

Application for Certificate of Conformance Non-Primary Percutaneous Coronary Intervention

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

<u>Information Regarding Application for a Certificate of Conformance to Provide Non-Primary PCI Services</u>

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 Non-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 or any of its authorized representatives 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 must file an original application, including the Applicant Affidavit with ink signature and supporting documents, and six copies of both the application and the affidavit with the Maryland Health Care Commission by February 16, 2018

, if a letter of intent was filed by January 12, 2018. 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

MARYLAND			
HEALTH		MATTER/DOCKET NO	0.
CARE			
COMMISSION		DATE DOCKETED	
Application for Certific		mance to Perform	Non-Primary
Applicant Information			
Applicant			
Street Address			
City	County	State	_Zip Code
Mailing Address (if different)			
City	County	State	_Zip Code
Medicare Provider Number(s)	1(National Provider Iden	ntifier
Person to be contacted on matter	rs involving this ap	plication:	
Name			

Address_____

Address_____

City______State____Zip Code_____

Telephone_____ Facismile____ E-mail____

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

, ,	applicant hospital shall demonstrate its compliance with the general standards in R 10.24.10.04A.
Ql.	Is the applicant a Medicare Provider in good standing? Yes No If no, attach an explanation.
Q2.	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.	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 in the past 24 months, 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.
Q5.	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.
_	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 web site.
	(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

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

provide a copy of this policy.

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 is taking to improve performance for that Quality Measure.
- (2) An applicant shall document that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.
 - **Q10.** Please provide information on the expected transit time for the population to be served, if that population was not able to obtain emergency PCI services at the applicant hospital and alternatively had to seek this service at the nearest available provider of primary PCI services.
- (3) 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 l PCI service (emergency and elective) to achieve financial viability.

Q11.	e you requesting that the volume requirement of 200 cases be waived?
	es No
	yes, skip question 12.

- **Q12.** 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.
- (4) An applicant shall document that its proposed elective PCI program will achieve financial viability.

Q13.	Will the introduction of elective PCI services require a capital expenditure by the hospital? Yes No
	If yes, please provide an estimate of these costs using Form A.

Q14. Please complete and submit a schedule of revenues and expenses for PCI services, using Form B. Please note that this schedule requires the reporting of revenues and expenses associated with the existing primary PCI program, for the current fiscal year and the two most recently ended fiscal years. In addition, it requires projected revenue

and expenses for future years through the third year of operation as a provider of both emergency and elective PCI services.

- (5) An applicant shall commit to providing elective PCI services only for suitable patients. Suitable patients are patients described as appropriate for elective PCI in the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or 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. For elective PCI programs without cardiac surgery on-site, patients at high procedural risk are not suitable for elective PCI, as described in the ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.
 - Q15. Please provide a signed statement from the hospital's chief executive officer and medical director of cardiac interventional services indicating agreement with the above statement.
- (6) An applicant shall commit to providing elective 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/AHA) 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 PCI); patients with acute myocardial infarction in cardiogenic shock that the treating physicians believes may be harmed by transfer to a tertiary institution, either because the patient is too unstable or because of the temporal delay will result in worse outcomes; patients for whom primary PCI services were not initially available and who received thrombolytic therapy that subsequently failed. Such cases should constitute no more than 10 percent of total PCI cases; patients who experience 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) believe that transfer to a tertiary institution may be harmful for the patient.
 - Q16. Please indicate how many patients received thrombolytic therapy because primary PCI services were not initially available and how often this therapy failed, since the end of the period last reported on the hospital's waiver renewal through September 30, 2017.
- (7) An applicant 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.** Use the table below to indicate the routine availability of each procedure room in the hospital's cardiac catheterization laboratory (CCL) suite for the period since this information was last reported through a waiver renewal, through September 30, 2017.

Reporting Period: _			
_	From (mmddyy)	-	To (mmddyy)

CCL Room	Days and Hours of Operation							
	Hours	Mon	Tue	Wed	Thu	Fri	Sat	Sun
	Regular:							
	On-Call:							
	Regular:							
	On-Call:							

Q18. Using the table shown below, indicate all dates when CCL services were unavailable, since this information was last reported through a waiver renewal application, through September 30, 2017.

			CCI	L Downtime
	Γ	Date	Duration	
Room	Begin	End	(Hours)	Reason Unavailable

⁽⁸⁾ 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. Have there been any changes to the number or the on-call availability of physicians, nurses, technicians, and other staff who comprise each on-call team (e.g., 1 MD, 1 nurse, and 2 technicians) since the MHCC granted an extension of the hospital's primary PCI waiver? Yes __ No__

If yes, use the following chart to specify the changes in the frequency and duration of on-call service (e.g., days/week or month, 1700-0700 hours; weekends/month), and the time established by hospital policy for on-call staff to respond to the call (e.g., telephone or pager). Note that response time covers the period from receipt of call until arrival at the hospital.

Type of Clinical	Number		
Staff on Team	of Staff	Call Rotation	Response Time
MD			
Fellow			
Nurses			
Technicians			
Other (specify)			

Q20. Complete the following table to show the number of physicians, nurses, and technicians who currently 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:

(mmddyy)

	Number/FTEs	Cross-Training (S/C/M)
Physician		
Nurse	(FTE)	
Technician	(FTE)	

(9) 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 door-to-balloon times for transfer cases and evaluate areas for improvement.

Q21. Please provide information in the first table below on the number and percentage of STEMI patients meeting the door to balloon time standard of 90 minutes or less for each quarter since the hospital last reported DTB time information in its waiver renewal application, excluding patients who were transferred to the hospital from another acute care hospital. Please also report information on the number of transfer cases and mean door-to-balloon time for transfer cases in the second table shown below.

	Number of	Number of STEMI Patients Receiving	STEMI Patients* with DTB Time < 90 Minutes²		
Quarter Ending	STEMI Patients*	Primary PCI	Number	%	

Note: STEMI patients refers to both STEMI patients and STEMI equivalent patients, as defined in the NCDR CathPCI Data Registry. DTB time is the difference in minutes between the patient's arrival in the hospital emergency room and the time of insertion of the first device (usually a balloon-type device, but occasionally a thrombectomy device). Exceptions to this calculation method most commonly occur when the patient arrives with a *history* of chest discomfort but a normal or non-diagnostic initial electrocardiogram (ECG). *If and only if* the first ECG is normal/non-diagnostic *and* is noted in the NCDR CathPCI Registry database for review and confirmation along with a second ECG showing STEMI, then the date and time of the second (diagnostic) ECG are used as the "door" or "clock start" time to calculate DTB time.

Quarter Ending	Number of STEMI Patients* Transferred Receiving Primary PCI	Transfer Patients with DTB Time < 120 Minutes	Median DTB Time for Transfer Patients

Note: STEMI patients refers to both STEMI patients and STEMI equivalent patients, as defined in the NCDR CathPCI Data Registry. DTB time is the difference in minutes between the patient's arrival in the hospital emergency room and the time of insertion of the first device (usually a balloon-type device, but occasionally a thrombectomy device). Exceptions to this calculation method most commonly occur when the patient arrives with a *history* of chest discomfort but a normal or non-diagnostic initial electrocardiogram (ECG). *If and only if* the first ECG is normal/non-diagnostic *and* is noted in the NCDR CathPCI Registry database for review and confirmation along with a second ECG showing STEMI, then the date and time of the second (diagnostic) ECG are used as the "door" or "clock start" time to calculate DTB time.

Q22	• Is the hospital meeting the door-to-balloon (DTB) time requirements in its
	provision of primary PCI for the time period following the hospital's last primary
	PCI waiver renewal through September 30, 2017?

Yes	N	O

If no, for each quarter in which the hospital did not meet the DTB time standard, please identify the DTB time for each case that had excessive DTB time and list the reason(s) for the excessive DTB time for each case. In addition, please explain what steps the hospital is taking to assure that it will meet the primary PCI requirements in the future.

- (10) The hospital president or Chief Executive Officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.
 - **Q23.** Submit a letter of commitment, signed by the hospital chief executive officer, indicating 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.
 - **Q24.** Please list each position responsible for these activities for primary PCI services and the FTEs devoted 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.
 - **Q25.** 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 design and implement a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.
 - **Q26.** Please provide a list of continuing educational activities in which staff in the CCL and the Coronary Care Unit participated, from the time last reported in the hospital's most recent waiver renewal through September 30, 2017.
- (14) The hospital shall maintain a formal and properly executed written agreement with a tertiary care center that provides for the unconditional transfer of each non-primary PCI

patient who requires additional care, including emergent or non-primary cardiac surgery or PCl, from the applicant hospital to the tertiary institution.

Q27.	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.
medical s	spital shall maintain its agreement with an advanced cardiac support emergency ervices provider that guarantees arrival of the air or ground ambulance at the hospital within 30 minutes of a request for non-primary PCI patient transport by the
Q28.	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 an npPCI 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.
month) in	spital shall develop a formal, regularly scheduled (meetings at least every other atterventional case review that requires attendance by interventionalists and other as, nurses, and technicians who care for primary PCI patients.
Q	29. Please use Form C to report attendance at the interventional case review meetings.
unit, and nursing l	spital shall create a multiple care area group (emergency department, coronary care cardiac catheterization laboratory) that includes, at a minimum, the physician and eadership of each care area and meets monthly to review any and all issues related mary PCI system, identify problem areas, and develop solutions.
Q	30. Please use Form D to report attendance at the multiple care area group meetings.

(18) 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 use Form E to report individual physician volumes for the previous two years.

<u>Section E – Applicant Affidavit</u>

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 npPCI 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 non-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 Conformance and other applicable State requirements.

I acknowledge that the hospital shall agree to voluntarily relinquish its authority to provide elective PCI services if it fails to meet the applicable standards for a Certificate of Conformance 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.

Signature of Hospital-designated Official
Printed Name of Hospital-designated Official
Γitle:
Date:

Form A: PROJECT BUDGET

INSTRUCTION: This form is to be completed if capital expenditures will be necessary for the applicant hospital to provide npPCI 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 SHEET.

A. <u>Use of Funds</u>

1.

Capita	l Costs:		
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)	\$	
SUBT	_	\$	
b. (1)	Renovations Building	\$	
(2)	Fixed Equipment (not	Ψ .	
(3)	included in construction) Architect/Engineering Fees		
(4)	Permits, (Building, Utilities, Etc.)		
SUBT	OTAL	\$	
C.	Other Capital Costs	,	
(1) (2)	Major Movable Equipment Minor Movable Equipment		
(3)	Contingencies		
(4)	Other (Specify)		
TOTAL (a - c)	CURRENT CAPITAL COSTS	\$	
	Non Current Capital Cost		
d. (1)	Non Current Capital Cost Interest (Gross)	\$	
(2)	Inflation (state all assumptions,	ው	
	Including time period and rate)	\$	

TOTAL PROPOSED CAPITAL COSTS

(a - d)

2.	Financing Cost and Other Cash Requirer	nents:	
	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)		
	TOTAL (a - j)	\$	
	· ·		
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.	Authorized Bonds Mortgage		
7.	Mortgage Working capital loans		
	Mortgage Working capital loans Grants or Appropriation		
7.	Mortgage Working capital loans Grants or Appropriation (a) Federal		
7.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State		
7. 8.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State (c) Local		
7.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State		
7.8.9.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State (c) Local	\$	
7.8.9.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State (c) Local Other (Specify) AL SOURCES OF FUNDS (1-9) Lease Costs:	\$	
7.8.9.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State (c) Local Other (Specify) AL SOURCES OF FUNDS (1-9) Lease Costs: a. Land \$	\$ = \$	
7.8.9.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State (c) Local Other (Specify) AL SOURCES OF FUNDS (1-9) Lease Costs: a. Land b. Building Suntable Specify \$	\$ = \$ = \$	
7.8.9.	Mortgage Working capital loans Grants or Appropriation (a) Federal (b) State (c) Local Other (Specify) AL SOURCES OF FUNDS (1-9) Lease Costs: a. Land \$	\$ = \$	

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.

	Two Most Ended Re Years		Current Year Projected	Projected Years (ending with third full year in which the applicant projects provision of npPCI services					
CY or FY (Circle)	20	20	20	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									
h. Other Operating									
i. Net Operating Revenue									

Revenues and Expenses – PCI Services		,			Projected Years (ending with third full year in which the applicant projects provision of npPCI service				
CY or FY (Circle)	20	20	20	20	20	20	20		
2. 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									
h. Project Amortization									
i. Supplies									
j. Other Expenses (Specify)									
k. Total Operating Expenses									
	1								
3. Income									
a. Income from Operation									
b. Non-Operating Income									
c. Subtotal									
d. Income Taxes									
e. Net Income (Loss)									

Revenues and Expenses – PCI Services	Two Most Actual Ended Recent Years		Current Year Projected		vith third fu	ıll year in wh	in which the n of npPCI	
CY or FY (Circle)	20	20	20	20	20	20	20	
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								
B. Percent of PCI Cases (as ap	plicable)							
1) Medicare								
2) Medicaid								
3) Blue Cross								
4) Commercial Insurance								
5) Self-Pay								
6) Other								
7) TOTAL								

Form C. Identify all physicians, nurses, technicians, and other staff who participated in formal, regularly scheduled cardiac catheterization case review meetings. Provide the dates and staff attendance at all formal case review meetings during the period from the hospital's last waiver renewal application, until September 30, 2017.

		Date of Cardiac Catheterization Laboratory Case Review (mmddyy)										
Name and Credential	Title											
Physicians												
Nurses												
Technicians												
Other												

Form D. Identify all physicians, nurses, technicians, and other staff who participated in formal, regularly scheduled multiple area care group meetings. Provide the dates and staff attendance at all formal case review meetings during the period from the hospital's last waiver renewal application, until September 30, 2017.

		Date of Cardiac Catheterization Laboratory Case Review (mmddyy)											
Name and Credential	Title												
Physicians													
Nurses													
Technicians													
Other													

Quarter Ending	PCI Cases	at Applicant Hosp	ital	PCI Cases	PCI Cases at Other Hospitals				
	pPCI	npPCI	Total	pPCI	npPCI	Total	Hospitals		
ource of Dat	a:			A 66° 1 . 4					
				<u>Affidavit</u>					
solemnly affi formation, 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		
ate:	Signature of Physician:								