



**MARYLAND  
HEALTH CARE  
COMMISSION**

**Application for Certificate of Conformance  
Primary and Elective Percutaneous Coronary Intervention**

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

**Information Regarding Application for a Certificate of Conformance to Provide  
Primary and Elective PCI Services**

The following application form is to be used by hospitals without on-site cardiac surgical backup when applying for a **Certificate of Conformance to Perform Primary Percutaneous Coronary Intervention (PCI) and Elective PCI**. 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. Applicants are expected to enter narrative text where appropriate, complete the provided tables and forms, and/or submit applicant-prepared documents. The applicant may file the following with the Maryland Health Care Commission at any time: an original application, including the applicant affidavit with ink signature and supporting documents; and six copies of the application, with the applicant affidavit and supporting documents. The applicant must also submit an electronic copy of its application materials. The filing should be directed to:

Eileen Fleck  
Chief, Acute Care Policy and Planning  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, Maryland 21215

If you have any questions regarding the application form, please contact:

Eileen Fleck  
Chief, Acute Care Policy and Planning  
Maryland Health Care Commission  
410-764-3287  
eileen.fleck@maryland.gov

**MARYLAND**

\_\_\_\_\_

**HEALTH**

**MATTER/DOCKET NO.**

**CARE**

\_\_\_\_\_

**COMMISSION**

**DATE DOCKETED**

**Application for Certificate of Conformance to Perform Primary and Elective Percutaneous Coronary Interventions**

**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 Conformance (COMAR 10.24.17.06B)**

***(1) An applicant hospital shall demonstrate its compliance with the general standards in COMAR 10.24.10.04A.***

**Q1.** Is the applicant a Medicare provider in good standing? Yes\_\_ No \_\_  
If no, attach an explanation.

**Q2.** In the previous five years, has the applicant been sanctioned, barred, or otherwise excluded from participating in the Medicare program or been placed on a 23- or 90-day termination track? Yes \_\_ No \_\_\_\_  
If yes, attach an explanation.

**Q3.** Is the applicant accredited by the Joint Commission? Yes\_\_ No \_\_  
If no, attach an explanation.

**Q4.** In the previous three years, has the applicant had its accreditation denied, limited, suspended, withdrawn, or revoked by the Joint Commission or other accreditation organization, or had any other adverse action taken against it by an accreditation organization, including Provisional or Conditional Accreditation, Preliminary Denial of Accreditation, or Denial of Accreditation? Yes\_\_ No\_\_

If yes, attach an explanation and provide copies of correspondence from the accreditation organization notifying the hospital of each change in its accreditation status and any relevant resulting correspondence.

**Q5.** In the previous five years, has the applicant been placed on Accreditation Watch by the Joint Commission?  
Yes \_\_ No\_\_

If yes, attach an explanation and provide copies of correspondence from the accreditation organization notifying the hospital of each change in its accreditation status.

**Q6.** Please provide a copy of the written policy for the provision of information to the public concerning charges for its services. At a minimum this policy shall include:

(a) Maintenance of a representative list of services and charges that is readily available to the public in written form at the hospital and on the hospital's internet website.

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

**Q7.** Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay. Please provide a copy of this policy and details regarding its posting in the hospital and notice to the public, including the methods used to insure that public notice will reach the

relevant population.

- Q8.** A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Services Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.
- Q9.** A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it has taken or is taking to improve performance for that Quality Measure.

### **Need**

***(2) An applicant shall demonstrate that the proposed program is needed for its service area population through an analysis of current utilization patterns of the population for primary PCI services***

- Q10.** Please provide information on the number of primary PCI cases for the population originating in your hospital's service area and the estimated travel time for this population to reach the nearest existing primary PCI provider. Please identify the sources and assumptions used to estimate case volume, travel time, and door-to-balloon time.
- Q11.** Please provide information and analysis demonstrating that the simultaneous establishment of a primary PCI program and elective PCI program is required to assure the financial viability of the program. Please provide revenue and expense projections for the first four years of operation for both a primary PCI program only and for a program that includes both primary and elective PCI, using the attached Form B and adhering to the instructions provided for that form. Additionally, please provide an accompanying statement of all assumptions used in development of these revenue and expense projections.

### **Access**

***(3) An applicant shall present evidence, including emergency transport data and patient-level data that demonstrate that the proposed program's service area population has insufficient access to emergency PCI services and is receiving suboptimal therapy for STEMI.***

- Q12.** Please provide information that demonstrates that the population to be served by the proposed program has insufficient access to primary PCI services and currently receives suboptimal therapy for STEMI.

***(4) The hospital shall demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.***

- Q13.** Please provide information on the expected travel time for the population to be served, based on travel from their location of residence to the nearest available

provider of primary PCI services and to your hospital. Please identify the sources and assumptions used for this analysis.

### **Volume**

*(5) An applicant shall document that its proposed primary PCI program will achieve a volume of at least 36 PCI cases by the end of the second year of providing primary PCI services if the hospital is located in a rural area or an annual volume of at least 49 cases if the hospital is located in a non-rural area.*

**Q14.** Please provide information that supports your projection of primary PCI case volume at your hospital by the end of the second full year of operation as a provider of primary PCI.

*(6) An applicant shall document that its proposed elective PCI program will achieve a volume of 200 or more total PCI cases by the end of the second year of providing elective PCI services. The Commission may waive the volume requirement of 200 or more total PCI cases by the end of the second year, if the applicant demonstrates that adding an elective PCI program at its projected annual case volume will permit the hospital's 1 PCI service (emergency and elective) to achieve financial viability.*

**Q15.** Are you requesting that the volume requirement of 200 cases be waived?  
Yes\_\_\_ No\_\_\_

If yes, skip question 14.

**Q16.** Please provide information that supports a projected PCI case volume of 200 or more cases by the end of the second full year of operation as a provider of elective PCI. Please provide projections for primary PCI cases and elective PCI cases separately, and include an explanation of the assumptions used to develop the projected primary and elective PCI case volumes.

### **Institutional Resources**

*(7)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.*

**Q17.** Please provide information plans for handling downtime that may occur due to required equipment maintenance or unforeseen circumstances.

*(8) 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.*

**Q18.** Please provide a signed statement from the hospital's chief executive officer acknowledging agreement with the above statement.

*(9) 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.*

**Q19.** Please provide information on the proposed staffing pattern, including on-call coverage, and backup coverage that demonstrates the hospital will be able to meet the requirement that cardiac catheterization laboratory and coronary care unit services are available to patients with acute myocardial infarction 24 hours per day, seven days per week.

**Q20.** Complete the following table to show the number of physicians, nurses, and technicians who are available and 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)	

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

**Q21.** Submit a letter of commitment, signed by the hospital chief executive officer, acknowledging that the hospital will provide primary PCI services in accord with the requirements for primary PCI programs established by the Maryland Health Care Commission.

*(11) The hospital shall maintain the dedicated staff necessary for data collection, management, reporting, and coordination with institutional quality improvement efforts.*

**Q22.** Please list each position responsible for these activities for primary PCI services and the number of staff FTEs dedicated to these activities.

*(12) A hospital shall develop and complete a PCI development plan that includes an on-call coverage back-up plan for primary PCI cases, when an on-call interventionalist covers more than one hospital on a given shift, as well as when two simultaneous STEMI patients present at the hospital.*

**Q23.** Please submit a copy of the applicable policies and procedures. If simultaneous on-call coverage is not permitted, please state this.



***(13)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.***

**Q24.** Please name the anticipated director of interventional cardiology services, or if unknown, please commit to providing this information to Commission staff 90 days prior to first use approval.

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

**Q25.** Please provide a list of the continuing educational programs and activities in which staff in the CCL and the Coronary Care Unit will participate in the first year of operation of the PCI program.

***(15) The hospital shall maintain a formal and properly executed written agreement with a tertiary care center that provides for the unconditional transfer of each primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI, from the applicant hospital to the tertiary institution.***

**Q26.** 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?  
Yes \_\_\_ No \_\_\_

If yes, please provide a copy. If no, provide either a new agreement or a signed and dated amendment to an existing agreement.

***(16) 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 at the applicant hospital within 30 minutes of a request for primary PCI patient transport by the applicant.***

**Q27.** Does the hospital's signed and dated formal written agreement with a currently licensed advanced cardiac support emergency medical services provider guarantee 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? Yes \_\_\_ No \_\_\_

If yes, please provide a copy. If no, provide either a new agreement or a signed and dated amendment to an existing agreement with a currently licensed advanced cardiac support emergency medical services provider that provides such a guarantee.

## Quality

*(17) A 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.*

**Q28.** Please submit a signed letter of commitment from the hospital chief executive officer, acknowledging that the hospital will meet this standard, if the applicant hospital obtains Commission approval to establish a primary PCI program.

*(18) 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.*

**Q29.** Please submit a signed letter of commitment from the hospital chief executive officer, acknowledging that the hospital will meet this standard, if the applicant hospital obtains Commission approval to establish a primary PCI program.

*(19) 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 and an internal review of at least 10 percent of randomly selected PCI cases performed in the applicable time period.\*\**

**Q30.** Please submit a signed letter of commitment from the hospital chief executive officer, acknowledging that, if the applicant hospital obtains Commission approval to establish a primary PCI program, the hospital will meet this standard.\*\*

## Physician Resources

*(20) Each physician who performs primary PCI services at a hospital that provides primary PCI without on-site cardiac surgery shall achieve an average annual case volume of 50 or more PCI cases over a two-year period.*

**Q31.** Please submit a signed letter from the hospital chief executive officer, acknowledging that, if the applicant hospital obtains Commission approval to establish a primary PCI program, it will submit documentation that demonstrates compliance with this standard 90 days prior to first use. The applicant shall submit to Commission staff a roster of all physicians who will be performing primary PCI with documentation showing that each currently meets the case volume requirement, using Form C.

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\*\* Although this is the current standard, a new standard was adopted in proposed regulations, COMAR 10.24.17, on July 16, 2015 that does not require hospitals with only primary PCI programs to conduct an external review. If COMAR 10.24.17 is adopted by the Commission as final regulations then the new standard would be applicable.

## Patient Selection

*(21) An applicant shall commit to providing primary PCI services only for suitable patients. Suitable patients are 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 in 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.*

- Q32.** Please provide a signed statement from the hospital's chief executive officer and medical director of cardiac interventional services attesting to the hospital's commitment to meeting the standards for patient selection.

## Financial Viability

*(22) An applicant shall document that its proposed primary PCI program will achieve financial viability.*

- Q33.** Will the introduction of primary PCI services require a capital expenditure by the hospital? Yes \_\_\_ No \_\_\_

If yes, please provide a project budget detailing the anticipated expenditures using Form A.

- Q34.** Please complete and submit a schedule of projected revenues and expenses for PCI services, using Form B. Please note that this schedule requires the reporting of projected revenues and expenses for future years through the third year of operation.

**Section E – Applicant Affidavit**

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 Conformance to permit the hospital to perform 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 Conformance to perform primary and elective percutaneous coronary interventions 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 Conformance and with other applicable State requirements.

If the Commission issues a Certificate of Conformance to permit the hospital to perform PCI procedures, the hospital agrees that it will voluntarily relinquish its authority to provide PCI services upon receipt of notice from the Executive Director of the Commission if the hospital fails to meet the applicable standards for a Certificate of Conformance, Certificate of Ongoing Performance, or 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 designated by the Board of Directors of the applicant hospital to complete this affidavit on its behalf.

Signature of Hospital-Designated Official \_\_\_\_\_

Printed Name of Hospital-Designated Official \_\_\_\_\_

Title: \_\_\_\_\_

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

**Form A: PROJECT BUDGET**

**INSTRUCTION: This form is to be completed if capital expenditures will be necessary for the applicant hospital to provide pPCI services. All estimates for 1.a.-d., 2.a.-h., and 3 are for current costs as of the date of application submission and should include the costs for all intended construction and renovations to be undertaken. DO NOT CHANGE THIS FORM OR ITS LINE ITEMS. IF ADDITIONAL DETAIL OR CLARIFICATION IS NEEDED, ATTACH ADDITIONAL SHEETS.**

**A. Use of Funds**

1. Capital Costs:

- a. New Construction \$ \_\_\_\_\_
- (1) Building \_\_\_\_\_
- (2) Fixed Equipment (not included in construction) \_\_\_\_\_
- (3) Land Purchase \_\_\_\_\_
- (4) Site Preparation \_\_\_\_\_
- (5) Architect/Engineering Fees \_\_\_\_\_
- (6) Permits, (Building, Utilities, Etc) \_\_\_\_\_

**SUBTOTAL** \$ \_\_\_\_\_

- b. Renovations
- (1) Building \$ \_\_\_\_\_
- (2) Fixed Equipment (not included in construction) \_\_\_\_\_
- (3) Architect/Engineering Fees \_\_\_\_\_
- (4) Permits, (Building, Utilities, Etc.) \_\_\_\_\_

**SUBTOTAL** \$ \_\_\_\_\_

- c. Other Capital Costs
- (1) Major Movable Equipment \_\_\_\_\_
- (2) Minor Movable Equipment \_\_\_\_\_
- (3) Contingencies \_\_\_\_\_
- (4) Other (Specify) \_\_\_\_\_

**TOTAL CURRENT CAPITAL COSTS** \$ \_\_\_\_\_  
(a - c)

- d. Non Current Capital Cost
- (1) Interest (Gross) \$ \_\_\_\_\_
- (2) Inflation (state all assumptions, including time period and rate) \$ \_\_\_\_\_

**TOTAL PROPOSED CAPITAL COSTS** \$ \_\_\_\_\_  
(a - d)

2. Financing Cost and Other Cash Requirements:

a.	Loan Placement Fees	\$ _____
b.	Bond Discount	_____
c.	Legal Fees (CON Related)	_____
d.	Legal Fees (Other)	_____
e.	Printing	_____
f.	Consultant Fees	_____
	CON Application Assistance	_____
	Other (Specify)	_____
g.	Liquidation of Existing Debt	_____
h.	Debt Service Reserve Fund	_____
i.	Principal Amortization	_____
	Reserve Fund	_____
j.	Other (Specify)	_____
	<b>TOTAL (a - j)</b>	<b>\$ _____</b>

3. Working Capital Startup Costs \$ \_\_\_\_\_

**TOTAL USES OF FUNDS (1 - 3)** \$ \_\_\_\_\_

**B. Sources of Funds for Project:**

1.	Cash	_____
2.	Pledges: Gross _____,	
	less allowance for	
	uncollectables _____	
	= Net	_____
3.	Gifts, bequests	_____
4.	Interest income (gross)	_____
5.	Authorized Bonds	_____
6.	Mortgage	_____
7.	Working capital loans	_____
8.	Grants or Appropriation	
	(a) Federal	_____
	(b) State	_____
	(c) Local	_____
9.	Other (Specify)	_____
	<b>TOTAL SOURCES OF FUNDS (1-9)</b>	<b>\$ _____</b>

Lease Costs:

a.	Land	\$ _____	x	_____	= \$ _____
b.	Building	\$ _____	x	_____	= \$ _____
c.	Major Movable Equipment	\$ _____	x	_____	= \$ _____
d.	Minor Movable Equipment	\$ _____	x	_____	= \$ _____
e.	Other (Specify)	\$ _____	x	_____	= \$ _____

**Form B: REVENUES AND EXPENSES – Percutaneous Coronary Intervention Services**

**INSTRUCTIONS:** Specify whether data are for calendar year or fiscal year. All projected revenue and expense figures should be presented in current dollars. Specify sources of non-operating income. This table must be accompanied by a statement of all assumptions used in projecting all revenues and expenses. Please assure that the revenue and expenses figures in this table are consistent with the historic and project utilization of PCI services at the applicant hospital and the information on staffing of this service provided elsewhere in this application.

Revenues and Expenses – PCI Services	Projected Years (ending with third full year in which the applicant projects provision of primary PCI services)			
	CY or FY (Circle)	20__	20__	20__
<b>1. Revenue</b>				
a. Inpatient Services				
b. Outpatient Services				
c. Gross Patient Services				
<b>2. Adjustments to Revenue</b>				
d. Allowance for Bad Debt				
e. Contractual Allowance				
f. Charity Care				
g. Net Patient Services Revenue				
h. Other Operating Revenues (Specify)				
i. Net Operating Revenue				
<b>3. Expenses</b>				
a. Salaries, Wages, and Professional Fees, (including fringe benefits)				
b. Contractual Services				
c. Interest on Current Debt				
d. Interest on Project Debt				
e. Current Depreciation				
f. Project Depreciation				
g. Current Amortization				

Revenues and Expenses – PCI Services	Projected Years (ending with third full year in which the applicant projects provision of primary PCI services)			
	CY or FY (Circle)	20__	20__	20__
h. Project Amortization				
i. Supplies				
j. Other Expenses (Specify)				
k. Total Operating Expenses				
<b>4. Income</b>				
a. Income from Operation				
b. Non-Operating Income				
c. Subtotal				
d. Income Taxes				
e. Net Income (Loss)				
h. Project Amortization				
i. Supplies				
j. Other Expenses (Specify)				
<b>5. Patient Mix: A. Percent of Total Revenue</b>				
1) Medicare				
2) Medicaid				
3) Blue Cross				
4) Commercial Insurance				
5) Self-Pay				
6) Other (Specify)				
7) TOTAL				
1) Medicare				
2) Medicaid				
3) Blue Cross				
4) Commercial Insurance				
5) Self-Pay				
6) Other				
7) TOTAL				



**Form C.** 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 Physician: \_\_\_\_\_