

Application for Certificate of Conformance Primary and Elective Percutaneous Coronary Intervention

(Revised March 2022)

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

<u>Information Regarding Application for a Certificate of Conformance to Provide</u> 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	D .
CARE			
COMMISSION		DATE DOCKETED	
Application for Certifica Elective Perc		nance to Perform onary Intervention	•
Applicant Information			
Applicant			
Street Address			
City	_County	State	_Zip Code
Mailing Address (if different)_			
City	_County	State	_Zip Code
Medicare Provider Number(s)_	N	ational Provider Iden	tifier
Primary Person to be contacted or Name			
Title			

Address_____

Address____

City______County_____State____Zip Code_____

Telephone_____ Facsimile____ E-mail____

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:

Review Criteria for a Certificate of Conformance (COMAR 10.24.17.06B)

An applicant hospital shall demonstrate its compliance with the general standards in DMAR 10.24.10.04A.
Q1a. Is the applicant licensed and in good standing? Yes No If yes, skip question 1b.
Q1b . Has the hospital's license been suspended, revoked, or subject to disciplinary action in the last five years? Please explain.
Q2a. Is the applicant a Medicare provider in good standing? Yes No If no, attach an explanation.
Q2b . 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 ensure 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 is below the statewide average 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. For a hospital that seeks to relocate and which already has primary PCI services and plans to re-establish PCI services at its new location, please provide estimated travel time for the population in its service area assuming the hospital's current PCI program doesn't exist. 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 Forms A and B and adhering to the instructions provided for those forms. 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. For a hospital that seeks to relocate and which already has primary PCI services and plans to re-establish PCI services at its new location, please instead address the likely impact on access, if primary PCI services are not established at the new location of the hospital.

- (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.
 - Q13a. 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. For a hospital that seeks to relocate and which already has primary PCI services and plans to re-establish PCI services at its new location, please provide estimated travel time for the population in its service area based on the proposed new location of the hospital instead of the current location. Please identify the sources and assumptions used for this analysis.
 - **Q13b**. Please provide an explanation as to why an elective PCI program is needed to preserve timely access to emergency PCI services.

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 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 16.

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.
 - **Q17a**. Please provide information plans for handling downtime that may occur due to required equipment maintenance or unforeseen circumstances.
 - **Q17b.** For a hospital with PCI services that seeks to relocate, please provide updated information on the downtime of the CCL since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.
- (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.
 - **Q18a**. Please provide a signed statement from the hospital's chief executive officer acknowledging agreement with the above statement.
 - **Q18b.** For a hospital with PCI services that seeks to relocate, please provide updated information on the door-to-balloon times for non-transfer patients by quarter since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.
- (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 president or 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) The hospital shall complete a PCI development plan that includes appropriate training for the emergency room, catheterization laboratory, coronary care unit, if applicable, post-procedure unit. The plan shall include protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure. In addition, there shall be 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) A hospital performing 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.

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 that performs primary PCI without on-site cardiac surgery 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 the hospital.

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 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.
 - Q28a. 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.
 - **Q28b.** For a hospital with PCI services that seeks to relocate please provide updated information on the dates and attendees at interventional case review meetings since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.
- (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.
 - Q29a. 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.

- **Q29b.** For a hospital relocation project, in which the hospital already has PCI services, please provide updated information on the dates and attendees at multiple care area group meetings since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.
- (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 as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.
 - Q30a. 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.
 - Q30b. For a hospital relocation project, in which the hospital already has PCI services, please provide updated information on the results from external reviews completed since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.
- (20) The hospital shall evaluate the performance of each interventionalist through an internal or external review as described in COMAR 10.24.17.07C (4)(d).
 - Q31a. 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 and elective PCI program, the hospital will meet this standard.
 - **Q31b.** For a hospital relocation project, in which the hospital already has PCI services, please provide updated information that demonstrates the hospital has continued to comply with this standard the since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.

Physician Resources

- (20) Physicians who perform primary PCI services at a hospital that provides primary PCI without on-site cardiac surgery shall achieve an average annual case volume of 50 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.
 - Q32a. 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.
 - **Q32b.** For a hospital relocation project, in which the hospital already has PCI services, please provide updated information that demonstrates the hospital has continued to comply with this standard since last reported to MHCC staff as part of the

Certificate of Ongoing Performance application process. Staff notes that for the period of CY 2020 and CY 2021, this standard was waived due to the COVID-19 pandemic.

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 Expert Guidelines¹

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.

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.

Patient 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 for the patient.

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

Patients described as appropriate for elective PCI in Expert Guidelines.

For elective PCI programs without cardiac surgery on-site, patients at high procedural risk are not suitable for elective PCI, as described in Expert Guidelines.

Q33. 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.

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¹ Expert Guidelines are 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.

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.

Form A: PROJECT BUDGET

INSTRUCTION: This form is to be completed if capital expenditures will be necessary for the applicant hospital to provide primary PCI 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. <u>Use of Funds</u>

1. <u>Capital Costs</u>:

a. (1) (2) (3) (4) (5) (6)	New Construction Building Fixed Equipment (not included in construction) Land Purchase Site Preparation Architect/Engineering Fees Permits, (Building, Utilities, Etc)	\$	
	OTAL	\$	
b. (1) (2)	Renovations Building Fixed Equipment (not included in construction)	\$	
(3) (4)	Architect/Engineering Fees Permits, (Building, Utilities, Etc.)		
SUB1 c. (1) (2) (3)	OTAL Other Capital Costs Major Movable Equipment Minor Movable Equipment Contingencies	\$	
(4)	Other (Specify)		
(4)	L CURRENT CAPITAL COSTS	\$	
(4) TOT	L CURRENT CAPITAL COSTS	\$ \$ \$	

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 AmortizationReserve Fund		
	j. Other (Specify)		
	j. Other (Opcony)		
	TOTAL (a - j)	\$ 	
3.	Working Capital Startup Costs	\$ 	
	TOTAL USES OF FUNDS (1 - 3)	\$	
_	Occurs of Founds for Business		
В.	Sources of Funds for Project:		
1.	Cash		_
2.	Pledges: Gross,		
	less allowance for uncollectables		
	= Net		
3.	Gifts, bequests		
4.	Interest income (gross)		
5. 6.	Authorized Bonds		
6. 7.	Mortgage Working capital loans		
8.	Grants or Appropriation		
	(a) Federal		
	(b) State		
•	(c) Local		
9.	Other (Specify)		
TOTA	L SOURCES OF FUNDS (1-9)	\$ 	
	Lease Costs:		
		 _ X	
	b. Building \$ c. Major Movable Equipment \$	 _ X	· ·
	c. Major Movable Equipment \$ d. Minor Movable Equipment \$	 _ X	
	e. Other (Specify)	_ ^	

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	20
1. Revenue				
a. Inpatient Services				
b. Outpatient Services				
c. Gross Patient Services				
2. Adjustments to Revenue				
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				
3. Expenses				
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 20			
h. Project Amortization				
i. Supplies				
j. Other Expenses (Specify)				
k. Total Operating Expenses				
4. Income				
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)				
5. Patient Mix: A. Percent of Total Revenue				
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				

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 Dat	a:						
				Affidavit			
solemnly affi nformation, a		es of perjury that th	e information con	tained in the above	e table is true and c	orrect to the best	of my knowledge
)ata:	»:		Signature of Physician:				