Sinai, is a LifeBridge hospital.

Staff Analysis and Conclusion

MHCC staff concludes that Sinai complies with this standard.

10.24.17.07D(4)(g) The hospital shall design and implement a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

Sinai responded that education specialists and clinical nurse specialist resources are available to all staff for the CCL and coronary care unit. All team members are provided an individualized orientation designed to familiarize staff with their required duties and responsibilities and validate clinical competency. Annual competencies (i.e., fire safety, patient identification, blood borne pathogens, restraint safety, cyber awareness, basic life support and advanced cardiovascular life support) are completed and tracked through the HealthStream system and managers assure that all staff have completed these competencies.

Managers also host unit-based continuing education sessions. Examples include rotoblade refreshers, Impella heart pumps, closure devices, sheath removal techniques, and intra-aortic balloon pump (IABP) insertion. There are also a series of live online Impella conferences that CCL staff can access for education. Vendor and pharmaceutical representatives host education sessions on medications, systems, closure devices, and equipment. Clinical representatives present annually. Physicians also host educational sessions on post-procedure care, specifically focusing on access site care, sheath removal, and site holds. Additionally, Sinai reported that there is a clinical leader in the intensive care unit who teaches classes throughout the year and facilitates a monthly CCL journal club.

Sinai explained that the hospital follows the guidelines set up by the American Registry of Radiologic Technology and the Cardiovascular Credentialing Institute. Registered Cardiovascular Invasive Specialists are required to complete 36 continuing education units (CEUs) in a triannual period. Radiologic Technologists are required to complete 24 CEUs every two years. Registered Nurses are required to renew their license biannually.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that Sinai is in compliance with this standard.

10.24.17.07D(4)(h) The hospital shall have a formal, written agreement with a tertiary care center that provides for the unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

Sinai is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery; this standard is not applicable to Sinai.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Sinai.

10.24.17.07D(4)(i) A hospital shall maintain its agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

Sinai is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery; this standard is not applicable to Sinai.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Sinai.

Quality

10.24.17.07D(5)(a) The hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

Sinai submitted attendance records for interventional case review meetings held between 2018 Q3 and 2019Q2 and a list of the dates and invitees for meetings held between January 2015 and June 2018. Sinai stated that in 2018 Q2, the review process changed from morbidity and mortality (M&M) meetings to Peer Review Meetings. A schedule was established for peer review of specific cases once a month. Cases are identified through chart review, incident reports, and the review process for tracking hospital acquired conditions, or cases are referred due to morbidity or mortality. The peer review committee includes providers and is responsible for monitoring and evaluating providers on an ongoing basis for the professional competence of each individual practitioner.

Sinai explained that technicians are not currently involved in the M&M or peer review meetings because the types of cases that are brought to the Peer Review Committee are provider-specific care issues. The Sinai Cardiovascular Institute Peer Review Committee is a committee of the medical staff designated by the Medical Executive Committee that is authorized to conduct peer review for practitioners. The Peer Review Committee monitors and evaluates the professional competence of individual practitioners on an ongoing basis. Sinai states that the types of provider recommendations that may result from peer review include, but are not limited to, a provider self-acknowledged action plan, an educational letter, an informal improvement plan with provider, a formal improvement plan with monitoring, or an exemplary letter. For an informal or a formal improvement plan, the plan is discussed with the Department Chair. If system issues are identified during the review, the issues are considered by the appropriate workgroup, committee, or person for follow up and resolution. One of these forums is the Cardiovascular Institute Journal Club where case system issues are presented for widespread education and technicians participate in this monthly meeting. The Cardiovascular Institute Journal Club was established in 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the dates, attendees, and invitees for peer review meetings and M&M meetings, as available. Sinai held these meetings approximately bimonthly between January 2015 and March 2019. Seven meetings were held in 2015 and 2016, and six meetings were held in 2017 and 2018. Because technicians did not participate in the interventional case review meetings between 2015 and 2018, but a forum was established in 2019 that includes case review and participation by technicians, MHCC staff concludes that Sinai plans to fully comply with this standard in future years.

MHCC staff recommends that the Commission find that Sinai complies with this standard and include a condition on the Certificate of Ongoing Performance that Sinai track attendance and by November 30, 2021 submit attendance lists to Commission staff documenting that technicians for primary PCI patients participated in case review.

10.24.17.07D(5)(b) A hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

Sinai submitted meeting attendance records and dates for STEMI meetings held between January 2015 and April 2019.

Staff Analysis and Conclusion

MHCC staff reviewed the dates and attendees for Sinai's STEMI meetings. Ten meetings were held in 2015, twelve were held in 2016, ten were held in 2017, and twelve were held in 2018. Sinai reported two meeting cancellations due to weather (i.e., snowstorms) and two meeting cancellations due to the inability of two physicians to attend, a cardiac interventionalist and an emergency department physician.

MHCC staff concludes that Sinai complies with this standard.

10.24.17.07C(4)(c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

Sinai submitted copies of external reviews for January 2015 through June 2019. Reviews were conducted by the American Medical Foundation from January through September 2015 and by the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ) from October 2015 through June 2019. Sinai stated that the case reviews by the American Medical Foundation involved random case selection and that the review was blinded and conducted by impartial reviewers.

Staff Analysis and Conclusion

MHCC staff reviewed the external review reports submitted. The volume of elective PCI cases for each review period, the number of cases reviewed, and the percentage of cases reviewed is shown in Table 4. Although only 5% of cases are required to be reviewed, beginning in the second half of 2015, a minimum number of three cases per interventionalist was specified in COMAR 10.24.17. As shown in Table 4, between 9.0% and 19.9% of cases were reviewed each year, consistent with the requirement that at least 5% of cases be reviewed.

Table 4: Sinai External Review Numbers by Year

Calendar Year	Elective PCI Volume	Number of Cases Reviewed	Percentage of Cases Reviewed	Frequency of Reviews	Meets Standard*
CY 2015	709	69	9.7%	Tri-annual	Yes*
CY 2016	621	65	10.5%	Semiannual	Yes*
CY 2017	503	46	9.1%	Semiannual	Yes*
CY 2018	575	52	9.0%	Semiannual	Yes*
2019 Q1Q2	201	40	19.9%	Semiannual	Yes

Source: MHCC staff analysis of MACPAQ reports and American Medical Foundation letters and updated Q28.

* Each review during the time period included three cases per physician or all cases if interventionalist performed fewer than three cases during the review period.

For the period between January 2015 and June 2019, MHCC staff analyzed the ACC-NCDR CathPCI data and verified that at least five percent of elective PCI cases were reviewed. MHCC staff's analysis of the ACC-NCDR CathPCI data identified some discrepancies with the number of cases performed by some physicians and the number of cases reviewed as reported in MACPAQ reports. Sinai explained that the cases submitted to MACPAQ for calendar year 2015 through 2018 were identified through the billing system and only included non-STEMI cases. This resulted in the review of less than six cases annually for several interventionalists. However, the current process includes pulling all cases initially, and then excluding STEMI cases. This list is sent to MACPAQ for random selection and review in accordance with COMAR regulations. Sinai stated that the current process for review includes at least six cases per interventional physician per year or all cases if the interventional cardiologist performed fewer than six cases for that year.

MHCC staff recommends that the Commission find that Sinai complies with this standard.

10.24.17.07C(4)(d) The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:

- (i) An annual review of at least 10 cases or 10 percent of randomly selected PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided in Regulations .08 and .09; or***
- (ii) A semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in paragraph .07C(4)(c), through random selection of three cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the***

hospital during the six-month period, or all cases if the interventionalist has performed fewer than 3 cases during the relevant period, as provided in Regulation .08; or

- (iii) A quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Subparagraphs .07C(4)(d)(i).*

10.24.17.07D(5)(c) *The hospital shall evaluate the performance of each interventionalist through an internal or external review, as follows:*

- (i) An annual review of at least 10 cases or 10 percent of randomly selected primary PCI cases, whichever is greater, performed by the interventionalist at the hospital, or all cases if the interventionalist performed fewer than 10 cases at the hospital, as provided for in Regulations .08 and .09; or*
- (ii) For a hospital with both primary and elective PCI programs, a semi-annual review of each interventionalist conducted as part of the required semi-annual external review of the hospital's randomly selected PCI cases, as provided in Paragraph .07C(4)(c), through random selection of five cases or 10 percent of PCI cases, whichever is greater, performed by the interventionalist at the hospital during the six-month period, or all cases if the interventionalist has performed fewer than five cases during the relevant period at the hospital, as provided for in Regulation .08; or*
- (iii) For a hospital with both primary and elective PCI programs, a quarterly or other review period conducted in a manner approved by Commission's Executive Director that assures that the external review of the cases performed by the interventionalist at the hospital will satisfy the annual requirement in Paragraphs .07C(4)(c) and .07D(5)(c).*

10.24.17.07D(5)(d) *The performance review of an interventionalist referenced in Paragraph .07D(5)(c) shall:*

- (i) Include a review of angiographic images, medical test results, and patients' medical records; and*
- (ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.*

Sinai reported that all cases are reviewed internally for each interventionalist. Cases are also selected for review using multiple review indicators from: Get with the Guidelines®; CathPCI; AMI core measure guidelines; quality reviews; and internal incident reporting. Additional case review, beyond the initial peer review of a case, is based on core measure compliance and peer review indicators within the Cardiovascular Institute and Quality

departments. The internal review process includes a comprehensive review of all the available components of patients' medical records including but not limited to, angiographic images, diagnostic studies, and medical test results. Cases are routinely reviewed at bimonthly peer review meetings.

Staff Analysis and Conclusion

The standards for the review of individual interventionalists in COMAR 10.24.17.07C(4)(d)(ii) and .07D(5)(c)(ii) for hospitals with both primary and elective PCI programs reference a different minimum number of cases to be reviewed for each interventionalist, but both standards state that the greater of the minimum number of cases referenced or 10 percent of cases must be reviewed semiannually. An MHCC bulletin issued in October 2015 clarifies the case review requirements outlined in the Cardiac Surgery Chapter, including the minimum number of cases to be reviewed to satisfy the requirements for review of individual interventionalists. The bulletin states that a semi-annual review of at least three cases or 10% of cases, whichever is greater, per interventionalist, as part of an external review meets the standard, and the requirements in COMAR 10.24.17.07D(5)(c) are equivalent to those in COMAR 10.24.17.07C(4)(d).²

The external reviews conducted by MACPAQ for PCI cases performed from October 2015 through June 2019 meet the requirements of 10.24.17.07D(5)(c) because MACPAQ has been approved by MHCC as a reviewer that meets the requirements for an external review organization. The review of cases by MACPAQ includes a review of angiographic images, medical test results, and patients' medical records. Sinai also submitted information that supports the external reviews conducted through the American Medical Foundation meet the requirements of 10.24.17.07D(5)(d).

MHCC staff concludes that Sinai satisfactorily conducts individual interventionalist review as provided in COMAR 10.24.17.07C(4)(d) and described in the October 2015 bulletin, with respect to COMAR 10.24.17.07D(5)(c).³

10.24.17.07D(5)(e) 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.

Sinai submitted an affidavit from Jonathan Ringo, M.D., certifying that the hospital fully complies with each requirement for conducting and completing quality assurance activities, including regularly scheduled meetings for interventional case review, multiple care area group meetings, external reviews of randomly selected PCI cases, and semi-annual interventionalist review consistent with COMAR 10.24.17.07C(4)(c).

²https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_cardiacare/documents/con_cardiac_csac_bulletin_pci_cases_20151020.pdf

³ Staff recommends that the next revision to COMAR 10.24.17 should include clarification of the individual interventionalist review requirements.

Staff Analysis and Conclusion

MHCC staff concludes that Sinai complies with this standard.

10.24.17.07D (5)(f) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review cases.

- (i) The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.*
- (ii) All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.*
- (iii) Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.*

Sinai provided a description of activities related to quality assurance. For example, the STEMI meeting includes discussion of each individual patient as well as other performance indicators (e.g., DTB time). In response to a desire to improve inpatient DTB times, a Chest Pain Alert rapid response protocol was developed and has improved DTB times for STEMI patients. Sinai submitted a copy of the Chest Pain Alert Policy.

Sinai also described a monthly multidisciplinary committee meeting where patient outcomes are discussed. From these discussions, examples of quality improvement activities have emerged including a hydration protocol for PCI patients to prevent acute kidney injury. This committee also reviewed best practices for bleeding, resulting in increased uptake of ultrasound guided access among physicians. An additional ultrasound machine was purchased and is set up on every case. Another example of a quality improvement activity during the review period is the implementation of same day discharge for certain PCI patients. Sample quality improvement protocols were also submitted. Finally, Sinai submitted a Quality, Risk Management, and Patient Safety Plan from 2019 and STEMI meeting minutes.

Staff Analysis and Conclusion

MHCC staff reviewed case review documentation and description of quality assurance practices provided and concludes that Sinai complies with this standard.

Patient Outcome Measures

10.24.17.07D(5)(a) A primary PCI program shall meet all performance standards established in statute or in State regulations.

- (b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high*

quality patient care.

(c) A hospital with a risk-adjusted mortality rate for STEMI PCI cases that exceeds the established benchmark 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 a hospital's all-cause in-hospital risk-adjusted mortality rate for STEMI PCI cases.

(i) The primary benchmark is the national median risk-adjusted in-hospital mortality rate for STEMI PCI cases; and

(ii) If the statewide median risk-adjusted in-hospital mortality rate for primary PCI cases is obtained by the Commission within twelve months of the end of a reporting period, then the statewide median risk-adjusted in-hospital mortality rate for primary PCI cases will be used as a second benchmark.

10.24.17.07C(5)(a) An elective PCI program shall meet all performance standards established in statute or in State regulations.

(b) A hospital shall maintain a risk-adjusted mortality rate that is consistent with high quality patient care.

(c) A hospital with a risk-adjusted mortality rate for non-STEMI PCI cases that exceeds the established benchmark 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 a hospital's all-cause in-hospital risk-adjusted mortality rate for non-STEMI PCI cases.

(i) The primary benchmark is the national median risk-adjusted in-hospital mortality rate for non-STEMI PCI cases; and

(ii) If the statewide median risk-adjusted in-hospital mortality rate for primary PCI cases is obtained by the Commission within twelve months of the end of a reporting period, then the statewide median risk-adjusted in-hospital mortality rate for elective PCI cases will be used as a second benchmark.

Sinai submitted risk-adjusted mortality rates by rolling 12-month reporting period for 2015 Q1 through 2019 Q4 when available, as shown in Table 5. These data are not available for any hospitals participating in the ACC-NCDR CathPCI data registry for the rolling 12-month period of 2017 Q3 through 2018 Q2.

There were two review cycles when Sinai would not have met the MHCC benchmark for non-STEMI cases, if the standard had been applicable, the periods ending in 2015Q4 and 2016Q1, Sinai stated that during these periods, all non-STEMI cases were reviewed internally.

Subsequently, the hospital had four cases reviewed externally. Sinai provided detailed information about the findings from the external review of cases and the follow-up on these cases.

Table 5: Sinai Adjusted Mortality Rates (AMR) by Rolling 12-Month Reporting Period and Performance on MHCC Standards for PCI Programs

Reporting Period	STEMI				NON-STEMI			
	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard	Hospital AMR	95% CI	National Benchmark	Meets MHCC Standard
2019q1-2019q4	6.46	[2.64, 12.80]	6.01	Yes	0.40	[0.05, 1.44]	0.95	Yes
2018q4-2019q3	7.20	[3.17, 13.60]	6.06	Yes	0.76	[0.21, 1.93]	0.98	Yes
2018q3-2019q2	8.44	[3.94, 15.33]	6.38	Yes	0.80	[0.17, 2.33]	1.00	Yes
2018q2-2019q1	8.08	[3.56, 15.23]	6.13	Yes	0.95	[0.20, 2.75]	0.99	Yes
2018q1-2018q4	7.66	[3.77, 13.41]	6.00	Yes	1.42	[0.57, 2.91]	1.00	Yes
2017q4-2018q3	8.74	[4.09, 15.81]	6.54	Yes	1.23	[0.45, 2.65]	0.98	Yes
2017q3-2018q2	Not available for any hospitals participating in the ACC-NCDR CathPCI Data Registry							
2017q2-2018q1	8.37	[4.25, 15.21]	6.91	Yes	1.34	[0.54, 2.73]	1.03	Yes
2017q1-2017q4	6.72	[2.75, 13.24]	6.86	Yes	1.06	[0.29, 2.70]	0.99	Yes
2016q4-2017q3	8.13	[3.58, 15.34]	6.75	Yes	1.19	[0.32, 3.02]	0.98	Yes
2016q3-2017q2	7.14	[3.15, 13.46]	6.64	Yes	1.19	[0.32, 3.02]	0.95	Yes
2016q2-2017q3	6.09	[2.28, 12.69]	6.77	Yes	0.56	[0.12, 1.63]	0.97	Yes
2016q1-2017q4	6.62	[2.92, 12.43]	6.82	Yes	0.66	[0.18, 1.69]	0.95	Yes
2015q4-2016q3	4.79	[1.79, 10.00]	6.71	Yes	0.66	[0.18, 1.68]	0.95	Yes
2015q3-2016q2	6.33	[2.59, 12.52]	6.66	Yes	1.25	[0.54, 2.45]	0.93	Yes
2015q2-2016q1	5.15	[2.10, 10.25]	6.45	Yes	2.14	[1.03, 3.92]	0.90	No
2015q1-2015q4	4.79	[1.78, 10.10]	6.26	Yes	2.16	[1.08, 3.85]	0.90	No

Source: MHCC Staff compilation of results from the hospital's quarterly reports from the ACC-NCDR CathPCI Data Registry for PCI cases performed between January 2015 and December 2019.

Notes: A hospital's AMR meets the MHCC standard if the hospital's 95% confidence interval (CI) includes the national benchmark or indicates statistically significantly better performance than the National AMR for ST Elevated Myocardial Infarction (STEMI) or non-STEMI cases, as applicable. A hospital does not meet MHCC's standard when it performs statistically significantly worse than the national benchmark for STEMI or non-STEMI cases, as applicable. The national benchmarks are the national median risk-adjusted in-hospital mortality rate for STEMI and non-STEMI cases for each reporting period.

Staff Analysis and Conclusion

This standard is not applicable for most of the review periods for Sinai's Certificate of Ongoing Performance review because the current standard did not become effective until January 14, 2019. A similar standard that was adopted previously referenced a statewide average as the benchmark, but MHCC staff was not able to obtain a valid statewide average for all-cause 30-day risk adjusted mortality for the period between January 2015 and December 2018. However, MHCC staff has provided information below on how Sinai performed over the period between January 2015 and June 2019.

MHCC staff reviewed the adjusted mortality rate data by rolling 12-month period for both STEMI and non-STEMI patients and determined that the hospital's adjusted mortality rate was not statistically significantly different than the national benchmark in all reporting periods, except for 2015q2-2016q1 and 2015q1-2015q4 for non-STEMI cases because the national benchmark fell within the 95% confidence interval for Sinai for all but two 12-month reporting periods between 2015 Q1 and 2019 Q4, when an adjusted mortality rate was reported. The detailed information on external review of cases and the follow-up on those cases indicates that Sinai appropriately handled any issues identified.

The report for the hospital's performance for the period ending December 2019, is the first period for which the current standard applies. MHCC staff concludes that Sinai meets the standard for the period in which the current standard applies.

Physician Resources

10.24.17.07D(7)(a) Physicians who perform primary PCI at a hospital without on-site cardiac surgery shall perform a minimum of 50 PCI procedures annually averaged over a 24 month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight quarter basis and report the results to the Maryland Health Care Commission on a quarterly basis.

Sinai is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery; this standard is not applicable to Sinai.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Sinai.

10.24.17.07D(7)(b) Each physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery who does not perform 50 PCI procedures annually averaged over a 24 month period, for reasons other than a leave of absence, will be subject to an external review of all cases in that 24-month period to evaluate the quality of care provided. The results of this evaluation shall be reported to MHCC. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Sinai is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery; this standard is not applicable to Sinai.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Sinai.

10.24.17.07D(7)(c) A physician who performs primary PCI at a hospital that provides primary PCI without on-site cardiac surgery and who does not perform the minimum of 50 PCI procedures annually averaged over a 24 month period, who took a leave of absence of less than one year during the 24 month period measured, may resume the provision of primary PCI provided that:

- (i) The physician performed a minimum of 50 cases in the 12-month period preceding the leave of absence;***
- (ii) The physician continues to satisfy the hospital's credentialing requirements; and***
- (iii) The physician has performed 10 proctored cases before being allowed to resume performing PCI alone.***

Sinai is a tertiary care center providing the full spectrum of cardiac care, including cardiac surgery; this standard is not applicable to Sinai.

Staff Analysis and Conclusion

MHCC staff concludes that this standard does not apply to Sinai.

10.24.17.07D(7)(e) Each physician shall be board certified in interventional cardiology with an exception for those who performed interventional procedures before 1998 or completed their training before 1998 and did not seek board certification before 2003 [or physicians who completed a fellowship in interventional cardiology less than three years ago].

10.24.17.07D(7)(f) Each physician shall obtain board certification within three years of completion of a fellowship in interventional cardiology.

Sinai submitted a signed and dated statement from Dr. Cumming, Director of the CCL, certifying that all physicians performing primary PCI are board certified in interventional cardiology or are exempt from this requirement.

Staff Analysis and Conclusion

MHCC staff reviewed the information provided and concludes that Sinai meets these standards.

10.24.17.07D (7)(g) An interventionalist shall complete a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology during every two years of practice.

Sinai submitted signed and dated attestations from Drs. Cummings, Tabrizchi, Najafi, Pfeffer, Maniu, and Insel stating each has completed a minimum of 30 hours of continuing medical education credits in the area of interventional cardiology in the last two years.

Staff Analysis and Conclusion

MHCC staff found that signed attestations were not submitted for Drs. Bansal, Damluji, Gurbel, and Zaidi, each of whom performed one or more primary PCI cases at Sinai during calendar year 2018. Sinai responded with the following explanations: Dr. Bansal does not take call and no longer performs primary PCI; Dr. Damluji was no longer employed at Sinai when the hospital submitted its application; Dr. Zaidi is no longer employed by LifeBridge Health; and Dr. Gurbel started performing pPCI with LifeBridge Health on January 1, 2020. MHCC staff concludes that Sinai's explanations of the outstanding signed attestations, as noted above, are sufficient.

MHCC staff recommends that the Commission find that Sinai complies with this standard.

10.24.17.07D (7)(h) Each physician who performs primary PCI agrees to participate in an on-call schedule.

Sinai submitted a signed statement from Dr. Cummings, the Medical Director of the CCL, who acknowledged that each physician who has performed primary PCI services during the performance review period participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. Sinai also submitted a copy of its on-call schedule for June 2019. Additionally, Sinai submitted a copy of the Carroll Hospital Center on-call schedule for June 2019.

Staff Analysis and Conclusion

Staff examined the Sinai on-call schedule for June 2019 and observed that Drs. Grill, Insel, Najafi, Zaidi, Gioia, Tabrizchi, and Cummings were all scheduled to be on-call at different times during the month. The Carroll Hospital Center on-call schedule shows that Drs. Pfeffer and Maniu were scheduled to be on-call at different times during the month.

MHCC staff reviewed the information provided and concludes that Sinai meets this standard.

Volume

10.24.17.07C(7)(a) The target volume for an existing program with both primary and non-primary PCI services is 200 cases annually.

(b) A PCI program that provides both primary and elective PCI that fails to reach the target volume of 200 cases annually may be subject to a focused review.

Sinai provided the total PCI case volume for CY 2014 through CY 2019, as shown in Table 6.

Table 6: Sinai's Total PCI Volume, CY 2014- CY 2019

Calendar Year	Total Number of PCI Cases
2014	860
2015	775
2016	680
2017	564
2018	632
2019	485

Source: Sinai application, question 28, and updated question 28.

Staff Analysis and Conclusion

MHCC staff reviewed the information submitted by Sinai and the ACC-NCDR CathPCI data. Sinai performed well above the target volume of 200 PCI procedures annually between CY 2014 and CY 2019.

MHCC staff determines that Sinai complies with this standard.

10.24.17.07D(8)(a) For primary PCI cases, if a program falls below 36 cases for rural PCI providers and 49 cases for non-rural providers, a focused review will be triggered.

Sinai responded that this regulation is not applicable.

Staff Analysis and Conclusion

MHCC staff analyzed the ACC-NCDR CathPCI data to calculate the primary PCI volume for CY 2015 through CY 2019. This analysis shows that the number of primary PCI cases ranged from 98 to 127 cases each calendar year and confirms that Sinai exceeded the applicable threshold of 49 cases annually referenced in the standard.

Table 7: Sinai Primary PCI Case Volume, CY 2015- CY 2019

Calendar Year	Primary PCI Case Volume
2015	122
2016	113
2017	98
2018	108
2019	127

Source: MHCC staff analysis of ACC-NCDR CathPCI data, CY 2015- CY 2019.

MHCC staff determined that this standard does not apply to Sinai

10.24.17.07D(8)(b) The target volume for primary PCI operators is 11 or more primary cases annually.

Sinai provided the number of primary PCI cases by interventionalist from 2015 through 2019 Q1. This information shows that most physicians did not meet the target of performing 11 or more primary PCI procedures annually. In most years, only four physicians met the target among a total roster that ranged from nine to 13 physicians. In 2018, five of nine physicians met the target of 11 or more primary PCI procedures.

Staff Analysis and Conclusion

MHCC staff first notes that 11 primary PCI cases is a target rather than a strict requirement. MHCC staff reviewed the primary PCI case volume information submitted by Sinai, and MHCC staff also analyzed the ACC-NCDR CathPCI data for physicians who performed primary PCI procedures at Sinai during the review period. Staff's analysis of the ACC-NCDR CathPCI data is consistent with the information reported by Sinai, except that in both 2015 and 2016 the data shows that one additional physician met the target volume of 11 primary PCI procedures annually. This difference may be due to Sinai only having access to information regarding primary PCI procedures performed at its own hospital.

MHCC staff concludes that Sinai meets this standard.

Patient Selection

10.24.17.07C(8) The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

- (a) Patients described as appropriate elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.***
- (b) For elective PCI programs without cardiac surgery on-site, patients at high procedural risk, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, are not suitable for elective PCI.***

Sinai responded that cases identified between July and December 2016 were reviewed as part of the hospital's formal Ongoing Professional Practice process. This information is routinely provided to assist with the identification of practice trends that may impact quality of care and patient safety. Concerns or deviations would be shared with the Chief Quality Officer, Quality and Risk Management departments, and departmental chiefs/chairs for review. Sinai provided additional information about specific cases found to be rarely appropriate by one or more criteria during external reviews. Additionally, Sinai detailed plans for follow-up on cases determined to be rarely appropriate in the external review report for January to June 2019.

Staff Analysis and Conclusion

MHCC staff reviewed external review reports and noted that several cases were deemed rarely appropriate by one or more criteria through external review: 2 cases in 2015; 1 case in 2016; 1 case in 2018; and 2 cases in 2019. Staff determined that Sinai's follow-up on these cases was appropriate.

MHCC staff concludes that Sinai complies with this standard.

10.24.17.07D(9) A hospital shall commit to providing primary PCI services only for suitable patients. Suitable patients are:

- (a) Patients described as appropriate for primary PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.***
- (b) Patients with acute myocardial infarction in cardiogenic shock that the treating physician (s) believes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.***
- (c) Patients for whom the primary PCI system was not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.***
- (d) Patients who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) believes that transfer to a tertiary institution may be harmful to the patient***

Sinai stated that over the review period, there were no patients who received thrombolytic therapy that subsequently failed and that no patients received primary PCI services inappropriately based on internal or external review.

Staff Analysis and Conclusion

MHCC staff determined that Sinai complies with the standard.

RECOMMENDATION

Based on the above analysis and the record in this review, MHCC staff recommends that the Commission find that Sinai meets all of the requirements for a Certificate of Ongoing Performance. The Executive Director of Maryland Health Care Commission recommends that the Commission issue a Certificate of Ongoing Performance that permits Sinai to continue providing

primary and elective percutaneous coronary intervention services for four years, subject to the following condition:

Sinai Hospital of Baltimore shall track attendance at meetings with interventional case review and on or before November 30, 2021, submit attendance lists to Commission staff documenting that technicians for primary PCI patients participated in case review, as required in COMAR 10.24.17.07D(5)(a). This information shall be shared by staff with the Commission.