



MARYLAND
Health Care
Commission

**Application for Certificate of Ongoing Performance for
Primary and Elective Percutaneous Coronary
Intervention Services**

**Information Regarding the Application for a Certificate of Ongoing Performance to
Provide Primary and Elective PCI Services**

**NOTE: ALL PAGES OF A HOSPITAL'S APPLICATION SHOULD BE
NUMBERED CONSECUTIVELY.**

The following application form shall be used by hospitals when applying for a Certificate of Ongoing Performance to perform **Primary and Elective Percutaneous Coronary Interventions**. Specific provisions of COMAR 10.24.17 are shown in bold, and below each provision there is a request for the information that the Commission requires to evaluate each application.

The applicant shall cooperate with the Commission, Commission staff, or any authorized representative(s) that requests additional information in the course of the application's review.

The form is intended to be completed using Microsoft Word. An applicant is expected to enter narrative text in response to questions, complete the tables and forms, and/or submit additional documents as required. The applicant shall file the following with the Maryland Health Care Commission according to the schedule published in the Maryland Register: an original application, including the applicant affidavit with signature and supporting documents. **Please submit the application through MHCC's sFTP space. An account must be set up for the individual who will be submitting the application through MHCC's sFTP space. Please upload both a non-confidential version of the application and a confidential version. It should be assumed that the non-confidential version may be posted on MHCC's web site.** It is also fine to submit confidential information as separate files that are referenced in the application. An applicant is not required to submit paper copies of the application. Please contact MHCC staff if there are any questions regarding the submission of information. Questions should be directed to:

Alankrita Olson, MD, MPH
Chief, Acute Care Policy and Planning
alankrita.olson@maryland.gov

MARYLAND

HEALTH

MATTER/DOCKET NO.

CARE

COMMISSION

DATE DOCKETED

**Application for Certificate of Ongoing Performance to Perform
Primary and Elective Percutaneous Coronary Intervention**

Applicant Information

Applicant _____

Street Address _____

City _____ County _____ State _____ Zip Code _____

Mailing Address (if different) _____

City _____ County _____ State _____ Zip Code _____

Medicare Provider Number(s) _____ National Provider Identifier _____

Primary Person to be contacted on matters involving this application:

Name _____

Title _____

Address _____

Address _____

City _____ County _____ State _____ Zip Code _____

Telephone _____ Facsimile _____ E-mail _____

Additional or Alternate Person to be contacted on matters involving this application:

Name _____

Title _____

Address _____

Address _____

City _____ County _____ State _____ Zip Code _____

Telephone _____ Facsimile _____ E-mail _____

Review Criteria for a Certificate of Ongoing Performance

Data Collection

(1) 10.24.17.07C(3) and .07D(3) Each PCI program shall participate in uniform data collection and reporting. This requirement is met through participation in the ACC-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.

Q1a. Please explain the reason for any deficiencies in data collection known by the hospital or identified by MHCC staff. Examples include failing to provide required data or performance information or excessive delays in providing this information.

Q1b. If deficiencies in data resulted in an inability to obtain key performance indicators, please explain any steps the hospital has taken to address the situation. Please include this information, even if the hospital has previously corresponded with staff on how it will address the situation.

Institutional Resources

(2) 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.

Q2a. Please provide information for each cardiac catheterization laboratory (CCL), identifying any downtime that occurred due to required equipment maintenance or unforeseen circumstances. The information provided should be for the period beginning immediately following the last information reported as part of the hospital's last Certificate of Ongoing Performance review and ending no more than three months prior to the application deadline for the hospital's Certificate of Ongoing Performance. A template for providing the information requested is shown below.

Room Number	Date	Start Time	Duration	Reason for Downtime

Q2b. If downtime of the CCL resulted in delays for patients who required emergency PCI services, diversion of patients to other hospitals, or suboptimal treatment, please explain.

Q2c. Please describe the hospital's backup plan for CCLs not in service or CCLs with overlapping downtime and provide a copy of the hospital's policy, if applicable.

(3) 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.

Q3a. Please provide a statement signed by the hospital’s chief executive officer, acknowledging agreement with the above statement. The statement must be less than five years old and signed by the hospital’s current chief executive officer.

Q3b. For each quarter, please provide the hospital’s compliance with the door-to-balloon time standard for non-transfer cases, beginning with procedures performed since last reported in the hospital’s Certificate of Ongoing Performance application or since last reported to MHCC staff as part of the hospital’s compliance with a condition for its Certificate of Ongoing Performance, if applicable, and ending no more than three months prior to the application deadline for the hospital’s Certificate of Ongoing Performance. An example of the layout to use for presenting this information is shown below.

Quarter Ending	Number of Non-Transfer Primary PCI Patients	Number of Non-Transfer Patients with DTB Time \leq 90 Minutes	
		Number	Percent
CY 2024 Q1			
CY 2024 Q2			
CY 2024 Q3			
CY 2024 Q4			

Q3c. Please provide information on the hospital’s door-to-balloon times for transfer cases by quarter, specifically the total number of transfer cases and the number and percentage of cases with a door-to-balloon time of 120 minutes or less. Please report the requested information beginning with procedures performed since last reported in the hospital’s Certificate of Ongoing Performance application or since last reported to MHCC staff as part of the hospital’s compliance with a condition for its Certificate of Ongoing Performance, if applicable, and ending no more than three months prior to the application deadline for the hospital’s Certificate of Ongoing Performance. An example of the layout to use is shown below.

Quarter Ending	Number of Transfer Primary PCI Patients	Number of Transfer Patients with DTB Time \leq 120 Minutes	
		Number	Percent
CY 2024 Q1			
CY 2024 Q2			
CY 2024 Q3			
CY 2024 Q4			

Q3d. For patients who were transferred to the hospital and required primary PCI, please describe the steps the hospital has taken to improve DTB times for those patients who were transferred from another hospital without PCI services.

(4) 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 acute MI patients 24 hours per day, seven days per week.

Q4a. Complete the following table to show the number of physicians, nurses, and technicians who are available to provide cardiac catheterization services to acute myocardial infarction patients (as of one week before the due date of this application). Also indicate whether the nursing and technical staff are cross-trained to scrub (S), circulate (C), and monitor (M).

Total Number of CCL Physician, Nursing, and Technical Staff		
	Number/FTEs	Cross-Training (S/C/M)
Physician		
Nurse	(FTE)	
Technician	(FTE)	

Q4b. If the staffing levels reported in the table above are not consistent with the typical staffing levels for the hospital’s CCL, please explain.

(5) 10.24.17.07D(4)(d) *The hospital president or chief executive officer, as appropriate, shall provide a written commitment stating the hospital administration will support the program.*

Q5. Please submit a letter of commitment, signed by the current hospital’s current president or chief executive officer, acknowledging that the hospital will provide primary PCI services in accordance with the requirements established by the Maryland Health Care Commission in COMAR 10.24.17. The signed statement must be less than five years old.

(6) 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.*

Q6. Please provide a list of each position responsible for these activities for PCI services and the number of staff FTEs dedicated to data management, reporting, and coordination with institutional quality improvement efforts.

(7) 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 cardiac 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.*

Q7. Please provide the name of the physician director of interventional cardiology services, the date the physician was named the director, and a description of the director’s responsibilities. If the current director has not been in place since renewal of the hospital’s last Certificate of Ongoing Performance, then please provide the history of changes in the director role since last reported to the Commission. If other staff are

primarily directly responsible for some of the responsibilities described in COMAR 10.24.17.07D(4)(f), please explain.

(8) 10.24.17.07D(4)(g) The hospital shall have a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

Q8a. Please provide a list of continuing educational programs and activities, with dates, in which staff in the CCL and the coronary care unit participated, since this information was reported to MHCC staff as part of the hospital's last application for a Certificate of Ongoing Performance. For a new program, report this information since the PCI program was first established.

Q8b: Please describe how continuing education programs and activities are tracked for staff in the CCL and coronary care unit.

(9) 10.24.17.07D(4)(h) A hospital that performs primary PCI without on-site cardiac surgery shall have a formal, written agreement with a tertiary institution that provides for the unconditional transfer of the hospital's patients for any required additional care, including emergent or elective cardiac surgery or PCI.

Q9. For hospitals without cardiac surgery on-site, please provide a copy of a current signed and dated agreement between the hospital and a tertiary institution that provides for the unconditional transfer of primary PCI patients from the applicant hospital to the tertiary institution and that covers the transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI.

(10) 10.24.17.07D(4)(i) A hospital shall maintain a formal written 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.

Q10. For hospitals without cardiac surgery on-site, please provide a copy of the hospital's current signed and dated formal written agreement with a licensed advanced cardiac support emergency medical service provider that guarantees the arrival of an air or ground ambulance at the applicant hospital within 30 minutes of a request from that hospital for the transport of a primary PCI patient to a tertiary care center.

Quality

(11) 10.24.17.07C(4)(a) and .07D(5)(a) The hospital shall develop a formal process for interventional case review that includes regularly scheduled meetings (at least every other month) with required attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

Q11a. Please provide a list of the dates of interventional case review meetings and the names and titles of those in attendance at each meeting. It is also acceptable to provide roles rather than titles for meeting attendees.

Q11b. Please provide documentation of any corrective actions and plans derived from case reviews and their implementation.

Q11c. If routine attendance did not include other physicians, nurses, or technicians, please explain the reason for this.

Q11d. If meetings did not take place as required at least every other month, please explain.

(12) 10.24.17.07C(4)(b) and .07D(5)(b) *The 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.*

Q12a. Please provide a list of the dates of the multiple care area group meetings and the names and titles of those in attendance at each meeting.

Q12b. Please provide meeting minutes of the multiple care area group meetings

Q12c. If meetings did not take place as required monthly, please explain.

(13) 10.24.17.07C(4)(c) and (d) *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. 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 three cases at the hospital during the relevant period, as provided in Regulation .08; or*

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

Q13a. Please provide a copy of the results of the external review for each review cycle. This information should be submitted through secure electronic transmission, rather

than in hard copy.¹ Only the results need to be submitted, not the medical records reviewed. If external review reports have already been submitted to MHCC, please indicate this.

Q13b. Please provide the number of cases reviewed externally, by calendar year and interventionalist.

(14) 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 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.*

Q14a. Please identify the review organization or individual(s) who conducted the required performance review, and if applicable, document that the review organization or individual(s) meet the standards established by the Commission. If an external

¹ As noted on the information page at the beginning of this application, any sensitive information pertaining to quality assurance activities must be transmitted through a secure method, such as a secure email or providing access to download files from a secure space. Due to changes in security policies, MHCC staff is unable to accept USB drives. Please contact MHCC staff if there are any questions regarding the secure transmission of sensitive information. Transmitting unencrypted files in paper format or as email attachment is not permitted because such a transmission is not secure.

review organization approved by the Maryland Health Care Commission conducted the reviews, then no further documentation is required.

Q14b. If an internal review of interventionalists was conducted, to demonstrate compliance with this standard, please provide documentation that the hospital followed the case selection procedures according to COMAR 10.24.17.09.

Q14c. Please provide the number of cases reviewed internally for each interventionalist, by calendar year.

(15) 10.24.17.07C(4)(f) and .07D(5)(e) *The chief executive officer of the hospital shall certify upon request by Commission staff 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.*

Q15. Please provide the requested certification signed by the hospital's CEO, using the form provided (Form B).

(16) 10.24.17.07C(4)(g) and .07D(5)(f) *The hospital's application for a Certificate of Ongoing Performance shall demonstrate that it has taken appropriate action in response to each concern identified through its quality assurance processes.*

- (i)** *All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.*
- (ii)** *Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.*

Q16. Please provide information about recent quality assurance activities related to PCI services including a description of the results of quality improvement activities and, if available, documentation of the results. Please clearly indicate if information regarding these quality improvement activities can be shared in a public report. This is best achieved by providing a confidential version of the hospital's Certificate of Ongoing Performance application and a non-confidential version, and if applicable, any separate files clearly labeled as confidential.

****As stated in the instructions for this application, please send any sensitive information pertaining to quality assurance activities only through uploading files to MHCC's sFTP space. Please contact MHCC staff if there are any questions regarding the secure transmission of sensitive information.**

Patient Outcome Measures

(17) 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 shall be subject to a focused review if it has a risk-adjusted mortality rate for non-STEMI PCI cases that exceeds an established benchmark beyond the 95 percent confidence interval calculated for the hospital's all-cause in-hospital risk-adjusted mortality rate for non-STEMI PCI cases.

Q17. MHCC staff will provide each hospital with its risk-adjusted mortality rate for non-STEMI PCI and the national average with confidence interval information. If a hospital fails to meet the standard in COMAR 10.24.17.07C(5)(c), then a focused review may be conducted. If MHCC staff notifies the hospital that a focused review will be conducted, then no additional information regarding this standard should be submitted until further instruction from MHCC staff has been given.

(18) 10.24.17.07D(6)(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.

Q18. MHCC staff will provide each hospital with its risk-adjusted mortality rate for STEMI PCI cases and the national average with confidence interval information. If a hospital fails to meet the standard in COMAR 10.24.17.07D(6)(c), then a focused review may be conducted. If MHCC staff notifies the hospital that a focused review will be conducted, then no additional information regarding this standard should be submitted until further instruction from MHCC staff has been given.

Physician Resources

(19) 10.24.17.07C(6)(a) and .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 Commission on a quarterly basis.*

Q19a. Please submit documentation that demonstrates compliance with this standard. For each physician who performed primary PCI during the review period, the hospital shall fill out and submit Form A.

Q19b. If less than 50 PCI procedures are performed by an interventionalist annually, averaged over a 24-month period, please explain.

(20) 10.24.17.07C(6)(b) and .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 the Commission. A hospital may be required to develop a plan of correction based on the results of the physician's evaluation.

Q20. If applicable, please provide a copy of the results of this evaluation to MHCC staff.

(21) 10.24.17.07C(6)(c) and .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.**

Q21. If applicable, please provide documentation of compliance with this standard.³

(22) 10.24.17.07C(6)(e) and .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.

10.24.17.07C(6)(f) and .07D(7)(f) Each physician shall obtain board certification in interventional cardiology within three years of completion of a fellowship in interventional cardiology.

Q22. Please provide a signed statement from the hospital's medical director of cardiac interventional services acknowledging that each physician that performed primary PCI services during the review period is board certified in interventional cardiology or exempt from this requirement.

³ Please note that COMAR 10.24.17.07D(7)(d) (emphasis added) provides that "[t]he hospital shall notify the Commission in writing of a physician's leave of absence within fourteen days of the initiation of the leave of absence. This notification shall provide documentation of the number of PCI cases that the physician performed in the 12-month period preceding the leave of absence, an estimated time frame for the leave of absence, an estimated impact of the leave of absence on the physician's PCI case volume, and an estimate of the leave of absence on the hospital's PCI case volume."

(23) 10.24.17.07C(6)(g) and .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.

Q23. Please submit signed attestations from each interventionalist in the primary PCI program that he or she has completed a minimum of 30 hours of continuing medical education credits in interventional cardiology during the last two years.

(24) 10.24.17.07C(6)(h) and .07D (7)(h) Each physician who performs primary PCI agrees to participate in an on-call schedule.

Q24. Please provide a signed statement from the medical director of cardiac interventional services acknowledging that each physician who has performed primary PCI services during the performance review period has participated in an on-call schedule and that all physicians currently performing primary PCI services are participating in the on-call schedule. Attach a copy of the current on-call schedule. If a physician who performs primary PCI is not included in the on-call schedule, please explain.

Volume

(25) 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.

Q25. Please provide the total annual PCI case volume for each calendar year or fiscal year for the review period. The review period begins from when the hospital last reported this information as part of the Certificate of Ongoing Performance review process and continues through the most recent calendar or fiscal year that can be provided.

(26) 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.

(b) The target volume for each physician who performs primary PCI is 11 or more primary cases annually.

Q26a. For physicians who meet this standard based on primary PCI cases performed outside of a Maryland hospital, rather than solely based on procedures performed in Maryland hospitals or MedStar Washington Hospital Center, please submit signed statements from the physician and from the medical director for the cardiac catheterization laboratory at each hospital where primary PCI cases were performed attesting to the volume of primary PCI cases performed annually for the review period covered. The signature of the physician must be preceded by the following language: "I solemnly affirm under penalties of perjury and upon personal

knowledge that the preceding statement is true.” The signature of the medical director must be preceded by the following language: “I solemnly affirm under penalties of perjury that the foregoing statement is true to the best of my knowledge, information, and belief.”

Q26b. Please provide the number of primary PCI cases performed at the hospital for each calendar year or fiscal year during the review period.

Patient Selection

(27) 10.24.17.07C(8) *The hospital shall commit to providing elective PCI services only for appropriate patients, as described in Expert Guidelines for hospitals with and without cardiac surgery on-site.*

Q27. Please indicate whether any patients received elective PCI services inappropriately, based on an internal or external review of elective PCI cases for the review period. The response to this question may be provided in a separate confidential file that is encrypted and securely transmitted to Commission staff.

(28) 10.24.17.07D (9) *A hospital shall commit to only providing primary PCI services for suitable patients. Suitable patients are:*

(a) *Patients described as appropriate for primary PCI in Expert Guidelines.*

(b) *Patients with acute myocardial infarction in cardiogenic shock that the treating physician (s) reasonably concludes 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 primary PCI services were 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) reasonably concludes that transfer to a tertiary institution may be harmful to the patient.*

Q28a. Please provide the number of PCI patients who received thrombolytic therapy that subsequently failed, as described in COMAR 10.24.17.07D(9)(c), during the review period.

Q28b. Please indicate whether any patients received primary PCI services inappropriately, based on an internal or external review of primary PCI cases for the review period. The response to this question may be provided in a separate confidential file that is encrypted and securely transmitted to Commission staff.

Applicant Affidavit and Agreement

I solemnly affirm under penalties of perjury that the contents of this application, including all attachments, are true and correct to the best of my knowledge, information, and belief. I understand that if any of the facts, statements, or representations made in this application change, the hospital is required to notify the Commission in writing.

If the Commission issues a Certificate of Ongoing Performance to permit the hospital to perform primary and elective PCI procedures, the hospital agrees to timely collect, and report, complete and accurate data as specified by the Commission. I further affirm that this application for a Certificate of Ongoing Performance to perform primary and elective percutaneous coronary intervention has been duly authorized by the governing body of the applicant hospital, and that the hospital will comply with the terms and conditions of the Certificate of Ongoing Performance and with other applicable State requirements.

The hospital agrees that it will voluntarily relinquish its authority to provide primary and elective PCI services upon receipt of notice from the Executive Director of the Commission if the hospital has failed to meet the applicable standards for a Certificate of Certificate of Ongoing Performance and subsequently fails to meet performance standards included in a plan of correction developed to address the hospital's deficiencies.

I have been designated by the Board of Directors of the applicant hospital to complete this affidavit and agreement on its behalf.

Signature of Hospital-Designated Official _____

Printed Name of Hospital-Designated Official _____

Title _____

Date _____

Form A. Please use this form to identify for each physician and quarter the volume of primary and non-primary PCI cases performed by the physician.

Interventionalist _____

Quarter Ending	PCI Cases at Applicant Hospital			PCI Cases at Other Hospitals			Total PCI Cases - All Hospitals
	pPCI	npPCI	Total	pPCI	npPCI	Total	

Source of Data: _____

Affidavit

I solemnly affirm under penalties of perjury that the information contained in the above table is true and correct to the best of my knowledge, information, and belief.

Date _____

Signature of Interventionalist _____

Form B

Please use this form for the chief executive officer to certify annually 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.

[Fill in hospital name] has formal, regularly scheduled meetings, at least every other month, for interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

[Fill in hospital name] has 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.

[Fill in hospital name] conducts 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.

[Fill in hospital name] evaluates the performance of each interventionalist through an internal or external review consistent with COMAR 10.24.17.07C(4)(c). This performance review of individual interventionalists is conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers. These reviews include a review of angiographic images, medical test results, and patients’ medical records.

Please circle or state the review period used for evaluating the performance of individual interventionalists: annual, semi-annual, quarterly, other.

Affidavit

I solemnly affirm under penalties of perjury that the information contained in the above table is true and correct to the best of my knowledge, information, and belief.

Signature_____

Date_____