



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

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

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

The following application form is to be used by hospitals without on-site cardiac surgical backup when applying for a Certificate of Ongoing Performance to Perform **Primary Percutaneous Coronary Interventions**. Specific provisions of COMAR 10.24.17 are shown in bold, and listed beneath each is the information that the Commission requires to evaluate each application.

The applicant shall cooperate with the Commission, Commission staff, or any authorized representative(s) in supplying 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 where appropriate, complete the provided tables and forms, and/or submit applicant-prepared documents. 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**

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**HEALTH**

**MATTER/DOCKET NO.**

**CARE**

\_\_\_\_\_

**COMMISSION**

**DATE DOCKETED**

**Application for Certificate of Ongoing Performance to Perform  
Primary 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

*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.*

**Q1.** Please address any deficiencies in data collection or reporting identified by MHCC staff.

### 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.*

**Q2.** Please provide information on any downtime that occurred due to required equipment maintenance or unforeseen circumstances for the period beginning January 2015 and ending no more than three months prior to the application deadline for the hospital's Certificate of Ongoing Performance.

*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.*

**Q3.** Please provide a signed statement from the hospital's chief executive officer acknowledging agreement with the above statement, if the last signed statement is over five years old or the chief executive officer has changed since the hospital last submitted the required signed statement.

**Q4.** Please report the hospital's door-to-balloon times for transfer and non-transfer cases separately for each quarter, beginning with procedures performed in January 2015 and ending no more than three months prior to the application deadline for the hospital's Certificate of Ongoing Performance.

**Q5.** Please describe the steps the hospital has taken to improve transfer times for patients who require primary PCI who have been transferred from another hospital without PCI services.

**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.***

**Q6a.** Complete the following table to show the number of physicians, nurses, and technicians who are able to provide cardiac catheterization services to acute myocardial infarction patients (as of one week before the due date of the 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)	

**Q6b.** If the level of staffing reported in the above table is not consistent with the typical staffing levels for the hospital’s CCL, please explain.

**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.***

**Q7.** Submit a letter of commitment, signed by the hospital president or chief executive officer, acknowledging that the hospital will provide primary PCI services in accord with the requirements established by the Maryland Health Care Commission. If the last signed statement is over five years old or the person who signed the statement no longer holds the same position since the hospital last submitted the required signed statement, then a new letter of commitment is required.

**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.***

**Q8.** Please list each position responsible for these activities for PCI services and the number of staff FTEs dedicated to these activities.

**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.***

**Q9.** Please identify the physician director of interventional cardiology services, the date the physician was named the director, and describe the director's responsibilities. If other staff are primarily directly responsible for some of the responsibilities described in COMAR 10.24.17.07D(4)(f), please explain.

**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.*

**Q10.** Please provide a list of continuing educational programs and activities in which staff in the CCL and the Coronary Care Unit participated over the review period identified by MHCC staff as applicable to the hospital's application for a Certificate of Ongoing Performance.

**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.*

**Q11.** Does the hospital have a current signed and dated agreement with a tertiary care center 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? Please provide a copy.

**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.*

**Q12.** Does the hospital's signed and dated formal written agreement with a currently 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? Please provide a copy.

### **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.*

**Q13.** Please provide a list of the dates of interventional case review meetings and list of those in attendance at each meeting.

**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.*

**Q14.** Please provide a list of the dates of the multiple care area group meetings and list of those in attendance at each meeting.

**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 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.*

**Q15.** 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 review organization approved by the Maryland Health Care Commission conducted the reviews, then no further documentation is required. If an internal review of interventionalists was conducted, in order to demonstrate compliance with this standard, please provide documentation that the hospital followed the case selection procedures at COMAR 10.24.17.09.

*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.*

**Q16.** Please provide the requested certification, if it has not yet been provided, using the form provided (Form B).

*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.*

**Q17.** Please provide information about recent quality assurance activities related to PCI services including results from internal peer review and external review of cases.<sup>1</sup> At a minimum, the information submitted should include minutes from meetings of committees that address quality issues that pertain to patients undergoing PCI, other than peer review meetings to discuss individual cases.

**\*\*As stated in the instructions for this application, please send any sensitive information pertaining to quality assurance activities only through a secure method, such as an encrypted file on a USB drive sent by mail with the password provided through email or by phone. Please contact MHCC staff if there are any questions regarding the secure transmission of sensitive information.**

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<sup>1</sup> Note that the Commission is a medical review committee under § 1-401(b)(15) of the Health-Occupations Article (“H-O”) of the Annotated Code of Maryland, provided that the data or medical information under review is furnished to the Maryland Health Care Commission by another medical review committee. The records of a medical review committee are not admissible or discoverable under most circumstances. See H-O § 1-401(d). In accordance with General Provisions Article § 4-301(l) and § 4-306, the Commission would deny requests under the Maryland Public Information Act to inspect records provided by a hospital’s medical review committee.

## 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 primary PCI cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review. The acceptable margin of error is the 95 percent confidence interval calculated for a hospital's all-cause 30-day risk-adjusted mortality rate for primary PCI cases.*

**Q18.** MHCC staff will provide each hospital with its risk-adjusted mortality rate and the statewide average with confidence interval information. If a hospital fails to meet the standard in (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

**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.*

**Q19.** Please submit documentation that demonstrates compliance with this standard. The applicant shall submit a roster of all physicians who performed primary PCI at the hospital during the time period defined by MHCC staff with documentation showing that each currently meets the case volume requirement, using Form A.

**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.*

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

**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.*

**Q21.** If applicable, please provide documentation of compliance with this standard.<sup>2</sup>

**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.*

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

**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.*

**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 the area of interventional cardiology during the last two years.

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<sup>2</sup>Please note that COMAR 10.24.17D(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.”

***10.24.17.07D (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, and attach a copy of the current on-call schedule.

### **Volume**

***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 primary PCI operators is 11 or more primary cases annually.***

**Q25.** 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."

### **Patient Selection**

***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.***

**Q26.** Please provide the number of PCI patients who received thrombolytic therapy that subsequently failed, as described in (c) above, during the review period.

**Q27.** 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.

**Section E – 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 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 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 requirements of the Commission or other State agencies.

The hospital agrees that it will voluntarily relinquish its authority to provide primary PCI services upon receipt of notice from the Executive Director of the Commission if the hospital it 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, when the hospital has been given an opportunity to correct deficiencies through a plan of correction.

I have been authorized 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 ] 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.

Date: \_\_\_\_\_